4.2.1.3.4.3 Acceptance Criteria

The following acceptance criteria are based on meeting the relevant requirements of 10 CFR 63.114(a)–(c) and (e)–(g), as they relate to the radionuclide release rates and solubility limits model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the radionuclide release rates and solubility limits abstraction process;

- The abstraction of radionuclide release rates and solubility limits uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, the assumptions used for this model abstraction are consistent with the abstractions of "Degradation of Engineered Barriers" (Section 4.2.1.3.1); "Mechanical Disruption of Waste Packages" (Section 4.2.1.3.2); Quantity and Chemistry of Water Contacting Waste Packages and Waste Forms" (Section 4.2.1.3.3); "Climate and Infiltration" (Section 4.2.1.3.5); and "Flow Paths in the Unsaturated Zone" (Section 4.2.1.3.6). The descriptions and technical bases provide transparent and traceable support for the abstraction of radionuclide release rates and solubility limits;

- The abstraction of radionuclide release rates and solubility limits provides sufficient, consistent design information on waste packages and engineered barrier systems. For example, inventory calculations and selected radionuclides are based on the detailed information provided on the distribution (both spatially and by compositional phase) of the radionuclide inventory, within the various types of high-level radioactive waste;

- The U.S. Department of Energy reasonably accounts for the range of environmental conditions expected inside breached waste packages and in the engineered barrier environment surrounding the waste package. For example, the U.S. Department of Energy should provide a description and sufficient technical bases for its abstraction of changes in hydrologic properties in the near field, caused by coupled thermal-hydrologic-mechanical-chemical processes;

- The description of process-level conceptual and mathematical models is sufficiently complete, with respect to thermal-hydrologic processes affecting radionuclide release from the emplacement drifts. For example, if the U.S. Department of Energy uncouples coupled processes, the demonstration that uncoupled model results bound predictions of fully coupled results is adequate;

- Technical bases for inclusion of any thermal-hydrologic-mechanical-chemical couplings and features, events, and processes in the radionuclide release rates and solubility

limits model abstraction are adequate. For example, technical bases may include activities, such as independent modeling, laboratory or field data, or sensitivity studies;

- The abstraction of in-package criticality or external-to-package criticality, within the emplacement drift, provides an adequate technical basis for screening these events. If either event is included in the total system performance assessment, then the U.S. Department of Energy uses acceptable technical bases for selecting the design criteria that mitigate the potential impact of in-package criticality on the repository performance; identifies the features, events, and processes that may increase the reactivity of the system inside the waste package; identifies the configuration classes and configurations that have potential for nuclear criticality; and includes changes in thermal conditions and degradation of engineered barriers in the abstraction of radionuclide release rates and solubility limits; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer reviews and data qualification, is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Geological, hydrological, and geochemical values used in the safety case are adequately justified. Adequate description of how the data were used, interpreted, and appropriately synthesized into the parameters is provided;

- Sufficient data have been collected on the characteristics of the natural system and engineered materials to establish initial and boundary conditions for conceptual models and simulations of thermal-hydrologic-chemical coupled processes. For example,

  sufficient data should be provided on design features, such as the type, quantity, and reactivity of materials, that may affect radionuclide release for this abstraction;

- Where the U.S. Department of Energy uses data supplemented by models to support abstraction of solubility limits, the anticipated range of proportions and compositions of phases under the various physicochemical conditions expected are supported by experimental data (U.S. Nuclear Regulatory Commission, 1984); and

- The corrosion and radionuclide release testing program for high-level radioactive waste forms intended for disposal provides consistent, sufficient, and suitable data for the in-package and in-drift chemistry used in the abstraction of radionuclide release rates and solubility limits. For expected environmental conditions, the U.S. Department of Energy provides sufficient justification for the use of test results, not specifically collected from the Yucca Mountain site, for engineered barrier components, such as high-level radioactive waste forms, drip shield, and backfill.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- Parameter values, assumed ranges, probability distributions, and bounding assumptions used in the abstractions of radionuclide release rates and solubility limits in the total system performance assessment are technically defensible and reasonable based on data from the Yucca Mountain region, laboratory tests, and natural analogs. For example, parameter values, assumed ranges, probability distributions, and bounding assumptions adequately reflect the range of environmental conditions expected inside breached waste packages;

- The U.S. Department of Energy uses reasonable or conservative ranges of parameters or functional relations to determine effects of coupled thermal-hydrologic-chemical processes on radionuclide release. These values are consistent with the initial and boundary conditions and the assumptions for the conceptual models and design concepts for natural and engineered barriers at the Yucca Mountain site. If any correlations between the input values exist, they are adequately established in the total system performance assessment. For example, estimations are based on a thermal loading and ventilation strategy; engineered barrier system design (including drift liner, backfill, and drip-shield); and natural system masses and fluxes that are consistent with those used in other abstractions;

- Uncertainty is adequately represented in parameter development for conceptual models, process models, and alternative conceptual models considered in developing the abstraction of radionuclide release rates and solubility limits, either through sensitivity analyses or use of bounding analyses;

- Parameters used to describe flow through and out of the engineered barrier, sufficiently bound the effects of backfill, excavation-induced changes, and thermally induced mechanical changes that affect flow;

- If criticality cannot be excluded from total system performance assessment, then the U.S. Department of Energy provides an appropriate range of input parameters for calculating the effective neutron multiplication factor;

- The U.S. Department of Energy uses an appropriate range of time-history of temperature, humidity, and dripping to constrain the probability for microbial effects, such as production of organic by-products that act as complexing ligands for actinides and microbially enhanced dissolution of the high-level radioactive waste glass form;

- The U.S. Department of Energy adequately considers the uncertainties, in the characteristics of the natural system and engineered materials, such as the type, quantity, and reactivity of material, in establishing initial and boundary conditions for

conceptual models and simulations of thermal-hydrologic-chemical coupled processes that affect radionuclide release; and

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate other sources, such as expert elicitation conducted in accordance with NUREG–1563 (Kotra, et al., 1996).

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations are appropriately considered in the abstraction;

- In considering alternative conceptual models for radionuclide release rates and solubility limits, the U.S. Department of Energy uses appropriate models, tests, and analyses that are sensitive to the processes modeled for both natural and engineering systems. Conceptual model uncertainties are adequately defined and documented, and effects on conclusions regarding performance are properly assessed. For example, in modeling flow and radionuclide release from the drifts, the U.S. Department of Energy represents significant discrete features, such as fault zones, separately, or demonstrates that their inclusion in the equivalent continuum model produces a conservative effect on calculated performance; and
- The effects of thermal-hydrologic-chemical coupled processes that may occur in the natural setting, or from interactions with engineered materials, or their alteration products, on radionuclide release, are appropriately considered.

Acceptance Criterion 5 Model Abstraction Output is Supported by Objective Comparisons.

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs);

- Results of thermal-hydrologic process-level models are verified by demonstrating consistency with observations and results from laboratory and field-scale thermal-hydrologic tests. In particular, the U.S. Department of Energy demonstrates that sufficient physical evidence exists, to support conceptual models used to predict thermally driven flow in the near field;

- The U.S. Department of Energy adopts well-documented procedures that have been accepted by the scientific community to construct and test the numerical models, used to simulate coupled thermal-hydrologic-chemical effects on radionuclide release. For example, the U.S. Department of Energy demonstrates that the numerical models used for high-level radioactive waste degradation and dissolution, and radionuclide release from the engineered barrier system, are adequate representations; include consideration of uncertainties; and are not likely to underestimate radiological exposures

to the reasonably maximally exposed individual and releases of radionuclides into the accessible environment; and

- If the U.S. Department of Energy will rely on the performance confirmation program to assess whether the natural system and engineered materials are functioning as intended, an adequate program for monitoring radionuclide release from the waste packages, during the performance confirmation period, is established, using assumptions and calculations of radionuclide release from the waste packages that are appropriately substantiated (the acceptability of the performance confirmation program is reviewed using Section 4.4 of the Yucca Mountain Review Plan).

4.2.1.3.4.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.4.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to radionuclide release rates and solubility limits, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of radionuclide release rates and solubility limits have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.4.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

U.S. Nuclear Regulatory Commission. "Determination of Radionuclide Solubility in Ground Water for Assessment of High-Level Waste Isolation, Technical Position." Washington, DC: U.S. Nuclear Regulatory Commission. 1984.

4.2.1.3.5 Climate and Infiltration

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on climate and infiltration to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on climate and infiltration to provide significant delay in the transport of radionuclides or a significant dilution in dose to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the delay in the transport of radionuclides to the reasonably maximally exposed individual, or insignificant dilution in dose, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary in a simplified review for those abstractions that have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.5.1 Areas of Review

This section reviews climate and net infiltration. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9)(10), (15), and (19), that is relevant to the abstraction of climate and infiltration.

The staff will evaluate the following parts of the abstraction of climate and infiltration, using the review methods and acceptance criteria in Sections 4.2.1.3.5.2 and 4.2.1.3.5.3:

- Description of the climatological, hydrological, geological, and geochemical aspects of net infiltration in the unsaturated zone, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;

- Sufficiency of the data and parameters used to justify the model abstraction;

- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty through the model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty through the model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.5.2 Review Methods

To review the abstraction of climate and infiltration, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of physical phenomena and couplings and the descriptions of the geological, hydrological, geochemical, paleohydrological, paleoclimatological, and climatological aspects of the abstraction of the climate and net infiltration that contribute to waste isolation. Assess the adequacy of the technical bases for these descriptions and for incorporating them in this abstraction.

Evaluate whether the description of aspects of geology, hydrology, geochemistry, physical phenomena, and couplings, that may affect climate and net infiltration, is adequate. Verify that conditions and assumptions used in this abstraction are consistent with the body of data presented in the description.

Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in this abstraction for consistency with other related U.S. Department of Energy abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for this abstraction.

Examine how the features, events, and processes related to climate and net infiltration have been included in the total system performance assessment abstractions.

Confirm that the U.S. Department of Energy abstractions employ adequate spatial and temporal variability of model parameters and boundary conditions to estimate net infiltration flux.

Ensure that averages of parameter estimates used in process-level models over time and space scales are appropriate for the model discretization.

Verify that paleoclimate information is evaluated over the past 500,000 years as the basis for projections of future climate change. For example, confirm that numerical climate models, if used for projection of future climate, are calibrated based on such paleoclimate data.

Verify that the U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or make an acceptable case for using alternative approaches.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the data used to support conceptual models, process-level models, and alternative conceptual models considered in this abstraction, and the parameters used for each of these models. Evaluate the basis for the data on physical phenomena, couplings, climatology, geology, hydrology, and geochemistry. This basis may include a combination of techniques, such as laboratory experiments, site-specific field measurements, natural analog research, process-level modeling studies, and expert elicitation.

Verify that the mathematical model estimates of present-day net infiltration are at appropriate time and space scales. Assure adequate site-specific climatic, surface, and subsurface information is used.

Verify that net infiltration is not underestimated. Assure adequate representation of the effects of fracture properties, fracture distributions, matrix properties, heterogeneities, time-varying boundary conditions, evapotranspiration, depth of soil cover, and surface-water runoff and run-on is incorporated in this abstraction.

Confirm the use of adequate sensitivity or uncertainty analyses to assess data sufficiency, and determine the possible need for additional data.

Assure adequate accepted and well-documented procedures are applied to develop and calibrate numerical models.

Verify that reasonably complete process-level conceptual and mathematical models are used in the analyses. Assure the mathematical models are consistent with conceptual models and site characteristics. Confirm that a comparison of the robustness of results from different mathematical models is provided.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation.

Review Method 3 Data Uncertainty

Verify that parameter values reasonably account for uncertainties and variabilities for the assumed ranges, probability distributions, and/or bounding assumptions. Evaluate the U.S. Department of Energy assessment of uncertainty and variability in parameters used in the model abstraction. Determine whether uncertainty in data, because of both temporal and spatial variations in conditions affecting climate and net infiltration, is incorporated into the parameter ranges. For example, evaluate the climatic and hydrostratigraphic parameters used in the abstracted model to verify that they are consistent with site characterization data, and sufficiently detailed to capture heterogeneities that may influence the distribution and rate of liquid-water flux that has moved beyond the zone of evapotranspiration.

Examine the technical bases for parameter values and ranges, probability distributions, or bounding values in conceptual models, process-level models, and alternative conceptual models considered in the abstraction. Determine whether the parameter values are derived from site-specific data, or an analysis is included to show that the assumed parameter values lead to a conservative assessment of performance. Evaluate the assessment of uncertainty and variability in these parameters.

Determine if the U.S. Department of Energy appropriately establishes possible statistical correlations between parameters. Verify that an adequate technical basis or bounding argument is provided for neglected correlations.

Confirm that performance assessments incorporate the hydrologic effects of future climate change that could alter the rates and patterns of present-day net infiltration into the unsaturated zone.

Review Method 4 Model Uncertainty

Evaluate the U.S. Department of Energy alternative conceptual models used in developing the abstraction for climate and net infiltration. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies. Where appropriate, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of climate and net infiltration.

Verify that the bounds of uncertainty created by the process-level models are adequately reflected in this abstraction. Where appropriate, use an alternative total system performance assessment model to verify that the U.S. Department of Energy total system performance assessment approach reflects or bounds the uncertainties in the process-level models.

Assure the conceptual model uncertainties are defined and documented, including their effects on conclusions regarding performance.

Review Method 5 Model Support

Evaluate the output from the abstraction of climate and net infiltration. Compare the results with an appropriate combination of site characterization data, process-level modeling, laboratory testing, field measurements, and natural analog data.

Assure adequate justification and technical bases exist to conservatively bound process-level models. In particular, verify that if the U.S. Department of Energy uses an abstracted model to predict water flux into the unsaturated zone, the abstracted model is shown to bound process-level model predictions of the net infiltration flux. Use detailed models of geological, hydrological, geochemical, and climatological processes to evaluate the abstraction of climate and net infiltration.

Evaluate the output of model abstractions against results produced by process-level models. Where practical, use an alternative total system performance assessment model to evaluate

selected parts of the U.S. Department of Energy abstraction, and to evaluate the effects of climate and net infiltration on repository performance.

4.2.1.3.5.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c) and (e)–(g), relating to the climate and net infiltration model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- The total system performance assessment adequately incorporates, or bounds, important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the climate and net infiltration abstraction process;

- The aspects of geology, hydrology, geochemistry, physical phenomena, and couplings, that may affect climate and net infiltration, are adequately considered. Conditions and assumptions in the abstraction of climate and net infiltration are readily identified and consistent with the body of data presented in the description;

- The abstraction of climate and net infiltration uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, the assumptions used for climate and net infiltration are consistent with the abstractions of flow paths in the unsaturated zone and flow paths in the saturated zone (Sections 4.2.1.3.6 and 4.2.1.3.8 of the Yucca Mountain Review Plan, respectively). The descriptions and technical bases provide transparent and traceable support for the abstraction of climate and net infiltration;

- Sufficient data and technical bases to assess the degree to which features, events, and processes have been included for this abstraction are provided;

- Adequate spatial and temporal variability of model parameters and boundary conditions are employed to model the different parts of the system;

- Average parameter estimates are used in process-level models over time and space scales that are appropriate for the model discretization;

- Projections of future climate change are based on evaluation of paleoclimate information over the past 500,000 years. For example, numerical climate models, if used for projection of future climate, are calibrated based on such paleoclimate data; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer reviews and data qualification, is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Climatological and hydrological values used in the safety case (e.g., time of onset of climate change, mean annual temperature, mean annual precipitation, mean annual net infiltration, etc.) are adequately justified. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Estimates of present-day net infiltration using mathematical models at appropriate time and space scales are reasonably verified with site-specific climatic, surface, and subsurface information;

- The effects of fracture properties, fracture distributions, matrix properties, heterogeneities, time-varying boundary conditions, evapotranspiration, depth of soil cover, and surface-water runoff and runon are considered, such that net infiltration is not underestimated;

- Sensitivity or uncertainty analyses are performed to assess data sufficiency and determine the possible need for additional data;

- Accepted and well-documented procedures are used to construct and calibrate numerical models;

- Reasonably complete process-level conceptual and mathematical models are used in the analyses. In particular: (i) mathematical models are provided that are consistent with conceptual models and site characteristics; and (ii) the robustness of results from different mathematical models is compared; and

- Any expert elicitation conducted is in accordance with NUREG–1563 (Kotra, et al., 1996), or other acceptable approaches.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- The technical bases for the parameter values used in this abstraction are provided;

- Possible statistical correlations are established between parameters in this abstraction. An adequate technical basis or bounding argument is provided for neglected correlations; and

- The hydrologic effects of future climate change that may alter the rates and patterns of present-day net infiltration into the unsaturated zone are addressed. Such effects may include changes in soil depths, fracture-fill material, and types of vegetation.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction

- Alternative modeling approaches of features, events, and processes, consistent with available data and current scientific understanding, are investigated. The results and limitations are appropriately considered in the abstraction;
- The bounds of uncertainty created by the process-level models are considered in this abstraction; and
- Conceptual model uncertainties and their effects on conclusions regarding performance are defined and documented.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testing and/or natural analogs);
- Abstractions of process-level models may conservatively bound process-level predictions; and
- Comparisons are provided of output of abstracted models of climate and net infiltration with output of sensitivity studies, detailed process-level models, natural analogs, and empirical observations, as appropriate.

4.2.1.3.5.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.5.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.1.1.1.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to climate and infiltration, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of

climate and net infiltration have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a))–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual doses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.5.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer-Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.6 Flow Paths in the Unsaturated Zone

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on flow paths in the unsaturated zone, to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on flow paths in the unsaturated zone to provide significant delay and/or dilution in the transport of radionuclides to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the delay in the transport of radionuclides to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that

have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.6.1 Areas of Review

This section reviews flow paths in the unsaturated zone. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (10), (15), and (19), that is relevant to the abstraction of flow paths in the unsaturated zone.

The staff will evaluate the following parts of the abstraction of flow paths in the unsaturated zone, using the review methods and acceptance criteria in Sections 4.2.1.3.6.2 and 4.2.1.3.6.3:

- Description of the hydrological, geological, and coupled thermal-hydrologic-mechanical-chemical processes of flow paths in the unsaturated zone, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;
- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.6.2 Review Methods

To review the abstraction of flow paths in the unsaturated zone, recognize that models used in the total system performance assessment may range from highly complex process-level models

to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of physical phenomena and couplings, and the descriptions of the geological, hydrological, geochemical, and thermal-hydrological-mechanical-chemical aspects

of the abstraction of flow paths in the unsaturated zone that affect waste isolation. Assess the adequacy of the technical bases for these descriptions and for incorporating them in this abstraction.

Evaluate whether the descriptions of aspects of geology, hydrology, geochemistry, physical phenomena, and couplings that may affect flow paths in the unsaturated zone are adequate. Verify that conditions and assumptions used in this abstraction are consistent with the body of data presented in the description.

Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in this abstraction for consistency with other related abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for this abstraction.

Determine whether the conditions and assumptions used to generate look-up tables or regression equations to describe initial and boundary conditions are consistent with other conditions and assumptions in this abstraction.

Examine how the features, events, and processes related to flow paths in the unsaturated zone have been included in the total system performance assessment abstraction.

Verify that the U.S. Department of Energy abstractions employ adequate spatial and temporal variability of model parameters and boundary conditions to estimate flow paths in the unsaturated zone, percolation flux, and seepage flux.

Verify that appropriate averages of parameter estimates are used in process-level models over time and space scales that are appropriate for the model discretization.

Confirm that potential reduction in unsaturated zone transport distances are accounted for after a climate-induced water table rise.

Verify that the U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or make an acceptable case for using alternative approaches for peer review and data qualification.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the data used to support conceptual models, process-level models, and alternative conceptual models considered in this abstraction, and the parameters used for each of these models. Evaluate the basis for the data on physical phenomena, couplings, climatology, geology, hydrology, and geochemistry. This basis may include a combination of techniques, such as laboratory experiments, site-specific field measurements, natural analog research, process-level modeling studies, and expert elicitation.

Verify that acceptable techniques, which may include laboratory experiments, site-specific field measurements, natural analog research, and process-level modeling studies, are used in collecting and interpreting the data regarding the geology, hydrology, and geochemistry of the unsaturated zone.

Assure that estimates of deep-percolation flux rates constitute an upper bound or reasonably represent the physical system. Verify that the flow model is calibrated using site-specific hydrologic, geologic, and geochemical data. Confirm that the mathematical model estimates of deep-percolation flux are at appropriate time and space scales.

Verify that appropriate thermal-hydrologic processes are evaluated by testing.

Confirm the use of adequate sensitivity or uncertainty analyses to assess data sufficiency, and determine the possible need for additional data.

Assure adequate accepted and well-documented procedures are applied to develop and calibrate numerical models.

Verify that reasonably complete process-level conceptual and mathematical models are used in the analyses. Assure the mathematical models are consistent with conceptual models and site characteristics. Confirm that a comparison of the robustness of results from different mathematical models is provided.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation.

Review Method 3 Data Uncertainty

Verify that parameter values reasonably account for uncertainties and variabilities for the assumed ranges, probability distributions, and/or bounding assumptions. Evaluate the U.S. Department of Energy assessment of uncertainty and variability in parameters used in the model abstraction. Determine whether uncertainty in data, from both temporal and spatial variations in conditions affecting flow paths in the unsaturated zone, is incorporated into the parameter ranges.

Examine the technical bases for parameter values and ranges, probability distributions, or bounding values in conceptual models, process-level models, and alternative conceptual models, considered in the total system performance assessment abstraction. Determine whether the parameter values are derived from site-specific data, or an analysis is included to show that the assumed parameter values lead to a reasonable assessment of performance. Evaluate the assessment of uncertainty and variability in these parameters.

Determine if the U.S. Department of Energy appropriately established possible statistical correlations between parameters. Verify that an adequate technical basis or bounding argument is provided for neglected correlations.

Examine the initial conditions, boundary conditions, and computational domain used in sensitivity analyses and/or similar analyses for consistency with available data.

Verify that coupled thermal-hydrologic-mechanical-chemical processes are properly evaluated. Ensure that uncertainties in the characteristics of the natural system and engineered materials are considered.

Confirm that parameter values are consistent with the initial and boundary conditions and the assumptions of the conceptual models for the Yucca Mountain site.

Review Method 4 Model Uncertainty

Evaluate the U.S. Department of Energy alternative conceptual models used in developing the abstraction for flow paths in the unsaturated zone. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies. Where appropriate, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of flow paths in the unsaturated zone.

Verify that the bounds of uncertainty created by the process-level models are adequately reflected in this abstraction. Where appropriate, use an alternative total system performance assessment model to verify that the U.S. Department of Energy total system performance assessment approach reflects or bounds the uncertainties in the process-level models.

Assure the conceptual model uncertainties are defined and documented, including their effects on conclusions regarding performance.

Review Method 5 Model Support

Evaluate the output from the abstraction of flow paths in the unsaturated zone. Compare the results with an appropriate combination of site characterization data, process-level modeling, laboratory testing, field measurements, and natural analog data.

Assure adequate justification and technical basis exist to conservatively bound process-level models. Use detailed models of geological, hydrological, geochemical, and thermal-hydrologic-mechanical-chemical processes, to evaluate the total system performance assessment abstractions of flow paths in the unsaturated zone.

Evaluate the output of model abstractions against results produced by process-level models. Where practical, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction, and to evaluate the effects of flow paths in the unsaturated zone on repository performance.

4.2.1.3.6.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)()–(c) and (e)–(g), relating to the flow paths in the unsaturated zone model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- The total system performance assessment adequately incorporates, or bounds, important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the flow paths in the unsaturated zone abstraction process. Couplings include thermal-hydrologic-mechanical-chemical effects, as appropriate;

- The aspects of geology, hydrology, geochemistry, physical phenomena, and couplings that may affect flow paths in the unsaturated zone are adequately considered. Conditions and assumptions in the abstraction of flow paths in the unsaturated zone are readily identified and consistent with the body of data presented in the description;

- The abstraction of flow paths in the unsaturated zone uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, the assumptions used for flow paths in the unsaturated zone are consistent with the abstractions of quantity and chemistry of water contacting waste packages and waste forms, climate and infiltration, and flow paths in the saturated zone (Sections 4.2.1.3.3, 4.2.1.3.5, and 4.2.1.3.8 of the Yucca Mountain Review Plan, respectively). The descriptions and technical bases are transparent and traceable to site and design data;

- The bases and justification for modeling assumptions and approximations of radionuclide transport in the unsaturated zone are consistent with those used in model abstractions for flow paths in the unsaturated zone and thermal-hydrologic-mechanical-chemical effects;

- Sufficient data and technical bases to assess the degree to which features, events, and processes have been included in this abstraction are provided;

- Adequate spatial and temporal variability of model parameters and boundary conditions are employed in process-level models to estimate flow paths in the unsaturated zone, percolation flux, and seepage flux;

- Average parameter estimates used in process-level models are representative of the temporal and spatial discretizations considered in the model;

- Reduction in unsaturated zone transport distances, after a climate-induced water table rise, is considered; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer review and data qualification, is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Hydrological and thermal-hydrological-mechanical-chemical values used in the safety case are adequately justified. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- The data on the geology, hydrology, and geochemistry of the unsaturated zone, are collected using acceptable techniques;

- Estimates of deep-percolation flux rates constitute an upper bound, or are based on a technically defensible unsaturated zone flow model that reasonably represents the physical system. The flow model is calibrated, using site-specific hydrologic, geologic, and geochemical data. Deep-percolation flux is estimated, using the appropriate spatial and temporal variability of model parameters, and boundary conditions that consider climate-induced change in soil depths and vegetation;

- Appropriate thermal-hydrologic tests are designed and conducted, so that critical thermal-hydrologic processes can be observed, and values for relevant parameters estimated;

- Sensitivity or uncertainty analyses are performed to assess data sufficiency, and determine the possible need for additional data;

- Accepted and well-documented procedures are used to construct and calibrate numerical models;

- Reasonably complete process-level conceptual and mathematical models are used in the analyses. In particular: (i) mathematical models are provided that are consistent with conceptual models and site characteristics; and (ii) the robustness of results from different mathematical models is compared; and

- Any expert elicitation conducted is in accordance with NUREG–1563 (Kotra, et al., 1996), or other acceptable approaches.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- The technical bases for the parameter values used in this abstraction are provided;

- Possible statistical correlations are established between parameters in this abstraction. An adequate technical basis or bounding argument is provided for neglected correlations;

- The initial conditions, boundary conditions, and computational domain used in sensitivity analyses and/or similar analyses are consistent with available data. Parameter values are consistent with the initial and boundary conditions and the assumptions of the conceptual models for the Yucca Mountain site;

- Coupled processes are adequately represented; and

- Uncertainties in the characteristics of the natural system and engineered materials are considered.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes, consistent with available data and current scientific understanding, are investigated. The results and limitations are appropriately considered in the abstraction;

- The bounds of uncertainty created by the process-level models are considered in this abstraction; and

- Conceptual model uncertainties, and their effects on conclusions regarding performance, are defined and documented.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testing and/or natural analogs);

- Abstractions of process-level models conservatively bound process-level predictions; and

- Comparisons are provided of output of abstracted model of flow paths in the unsaturated zone with outputs of sensitivity studies, detailed process-level models, natural analogs, and empirical observations, as appropriate.

4.2.1.3.6.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.6.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to flow paths in the unsaturated zone, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment

in the area of flow paths in the unsaturated zone have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.6.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer-Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.7 Radionuclide Transport in the Unsaturated Zone

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on radionuclide transport through the unsaturated zone, to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on the unsaturated zone to provide significant delay in the transport of radionuclides and/or dilution of concentration to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the delay, or a minor impact on the dose to the reasonably maximally exposed individual, then conduct a simplified review, focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The

demonstration of compliance with the performance objectives is evaluated using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.7.1 Areas of Review

This section reviews radionuclide transport in the unsaturated zone. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (10), (15), and (19), that is relevant to the abstraction of radionuclide transport in the unsaturated zone.

The staff will evaluate the following parts of the abstraction of radionuclide transport in the unsaturated zone, using the review methods and acceptance criteria in Sections 4.2.1.3.7.2 and 4.2.1.3.7.3

- Description of the geological, hydrological, and geochemical aspects of radionuclide transport in the unsaturated zone, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;
- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.7.2 Review Methods

To review the abstraction of radionuclide transport in the unsaturated zone, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geological, hydrological, and geochemical aspects of the unsaturated zone

included in the abstraction of radionuclide transport in the unsaturated zone, that affect waste isolation. Assess the adequacy of the technical bases for these descriptions, and for incorporating them in the abstraction of radionuclide transport in the unsaturated zone.

Evaluate whether the description of aspects of hydrology, geology, geochemistry, design features, physical phenomena, and couplings, that may affect radionuclide transport in the unsaturated zone, is adequate. Verify that conditions and assumptions used in the total system performance assessment abstraction of radionuclide transport in the unsaturated zone are consistent with the data presented in the description.

Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in the abstraction of radionuclide transport in the unsaturated zone for consistency with other related U.S. Department of Energy abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for the abstraction of radionuclide transport in the unsaturated zone.

Confirm that the U.S. Department of Energy has propagated boundary and initial conditions, used in the abstraction of radionuclide transport in the unsaturated zone throughout its abstraction approaches.

Examine how the features, events, and processes related to radionuclide transport in the unsaturated zone, have been included in the total system performance assessment abstraction.

Verify that the U.S. Department of Energy follows guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or makes an acceptable case for using alternative approaches for peer review and data qualification.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the geological, hydrological, and geochemical data used to support parameters, used in conceptual models, process-level models, and alternative conceptual models, considered in the abstraction of radionuclide transport in the unsaturated zone. Assess the sufficiency, transparency, and traceability of the data used to support the technical bases for features, events, and processes that have been included in the abstraction of radionuclide transport in the unsaturated zone.

Verify whether sufficient data have been collected on the characteristics of the geology, hydrology, and geochemistry of the natural system to establish initial and boundary conditions for the abstraction of radionuclide transport in the unsaturated zone.

Evaluate and confirm that data used to support the U.S. Department of Energy abstraction of radionuclide transport in the unsaturated zone are based on appropriate techniques, and are

adequate for the accompanying sensitivity/uncertainty analyses. Evaluate the need for additional data based on the sensitivity analyses.

Review Method 3 Data Uncertainty

Evaluate the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models considered in the abstraction of radionuclide transport in the unsaturated zone. Evaluate the assessment of uncertainty and variability in these parameters, and verify that the technical bases reasonably account for uncertainties and variabilities in the data.

Determine whether the U.S. Department of Energy has used flow and transport parameters that are based on techniques that may include laboratory experiments, field measurements, natural analog research, and process-level modeling studies, conducted under conditions relevant to the unsaturated zone at Yucca Mountain. Examine the results of the U.S. Department of Energy field transport tests, and confirm that the U.S. Department of Energy has provided adequate models.

If criticality in the unsaturated zone is included in the total system performance assessment, examine the methods and parameters used by the U.S. Department of Energy to calculate the effective neutron multiplication factor. Evaluate the consequences calculated by the U.S. Department of Energy for criticality in the unsaturated zone.

Assess how uncertainty is represented in parameter development for conceptual models, process-level models, and alternative conceptual models, considered in developing the abstraction of radionuclide transport in the unsaturated zone.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 4 Model Uncertainty

Evaluate the U.S. Department of Energy alternative conceptual models, used in developing the abstraction for radionuclide transport in the unsaturated zone. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies, and evaluate their consistency.

Where appropriate, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of radionuclide transport in the unsaturated zone. Examine the effects of the alternative conceptual model(s) on repository performance, and evaluate how model uncertainties are defined, documented, and assessed.

Examine the mathematical models included in the analyses of radionuclide transport in the unsaturated zone. Examine and evaluate the bases for excluding alternative conceptual models, and the limitations and uncertainties of the chosen model.

Review Method 5 Model Support

Evaluate the output from the abstraction of radionuclide transport in the unsaturated zone, and compare the results with an appropriate combination of site characterization data, process

modeling, laboratory testing, field measurements, and natural analog research. Evaluate the sensitivity analyses used to support the abstraction of radionuclide transport in the unsaturated zone in the total system performance assessment.

Use detailed models of geochemical, hydrological, and geological processes to evaluate the total system performance assessment abstractions of radionuclide transport in the unsaturated zone. If practical, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of radionuclide transport in the unsaturated zone, and evaluate the effects on repository performance. Compare results of the U.S. Department of Energy abstraction to approximations shown to be appropriate for closely analogous natural systems or experimental systems.

Examine the procedures used by the U.S. Department of Energy to develop and test its mathematical and numerical models.

As appropriate, use an alternative total system performance assessment model to evaluate the U.S. Department of Energy sensitivity or bounding analyses, and confirm that the U.S. Department of Energy has used ranges consistent with available site characterization data, field and laboratory tests, and natural analog research.

4.2.1.3.7.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)()–(c) and (e)–(g) , relating to the radionuclide transport in the unsaturated zone model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the radionuclide transport in the unsaturated zone abstraction process;

- The description of the aspects of hydrology, geology, geochemistry, design features, physical phenomena, and couplings, that may affect radionuclide transport in the unsaturated zone, is adequate. For example, the description includes changes in transport properties in the unsaturated zone, from water-rock interaction. Conditions and assumptions in the total system performance assessment abstraction of radionuclide transport in the unsaturated zone are readily identified, and consistent with the body of data presented in the description;

- The abstraction of radionuclide transport in the unsaturated zone uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, assumptions used for radionuclide transport in the unsaturated zone are consistent with the abstractions of radionuclide release rates and solubility limits and flow paths in the unsaturated zone

(Sections 4.2.1.3.4 and 4.2.1.3.6 of the Yucca Mountain Review Plan, respectively). The descriptions and technical bases provide transparent and traceable support for the abstraction of radionuclide transport in the unsaturated zone;

- Boundary and initial conditions used in the abstraction of radionuclide transport in the unsaturated zone are propagated throughout its abstraction approaches. For example, the conditions and assumptions used to generate transport parameter values are consistent with other geological, hydrological, and geochemical conditions in the total system performance assessment abstraction of the unsaturated zone;

- Sufficient data and technical bases for the inclusion of features, events, and processes, related to radionuclide transport in the unsaturated zone in the total system performance assessment abstraction, are provided; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches, is followed for peer review and data qualification.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Geological, hydrological, and geochemical values, used in the safety case, are adequately justified (e.g., flow-path length, sorption coefficients, retardation factors, colloid concentrations, etc.). Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Sufficient data have been collected on the characteristics of the natural system to establish initial and boundary conditions for the total system performance assessment abstraction of radionuclide transport in the unsaturated zone; and

- Data on the geology, hydrology, and geochemistry of the unsaturated zone, including the influence of structural features, fracture distributions, fracture properties, and stratigraphy, used in the total system performance assessment abstraction are based on appropriate techniques. These techniques may include laboratory experiments, site-specific field measurements, natural analog research, and process-level modeling studies. As appropriate, sensitivity or uncertainty analyses, used to support the U.S. Department of Energy total system performance assessment abstraction, are adequate to determine the possible need for additional data.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- For those radionuclides where the total system performance assessment abstraction indicates that transport in fractures and matrix in the unsaturated zone is important to performance: (i) estimated flow and transport parameters are appropriate and valid, based on techniques that may include laboratory experiments, field measurements,

natural analog research, and process-level modeling studies, conducted under conditions relevant to the unsaturated zone at Yucca Mountain; and (ii) models are demonstrated to adequately reproduce field transport test results. For example, if a sorption coefficient approach is used, the assumptions implicit in that approach are verified;

- If criticality in the unsaturated zone far field is included in the total system performance assessment, an appropriate range of input parameters for calculating the effective neutron multiplication factor is used. The effects on performance of criticality in the unsaturated zone are adequately evaluated;

- Uncertainty is adequately represented in parameter development for conceptual models, process-level models, and alternative conceptual models, considered in developing the abstraction of radionuclide transport in the unsaturated zone. This may be done either through sensitivity analyses or use of conservative limits.

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of expert elicitation, conducted in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations are appropriately considered in the abstraction;

- Conceptual model uncertainties are adequately defined and documented, and effects on conclusions regarding performance are properly assessed; and

- Appropriate alternative modeling approaches are consistent with available data and current scientific knowledge, and appropriately consider their results and limitations, using tests and analyses that are sensitive to the processes modeled. For example, for radionuclide transport through fractures, the U.S. Department of Energy adequately considers alternative modeling approaches, to develop its understanding of fracture distributions and ranges of fracture flow and transport properties in the unsaturated zone.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs);

- Outputs of radionuclide transport in the unsaturated zone abstractions reasonably produce or bound the results of corresponding process-level models, empirical

observations, or both. The U.S. Department of Energy abstracted models for radionuclide transport in the unsaturated zone are based on the same hydrological, geological, and geochemical assumptions and approximations, shown to be appropriate for closely analogous natural systems or experimental systems;

- Well-documented procedures that have been accepted by the scientific community to construct and test the mathematical and numerical models are used to simulate radionuclide transport through the unsaturated zone; and

- Sensitivity analyses or bounding analyses are provided, to support the total system performance assessment abstraction of radionuclide transport in the unsaturated zone, that cover ranges consistent with site data, field or laboratory experiments and tests, and natural analog research.

4.2.1.3.7.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.7.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to radionuclide transport in the unsaturated zone, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of radionuclide transport in the unsaturated zone have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.7.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer-Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.8 Flow Paths in the Saturated Zone

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on flow paths in the saturated zone to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on saturated zone flow to provide significant delay or dilution in the transport of radionuclides to the reasonably maximally exposed individual, then perform a review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the dose to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated, using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.8.1 Areas of Review

This section reviews flow paths in the saturated zone. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19), that is relevant to the abstraction of flow paths in the saturated zone.

The staff will evaluate the following parts of the abstraction of flow paths in the saturated zone, using the review methods and acceptance criteria in Sections 4.2.1.3.8.2 and 4.2.1.3.8.3:

- Description of the geological, hydrological, and geochemical aspects of flow paths in the saturated zone, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;

- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.8.2 Review Methods

To review the abstraction of flow paths in the saturated zone, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geological, hydrological, and geochemical aspects of the saturated zone, included in the abstraction of flow paths, in the saturated zone, that affect waste isolation. Assess the adequacy of the technical bases for these descriptions, and for incorporating them in the abstraction of flow paths in the saturated zone.

Evaluate whether the description of aspects of geology, hydrology, geochemistry, design features, physical phenomena, and couplings, that may affect flow paths in the saturated zone, is adequate. Verify that conditions and assumptions used in the abstraction of flow paths in the saturated zone are consistent with the body of data presented in the description.

Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in the abstraction of flow paths in the saturated zone for consistency with other related U.S. Department of Energy abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for the abstraction of flow paths in the saturated zone.

Confirm that the U.S. Department of Energy has propagated boundary and initial conditions, used in the abstraction of flow paths in the saturated zone, throughout its abstraction approaches.

Examine how the features, events, and processes, related to flow paths in the saturated zone have been included in the total system performance assessment abstraction.

Ensure that the U.S. Department of Energy delineates the flow paths in the saturated zone, considering natural site conditions.

Verify that the U.S. Department of Energy evaluates long-term climate change, based on known patterns of climatic cycles, during the Quaternary period, particularly the last 500,000 years, and other paleoclimate data.

Confirm that the U.S. Department of Energy considers potential geothermal and seismic effects on the ambient saturated zone flow system.

Ensure that the U.S. Department of Energy considers the impact of the expected water table rise on potentiometric heads and flow directions, and consequently on repository performance.

Verify that the U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or make an acceptable case for using alternative approaches.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the geological, hydrological, geochemical, and climatological data used to support parameters used in conceptual models, process-level models, and alternative conceptual models considered in the total system performance assessment abstraction of flow paths in the saturated zone. Evaluate the basis for the data on physical phenomena, couplings, climatology, geology, hydrology, and geochemistry used in the total system performance assessment abstraction of flow paths in the saturated zone. This basis may include a combination of techniques, such as laboratory experiments, site-specific field measurements, natural analog research, process-level modeling studies, and expert elicitation.

Verify that sufficient data have been collected on the characteristics of the geology, hydrology, and geochemistry of the natural system, to establish initial and boundary conditions for the total system performance assessment abstraction of flow paths in the saturated zone.

Evaluate and confirm that data used to support the U.S. Department of Energy total system performance assessment abstraction of flow paths in the saturated zone are based on appropriate techniques, and are adequate for the accompanying sensitivity/uncertainty analyses. Evaluate the need for additional data, based on sensitivity analyses.

Ensure that the U.S. Department of Energy provides sufficient information to substantiate that the proposed mathematical ground-water modeling approach, and proposed model(s) are applicable to site conditions.

Review Method 3 Data Uncertainty

Evaluate the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process-level models, and alternative conceptual models, considered in the total system performance assessment abstraction of flow paths in the saturated zone. Evaluate the assessment of uncertainty and variability in these

parameters, and verify that the technical bases reasonably account for uncertainties and variabilities in the data.

Confirm that model abstractions incorporate uncertainty in hydrologic effects of climate change, based on a reasonably complete search of paleoclimate data.

Assess how uncertainty is represented in parameter development for conceptual models, process-level models, and alternative conceptual models, considered in developing the total system performance assessment abstraction of flow paths in the saturated zone.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 4 Model Uncertainty

Evaluate the U.S. Department of Energy alternative conceptual models used in developing the abstraction for flow paths in the saturated zone. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies, and evaluate their consistency. Confirm that the U.S. Department of Energy has adequately addressed comments from external reviews of the model abstraction.

Where appropriate, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of flow paths in the saturated zone. Examine the effects of the alternative conceptual model(s) on repository performance, and evaluate how model uncertainties are defined, documented, and assessed.

Examine the mathematical models included in the analyses of flow paths in the saturated zone. Also, examine and evaluate the bases for excluding alternative conceptual models, and the limitations and uncertainties of the chosen model.

Review Method 5 Model Support

Evaluate the output from the abstraction of flow paths in the saturated zone, and compare the results with an appropriate combination of site characterization data, process-level modeling, laboratory testing, field measurements, and natural analog research.

Use detailed models of geological, hydrological, and geochemical processes to evaluate the total system performance assessment abstractions of flow paths in the saturated zone. If practical, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of flow paths in the saturated zone, and evaluate the effects on repository performance. Compare results of the U.S. Department of Energy abstraction to approximations shown to be appropriate for closely analogous natural systems or experimental systems.

Examine the procedures used by the U.S. Department of Energy to develop and test its mathematical and numerical models.

As appropriate, use an alternative total system performance assessment model to evaluate the U.S. Department of Energy sensitivity or bounding analyses, and confirm that the U.S. Department of Energy has used ranges consistent with available site characterization data, field and laboratory tests, and natural analog research.

4.2.1.3.8.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c) and (e)–(g), relating to the flow paths in the saturated zone model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions, throughout the flow paths in the saturated zone abstraction process;

- The description of the aspects of hydrology, geology, geochemistry, design features, physical phenomena, and couplings, that may affect flow paths in the saturated zone, is adequate. Conditions and assumptions in the abstraction of flow paths in the saturated zone are readily identified, and consistent with the body of data presented in the description;

- The abstraction of flow paths in the saturated zone uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, the assumptions used for flow paths in the saturated zone are consistent with the total system performance assessment abstraction of representative volume (Section 4.2.1.3.12 of the Yucca Mountain Review Plan). The descriptions and technical bases provide transparent and traceable support for the abstraction of flow paths in the saturated zone;

- Boundary and initial conditions used in the total system performance assessment abstraction of flow paths in the saturated zone are propagated throughout its abstraction approaches. For example, abstractions are based on initial and boundary conditions consistent with site-scale modeling and regional models of the Death Valley ground-water flow system;

- Sufficient data and technical bases to assess the degree to which features, events, and processes have been included in this abstraction are provided;

- Flow paths in the saturated zone are adequately delineated, considering natural site conditions;

- Long-term climate change, based on known patterns of climatic cycles during the Quaternary period, particularly the last 500,000 years, and other paleoclimate data, are adequately evaluated;

- Potential geothermal and seismic effects on the ambient saturated zone flow system are adequately described and accounted for;

- The impact of the expected water table rise on potentiometric heads and flow directions, and consequently on repository performance, is adequately considered; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer review and data qualification is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Geological, hydrological, and geochemical values used in the safety case to evaluate flow paths in the saturated zone are adequately justified. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Sufficient data have been collected on the natural system to establish initial and boundary conditions for the abstraction of flow paths in the saturated zone;

- Data on the geology, hydrology, and geochemistry of the saturated zone used in the total system performance assessment abstraction are based on appropriate techniques. These techniques may include laboratory experiments, site-specific field measurements, natural analog research, and process-level modeling studies. As appropriate, sensitivity or uncertainty analyses, used to support the U.S. Department of Energy total system performance assessment abstraction, are adequate to determine the possible need for additional data; and

- Sufficient information is provided to substantiate that the proposed mathematical ground-water modeling approach and proposed model(s) are calibrated and applicable to site conditions.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities. For example, the U.S. Department of Energy provides sufficient bases for selection of hydrologic parameter values and statistical distributions;

- Uncertainty is appropriately incorporated in model abstractions of hydrologic effects of climate change, based on a reasonably complete search of paleoclimate data;

- Uncertainty is adequately represented in parameter development for conceptual models, process-level models, and alternative conceptual models, considered in developing the abstraction of flow paths in the saturated zone. This may be done either through sensitivity analyses or use of conservative limits. For example, sensitivity analyses and/or similar analyses are sufficient to identify saturated zone flow parameters that are expected to significantly affect the abstraction model outcome; and

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of expert elicitation, conducted in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their uses.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations are appropriately considered in the abstraction;

- Conceptual model uncertainties are adequately defined and documented, and effects on conclusions regarding performance are properly assessed. For example, uncertainty in data interpretations is considered by analyzing reasonable conceptual flow models that are supported by site data, or by demonstrating through sensitivity studies that the uncertainties have little impact on repository performance; and

- Appropriate alternative modeling approaches are consistent with available data and current scientific knowledge, and appropriately consider their results and limitations, using tests and analyses that are sensitive to the processes modeled.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs);

- Outputs of flow paths in the saturated zone abstractions reasonably produce or bound the results of corresponding process-level models, empirical observations, or both;

- Well-documented procedures that have been accepted by the scientific community to construct and test the mathematical and numerical models are used to simulate flow paths in the saturated zone; and

- Sensitivity analyses or bounding analyses are provided to support the abstraction of flow paths in the saturated zone, that cover ranges consistent with site data, field or laboratory experiments and tests, and natural analog research.

4.2.1.3.8.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.8.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

Review Plan for Safety Analysis Report

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to flow paths in the saturated zone, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of flow paths in the saturated zone have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.8.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.9 Radionuclide Transport in the Saturated Zone

To review this model abstraction, the staff will evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on radionuclide transport through the saturated zone, to demonstrate its safety case. Review this model abstraction considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on the saturated zone to provide significant delay in the transport of radionuclides and/or dilution of concentration to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the dose to the reasonably maximally exposed individual, then conduct a

simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated, using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.9.1 Areas of Review

This section reviews radionuclide transport in the saturated zone. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19), that is relevant to the abstraction of radionuclide transport in the saturated zone.

The staff will evaluate the following parts of the abstraction of radionuclide transport in the saturated zone, using the review methods and acceptance criteria in Sections 4.2.1.3.9.2 and 4.2.1.3.9.3:

- Description of the geological, hydrological, and geochemical aspects of radionuclide transport in the saturated zone, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;
- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output with process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.9.2 Review Methods

To review the abstraction of radionuclide transport in the saturated zone, recognize that models used in the total system performance assessments may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geological, hydrological, and geochemical aspects of the saturated zone included in the abstraction of radionuclide transport in the saturated zone that contribute to waste isolation. Assess the adequacy of the technical bases for these descriptions, and for incorporating them in the abstraction of radionuclide transport in the saturated zone.

Evaluate whether the description of aspects of hydrology, geology, geochemistry, design features, physical phenomena, and couplings, that may affect radionuclide transport in the saturated zone, is adequate. Verify that conditions and assumptions used in the abstraction of radionuclide transport in the saturated zone are consistent with the body of data presented in the description.

Examine assumptions, technical bases, data, and models used by the U.S. Department of Energy in the total system performance assessment abstraction of radionuclide transport in the saturated zone for consistency with other related U.S. Department of Energy abstractions. Evaluate whether the descriptions and technical bases provide transparent and traceable support for the abstraction of radionuclide transport in the saturated zone.

Confirm that the U.S. Department of Energy has propagated boundary and initial conditions, used in the abstraction of radionuclide transport in the saturated zone, throughout its abstraction approaches.

Examine how the features, events, and processes, related to radionuclide transport in the saturated zone, have been included in the total system performance assessment abstraction.

Verify that the U.S. Department of Energy follows guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or makes an acceptable case for using alterative approaches to peer review and data qualification.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the geological, hydrological, and geochemical data used to support parameters used in conceptual models, process-level models, and alternative conceptual models, considered in the abstraction of radionuclide transport in the saturated zone. Assess the sufficiency, transparency, and traceability of the data, used to support the technical bases for features, events, and processes, that have been included in the abstraction of radionuclide transport in the saturated zone.

Verify whether sufficient data have been collected on the characteristics of the geology, hydrology, and geochemistry of the natural system to establish initial and boundary conditions for the abstraction of radionuclide transport in the saturated zone.

Evaluate and confirm that data used to support the U.S. Department of Energy abstraction of radionuclide transport in the saturated zone are based on appropriate techniques, and are adequate for the accompanying sensitivity/uncertainty analyses. Evaluate the need for additional data based on the sensitivity analyses.

Review Method 3 Data Uncertainty

Evaluate the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models considered in the abstraction of radionuclide transport in the saturated zone. Evaluate the assessment of uncertainty and variability in these parameters, and verify that the technical bases reasonably account for uncertainties and variabilities in the data.

Determine whether the U.S. Department of Energy has used flow and transport parameters that are based on techniques that may include laboratory experiments, field measurements, natural analog research, and process-level modeling studies, conducted under conditions relevant to the saturated zone at Yucca Mountain. Examine the results of the U.S. Department of Energy field transport tests, and confirm that the U.S. Department of Energy has provided adequate models.

If criticality in the saturated zone is included in the total system performance assessment, examine the methods and parameters used by the U.S. Department of Energy to calculate the effective neutron multiplication factor. Evaluate the consequences calculated by the U.S. Department of Energy for criticality in the saturated zone.

Assess how uncertainty is represented in parameter development for conceptual models, process-level models, and alternative conceptual models considered in developing the total system performance assessment abstraction of radionuclide transport in the saturated zone.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 4 Model Uncertainty

Evaluate the U.S. Department of Energy alternative conceptual models used in developing the total system performance assessment abstraction for radionuclide transport in the saturated zone. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies, and evaluate their consistency.

Where appropriate, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of radionuclide transport in the saturated zone. Examine the effects of the alternative conceptual model(s) on repository performance, and evaluate how model uncertainties are defined, documented, and assessed.

Examine the mathematical models included in the analyses of radionuclide transport in the saturated zone. Examine and evaluate the bases for excluding alternative conceptual models, and the limitations and uncertainties of the chosen model.

Review Method 5 Model Support

Evaluate the output from the abstraction of radionuclide transport in the saturated zone, and compare the results with an appropriate combination of site characterization data, process modeling, laboratory testing, field measurements, and natural analog research. Evaluate the sensitivity analyses used to support the abstraction of radionuclide transport in the saturated zone in the total system performance assessment.

Use detailed models of geochemical, hydrological, and geological processes to evaluate the abstraction of radionuclide transport in the saturated zone. If practical, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy abstraction of radionuclide transport in the saturated zone, and evaluate the effects on repository performance. Compare results of the U.S. Department of Energy abstraction with approximations shown to be appropriate for closely analogous natural systems or experimental systems.

Examine the procedures used by the U.S. Department of Energy to develop and test its mathematical and numerical models.

As appropriate, use an alternative total system performance assessment model to evaluate the U.S. Department of Energy sensitivity or bounding analyses, and confirm that the U.S. Department of Energy has used ranges consistent with available site characterization data, field and laboratory tests, and natural analog research.

4.2.1.3.9.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c) and (e)–(g), relating to the radionuclide transport in the saturated zone model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the radionuclide transport in the saturated zone abstraction process;

- The description of the aspects of hydrology, geology, geochemistry, design features, physical phenomena, and couplings, that may affect radionuclide transport in the saturated zone, is adequate. For example, the description includes changes in transport properties in the saturated zone, from water-rock interaction. Conditions and assumptions in the abstraction of radionuclide transport in the saturated zone are readily identified, and consistent with the body of data presented in the description;

- The abstraction of radionuclide transport in the saturated zone uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions. For example, assumptions used for radionuclide transport in the saturated zone are consistent with the total system performance assessment abstractions of radionuclide release rates and solubility limits, and flow paths in the saturated zone (Sections 4.2.1.3.4 and 4.2.1.3.8 of the Yucca Mountain Review Plan, respectively). The descriptions and technical bases provide transparent and traceable support for the abstraction of radionuclide transport in the saturated zone;

- Boundary and initial conditions used in the abstraction of radionuclide transport in the saturated zone are propagated throughout its abstraction approaches. For example, the conditions and assumptions used to generate transport parameter values are consistent with other geological, hydrological, and geochemical conditions in the total system performance assessment abstraction of the saturated zone;

- Sufficient data and technical bases for the inclusion of features, events, and processes related to radionuclide transport in the saturated zone in the total system performance assessment abstraction are provided; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer review and data qualification is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Geological, hydrological, and geochemical values used in the safety case are adequately justified (e.g., flow path lengths, sorption coefficients, retardation factors, colloid concentrations, etc.). Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Sufficient data have been collected on the characteristics of the natural system to establish initial and boundary conditions for the total system performance assessment abstraction of radionuclide transport in the saturated zone; and

- Data on the geology, hydrology, and geochemistry of the saturated zone, including the influence of structural features, fracture distributions, fracture properties, and stratigraphy, used in the total system performance assessment abstraction, are based on appropriate techniques. These techniques may include laboratory experiments, site-specific field measurements, natural analog research, and process-level modeling studies. As appropriate, sensitivity or uncertainty analyses used to support the U.S. Department of Energy total system performance assessment abstraction are adequate to determine the possible need for additional data.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- For those radionuclides where the total system performance assessment abstraction indicates that transport in fractures and matrix in the saturated zone is important to performance: (i) estimated flow and transport parameters are appropriate and valid, based on techniques that may include laboratory experiments, field measurements, natural analog research, and process-level modeling studies conducted under conditions relevant to the saturated zone at Yucca Mountain; and (ii) models are demonstrated to adequately predict field transport test results. For example, if a sorption coefficient approach is used, the assumptions implicit in that approach are validated;

- If criticality in the saturated zone is included in the total system performance assessment, an appropriate range of input parameters for calculating the effective neutron multiplication factor is used. The effects on performance of criticality in the saturated zone are adequately evaluated;

- Parameter values for processes, such as matrix diffusion, dispersion, and ground-water mixing, are based on reasonable assumptions about climate, aquifer properties, and ground-water volumetric fluxes (Section 4.2.1.3.8 of the Yucca Mountain Review Plan);

- Uncertainty is adequately represented in parameter development for conceptual models, process-level models, and alternative conceptual models considered in developing the abstraction of radionuclide transport in the saturated zone. This may be done either through sensitivity analyses or use of conservative limits; and

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of other sources, such as expert elicitation conducted in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations are appropriately considered in the abstraction;

- Conceptual model uncertainties are adequately defined and documented, and effects on conclusions regarding performance are properly assessed; and

- Appropriate alternative modeling approaches are consistent with available data and current scientific knowledge, and appropriately consider their results and limitations

using tests and analyses that are sensitive to the processes modeled. For example, for radionuclide transport through fractures, the U.S. Department of Energy adequately considers alternative modeling approaches to develop its understanding of fracture distributions and ranges of fracture flow and transport properties in the saturated zone.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- The models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs);

- Outputs of radionuclide transport in the saturated zone abstractions reasonably produce or bound the results of corresponding process-level models, empirical observations, or both. The U.S. Department of Energy-abstracted models for radionuclide transport in the saturated zone are based on the same hydrological, geological, and geochemical assumptions and approximations shown to be appropriate for closely analogous natural systems or experimental systems;

- Well-documented procedures that have been accepted by the scientific community to construct and test the mathematical and numerical models are used to simulate radionuclide transport through the saturated zone; and

- Sensitivity analyses or bounding analyses are provided, to support the total system performance assessment abstraction of radionuclide transport in the saturated zone, that cover ranges consistent with site data, field or laboratory experiments and tests, and natural analog research.

4.2.1.3.9.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.9.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to radionuclide transport in the saturated zone ,and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of radionuclide transport in the saturated zone have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided, for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.9.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer-Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.10 Volcanic Disruption of Waste Packages

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on volcanic disruption of waste packages to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" (Section 4.2.1.1). For example, if the U.S. Department of Energy relies on waste package integrity to have a significant effect on dose to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on dose to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated, using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.10.1 Areas of Review

This section reviews volcanic disruption of waste packages. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15) and (19), that is relevant to the abstraction of volcanic disruption of waste packages.

The staff will evaluate the following parts of the abstraction of volcanic disruption of waste packages, using the review methods and acceptance criteria in Sections 4.2.1.3.10.2 and 4.2.1.3.10.3:

- Description of the geological, hydrological, geochemical and design aspects of volcanic disruption of waste packages, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;
- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output with process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.10.2 Review Methods

To review the abstraction of volcanic disruption of waste packages, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geology, geophysics, and geochemistry included in the abstraction of volcanic disruption of waste packages. Assess the adequacy and consistency of the technical bases for these descriptions, and for incorporating them into the total system performance assessment abstraction for volcanic disruption of waste packages. Confirm that models and assumptions used to evaluate volcanic disruption of waste packages are consistent with models and assumptions used elsewhere in the license application.

Determine that models used to assess volcanic disruption of waste packages are consistent with physical processes generally interpreted from igneous features in the Yucca Mountain region. Verify that models of active igneous processes are consistent with processes generally observed at active igneous features.

Evaluate the technical bases used to assess the effects of interactions between engineered repository systems and igneous systems.

Verify that U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or make an acceptable case for using alternative approaches to peer review and data qualification.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the geological, geophysical, and geochemical data used to support parameters used in conceptual models, process-level models, and alternative conceptual models considered in the total system performance assessment abstraction of volcanic disruption of waste packages.

Determine whether the technical bases for these data are adequately justified, and that data used to model processes affecting volcanic disruption of waste packages are derived, to the extent possible, from adequately documented techniques. Such techniques may include site-specific field measurements, natural analog investigations, and laboratory experiments.

Determine that sufficient data are available to integrate features, events, and processes relevant to volcanic disruption of waste packages into process-level models. Determine that appropriate interrelationships and correlations between relevant features, events, and processes are adequately considered in resulting model abstractions.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 3 Data Uncertainty

Examine the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions used in conceptual models, process-level models, and alternative conceptual models, considered in the total system performance assessment abstraction of volcanic disruption of waste packages. Evaluate the assessment of uncertainty and variability in these parameters, and verify that the technical bases reasonably account for uncertainties and variabilities in the data.

Examine the technical bases used to quantify uncertainty in parameter values observed in site data and the available literature (i.e., data precision), and the uncertainty in abstracting parameter values to process-level models (i.e., data accuracy), to ensure that adequate measures of uncertainty and variability have been considered.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 4 Model Uncertainty

Evaluate the alternative conceptual models used in developing the total system performance assessment abstraction for volcanic disruption of waste packages. Examine the model parameters, considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies, and evaluate their consistency.

Determine that uncertainties in abstracted models are adequately defined and documented. Verify that effects of these uncertainties are assessed in the total system performance assessment. Where appropriate, use an alternative total system performance assessment model to evaluate the effects of alternative models on repository performance.

Review Method 5 Model Support

Evaluate the output from the abstraction of volcanic disruption of waste packages, and compare the results with an appropriate combination of site characterization data, detailed process-level modeling, laboratory testing, field measurements, and natural analog research.

Determine that inconsistencies between abstracted models and comparative data are explained and quantified. Confirm that the resulting uncertainty is accounted for in the model results.

4.2.1.3.10.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c) and (e)–(g), relating to the volcanic disruption of waste package model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the volcanic disruption of the waste package abstraction process;
- Models used to assess volcanic disruption of waste packages are consistent with physical processes generally interpreted from igneous features in the Yucca Mountain region and/or observed at active igneous systems;
- Models account for changes in igneous processes, that may occur from interactions with engineered repository systems; and
- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Parameter values used in the safety case to evaluate volcanic disruption of waste packages are sufficient and adequately justified. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Data used to model processes affecting volcanic disruption of waste packages are derived from appropriate techniques. These techniques may include site-specific field measurements, natural analog investigations, and laboratory experiments;

- Sufficient data are available to integrate features, events, and processes, relevant to volcanic disruption of waste packages into process-level models, including determination of appropriate interrelationships and parameter correlations; and

- Where sufficient data do not exist, the definition of parameter values and associated conceptual models is based on appropriate use of expert elicitation, conducted in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- Parameter uncertainty accounts quantitatively for the uncertainty in parameter values observed in site data and the available literature (i.e., data precision), and the uncertainty in abstracting parameter values to process-level models (i.e., data accuracy); and

- Where sufficient data do not exist, the definition of parameter values and associated uncertainty is based on appropriate use of expert elicitation, conducted in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches to volcanic disruption of the waste package are considered and are consistent with available data and current scientific understandings, and the results and limitations are appropriately considered in the abstraction; and

- Uncertainties in abstracted models are adequately defined and documented, and effects of these uncertainties are assessed in the total system performance assessment.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- Models implemented in the volcanic disruption of waste packages abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs); and

- Inconsistencies between abstracted models and comparative data are documented, explained, and quantified. The resulting uncertainty is accounted for in the model results.

4.2.1.3.10.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.10.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to volcanic disruption of waste packages, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 in this section. Technical requirements for conducting a performance assessment in the area of volcanic disruption of waste packages have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that, in regard to volcanic disruption of the waste package:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.10.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer-Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.11 Airborne Transport of Radionuclides

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which the U.S. Department of Energy relies on airborne transport of radionuclides, to demonstrate its safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy relies on waste package integrity to provide significant delay or dilution in the transport of radionuclides to the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the delay of radionuclides to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the performance objectives is evaluated, using Section 4.2.1.4 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.11.1 Areas of Review

This section reviews airborne transport of radionuclides. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19), that is relevant to the abstraction of airborne transport of radionuclides.

The staff will evaluate the following parts of the abstraction of airborne transport of radionuclides, using the review methods and acceptance criteria in Sections 4.2.1.3.11.2 and 4.2.1.3.11.3:

- Description of the geological, hydrological, geochemical, and meteorological aspects of airborne transport of radionuclides, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;

- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;

- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.11.2 Review Methods

To review the abstraction of airborne transport of radionuclides, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geology, geophysics, geochemistry, and meteorological conditions included in the abstraction of airborne transport of radionuclides. Assess the adequacy and consistency of the technical bases for these descriptions, and for incorporating them into the total system performance assessment abstraction for airborne transport of radionuclides. Confirm that models and assumptions used to evaluate airborne transport of radionuclides are consistent with models and assumptions used elsewhere in the license application.

Determine that models used to assess airborne transport of radionuclides are consistent with physical processes generally interpreted from igneous features in the Yucca Mountain region. Verify that models of active igneous processes are consistent with processes generally observed at active igneous features.

Evaluate the technical bases used to assess the effects of engineered repository systems on the consequences of igneous processes.

Verify that the U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or make an acceptable case for using alternative approaches.

Review Method 2 Data and Model Justification

Evaluate the sufficiency of the geological, geophysical, geochemical, and meteorological data used to support parameters, used in conceptual models, process-level models, and alternative conceptual models, considered in the abstraction of airborne transport of radionuclides.

Determine that the technical bases for these data are adequately justified, and that data used to model processes affecting airborne transport of radionuclides are derived from adequately documented techniques. Such techniques may include site-specific field measurements, natural analog investigations, and laboratory experiments.

Determine that sufficient data are available to integrate features, events, and processes, relevant to airborne transport of radionuclides into process-level models. Determine that appropriate interrelationships and correlations between relevant features, events, and processes are adequately considered in resulting model abstractions.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 3 Data Uncertainty

Examine the technical bases for parameter values, assumed ranges, probability distributions, and bounding assumptions, used in conceptual models, process-level models, and alternative conceptual models, considered in the abstraction of airborne transport of radionuclides. Evaluate the assessment of uncertainty and variability in these parameters, and verify that the technical bases reasonably account for uncertainties and variabilities in the data.

Examine the technical bases used to quantify uncertainty in parameter values observed in site data and the available literature (i.e., data precision), and the uncertainty in abstracting parameter values to process-level models (i.e., data accuracy), to ensure that adequate measures of uncertainty and variability have been considered.

Evaluate the methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Review Method 4 Model Uncertainty

Evaluate the alternative conceptual models used in developing the abstraction for airborne transport of radionuclides. Examine the model parameters considering available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies, and evaluate their consistency.

Determine that uncertainties in abstracted models are adequately defined and documented. Verify that effects of these uncertainties are assessed in the total system performance assessment. Where appropriate, use an alternative total system performance assessment model to evaluate the effects of alternative models on repository performance.

Review Method 5 Model Support

Evaluate the output from the abstraction of airborne transport of radionuclides, and compare the results with an appropriate combination of site characterization data, detailed process-level modeling, laboratory testing, field measurements, and natural analog research.

Determine that inconsistencies between abstracted models and comparative data are explained and quantified. Confirm that the resulting uncertainty is accounted for in the model results.

4.2.1.3.11.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c) and (e)–(g), relating to the airborne transport of radionuclide model abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the airborne transport of radionuclides abstraction process;
- Models used to assess airborne transport of radionuclides are consistent with physical processes generally interpreted from igneous features in the Yucca Mountain region and/or observed at active igneous systems;
- Models account for changes in igneous processes that may occur from interactions with engineered repository systems; and
- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or in other acceptable approaches for peer review and data qualification is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Parameter values used in the safety case to evaluate airborne transport of radionuclides are sufficient and adequately justified. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;
- Data used to model processes affecting airborne transport of radionuclides are derived from appropriate techniques. These techniques may include site-specific field measurements, natural analog investigations, and laboratory experiments;
- Sufficient data are available to integrate features, events, and processes, relevant to airborne transport of radionuclides into process-level models, including determination of appropriate interrelationships and parameter correlations; and
- Where sufficient data do not exist, the definition of parameter values and associated conceptual models is based on appropriate use of expert elicitation conducted, in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible, and reasonably account for uncertainties and variabilities;

- Parameter uncertainty accounts quantitatively for the uncertainty in parameter values derived from site data and the available literature (i.e., data precision), and the uncertainty introduced by model abstraction (i.e., data accuracy); and

- Where sufficient data do not exist, the definition of parameter values and associated uncertainty is based on appropriate use of expert elicitation conducted, in accordance with NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches to airborne transport of radionuclides are considered and are consistent with available data and current scientific understandings, and the results and limitations are appropriately considered in the abstraction; and

- Uncertainties in abstracted models are adequately defined and documented, and effects of these uncertainties are assessed in the total system performance assessment.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- Models implemented in the airborne transport of radionuclide abstraction provide results consistent with output from detailed process-level models and/or empirical observations (laboratory and field testings and/or natural analogs); and

- Inconsistencies between abstracted models and comparative data are documented, explained, and quantified. The resulting uncertainty is accounted for in the model results.

4.2.1.3.11.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.11.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to the airborne transport of radionuclides and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114 for model abstraction in this section. Technical requirements for conducting a performance assessment in the area of airborne transport of radionuclides have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effect on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.3.11.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.12 Representative Volume

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which representative volume affects the U.S. Department of Energy safety case. Review this model abstraction, considering the risk information evaluated in the "Multiple Barriers" (Section 4.2.1.1). For example, if the U.S. Department of Energy indicates that dilution from well pumping significantly reduces the concentration of radionuclides in water used by the reasonably maximally exposed individual, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the dose to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding

assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the individual protection standard is evaluated using Section 4.2.1.4.1, and compliance with the ground-water protection standard is evaluated using Section 4.2.1.4.3 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.12.1 Areas of Review

This section reviews the representative volume abstraction. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19), that is relevant to the representative volume abstraction.

The staff will evaluate the following parts of the abstraction of the representative volume, using the review methods and acceptance criteria in Sections 4.2.1.3.12.2 and 4.2.1.3.12.3.

- Description of the geological and hydrological aspects of the representative volume, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;
- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.12.2 Review Methods

To review the abstraction of representative volume, recognize that models used in the total system performance assessments may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of design features, physical phenomena, and couplings, and the description of the geological, hydrological, and geochemical aspects of the abstraction of representative volume that contribute to repository performance.

Assess whether the technical bases for the descriptions of the aspects of dilution from well pumping that are important to repository performance are adequate.

Evaluate whether the description of the aspects of hydrology and geology that may affect the representative volume is adequate. Evaluate whether the descriptions provide transparent and traceable support for the abstraction.

Examine the assumptions, technical bases, data, and models used by the U.S. Department of Energy in the total system performance assessment abstraction of representative volume to determine whether they are appropriate and consistent with other related U.S. Department of Energy abstractions.

Examine how the features, events, and processes, related to representative volume have been included in the total system performance assessment abstraction.

Verify that the U.S. Department of Energy has followed the guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or makes an acceptable case for using alternative approaches.

Review Method 2 Data and Model Justification

Evaluate whether sufficient justification has been provided for climatological and hydrological values used in the safety case, and whether the description of how the data are used, interpreted, and appropriately synthesized into the parameters is sufficiently transparent and traceable.

Evaluate whether sufficient data have been used to support the development of conceptual models used in the abstraction of representative volume as well as the parameters used for each of these models. Determine whether sufficient data have been used in characterizing relevant features, events, and processes and incorporating these features, events, and processes into the abstraction of representative volume.

Determine whether the quality and quantity of data are sufficient for those parameter groups considered important for developing the model abstraction, including groups, such as well classification and design, pumping rates, aquifer parameters, and transport parameters. Where applicable, determine whether reliable statistical estimates can be obtained from the relevant parameter data that can be used to either establish meaningful confidence limits or set meaningful bounding estimates, and determine whether the scales of measured data are appropriately factored into the abstraction.

Review Method 3 Data Uncertainty

Determine whether the use of parameter values, assumed ranges, probability distributions, and bounding assumptions reasonably account for uncertainties and variabilities in the repository system.

Examine the technical bases for parameter values and ranges used in conceptual models, process models, and alternative conceptual models considered in the total system performance assessment abstraction of representative volume. Assess whether these parameter values and distributions are consistent with site characterization data, laboratory experiments, field measurements, and natural analog research.

Assess whether uncertainty is adequately represented in parameters of conceptual models, process models, and alternative conceptual models, considered in developing the total system performance assessment abstraction of representative volume, either through sensitivity analyses, conservative limits, or bounding values supported by data.

Examine the parameters that are identified as being important for the abstraction, and ensure that the level of support for the parameter values and distributions is commensurate with the effect that the parameter has on the total system performance assessment results. To the extent feasible, use an alternative total system performance assessment code to test the sensitivity of the repository performance to the parameter value or model.

Examine the U.S. Department of Energy use of expert elicitation, and confirm that where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of other sources, such as expert elicitation, conducted in accordance with appropriate guidance, such as NUREG–1563 (Kotra, et al., 1996).

Review Method 4 Model Uncertainty

Evaluate whether appropriate alternative conceptual models are used in developing the abstraction for representative volume, and examine the model parameters in the context of available data. Compare the results of alternate process models to results from process models used by the U.S. Department of Energy to assess the uncertainty, limitations, and the degree of conservatism present in the U.S. Department of Energy model. Ascertain whether any limitations identified in the U.S. Department of Energy process model, through this comparison, are adequately accounted for in the U.S. Department of Energy abstraction. Confirm that the U.S. Department of Energy has adequately addressed comments from external reviews of the model abstraction.

Determine whether the results of plausible alternative conceptual models have been considered appropriately in the abstraction, in the context of site characterization data, laboratory experiments, field measurements, natural analog research, and process modeling studies. In particular, use an alternative total system performance assessment model to evaluate the effect of the alternative conceptual model(s) on repository performance.

Review Method 5 Model Support

Evaluate the output from the total system performance assessment model abstraction of representative volume, and determine whether the U.S. Department of Energy compares the results with an appropriate combination of site characterization data, process modeling, laboratory testing, field measurements, and natural analog research. Use detailed models of geochemical, hydrological, and geological processes and an alternative total system performance assessment model to selectively probe the U.S. Department of Energy total system performance assessment analyses, and evaluate selected parts of the U.S. Department of Energy abstraction of representative volume.

4.2.1.3.12.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c), (e)–(g), and 63.30 5, 63.312, and 63.332, relating to the representative volume abstraction. Compliance with the ground-water protection standard is evaluated using Section 4.2.1.4.3 of the Yucca Mountain Review Plan. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important design features, physical phenomena, and couplings, and uses consistent and appropriate assumptions throughout the representative volume abstraction process;

- The total system performance assessment model abstraction of representative volume adequately identifies and describes aspects of dilution, from well pumping, that are important to repository performance, and includes the technical bases for these descriptions;

- The description of aspects of hydrology and geology that may affect the representative volume is adequate, and identifies those parameters to which the abstraction is sensitive;

- The total system performance assessment abstraction of representative volume uses assumptions, technical bases, data, and models that are appropriate and consistent with other related U.S. Department of Energy abstractions (see Section 4.2.1.4.3 of the Yucca Mountain Review Plan). For example, the approach for modeling dilution from well pumping adequately accounts for observed well design practices, and is consistent with the approach used to model radionuclide transport from the source to the pumping well;

- Sufficient data and technical bases for the inclusion of features, events, and processes, related to representative volume in the total system performance assessment abstraction, are provided; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or in other acceptable approaches for peer review and data qualification is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Climatological and hydrological values used in the safety case are adequately justified (e.g., well classification and design, aquifer parameters, transport parameters, etc.). Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided;

- Sufficient data (field, laboratory, and/or natural analog data) are available to adequately define relevant parameters and conceptual models, necessary for developing the representative volume abstraction, in total system performance assessment; and

- The quality and quantity of data are sufficient for those parameter groups considered important for developing and calibrating the abstraction model, including groups such as well classification and design, aquifer parameters, and transport parameters.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and/or bounding assumptions that are technically defensible and reasonably account for uncertainties and variabilities, and are consistent with the characteristics of the reasonably maximally exposed individual and the representative volume of water defined in 10 CFR Part 63;

- The technical bases for the parameter values and ranges in performance assessment and process models used for estimating representative volume such as pumping rates, well depths, and screen length are consistent with public water supply wells in the town of Amargosa Valley, Nevada, other site characterization data, laboratory experiments, field measurements, and natural analog research, as appropriate;

- Uncertainty is adequately represented in parameters of conceptual models, process models, and alternative conceptual models considered in developing the total system performance assessment abstraction of representative volume either through sensitivity analyses, conservative limits, or bounding values supported by data, as necessary;

- Parameters that are important for the abstraction, through total system performance assessment and sensitivity analyses, are identified;

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of expert elicitation, conducted in accordance with appropriate guidance, such as NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their use.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations are appropriately considered in the abstraction; and

- Sufficient evidence is provided that existing alternative conceptual models of features and processes have been considered, that the models are consistent with available data (e.g., field, laboratory, and natural analog) and current scientific understanding, and that the effects of these alternative conceptual models on total system performance assessment results are adequately evaluated.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- Models implemented in this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (e.g., laboratory testing, field measurements, and/or natural analogs).

4.2.1.3.12.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.12.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114. Technical requirements for conducting a performance assessment, with respect to the representative volume, have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to dilution in ground water due to well pumping, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.115. The required characteristics of the reference biosphere have been satisfied. In particular the U.S. Nuclear Regulatory Commission staff found reasonable expectation that:

- The features, events, and processes used to describe the reference biosphere, the biosphere pathways, the evolution of climate, and the evolution of the geologic setting are consistent with present knowledge of the region, conditions, and past processes in the Yucca Mountain region, as required by 10 CFR 63.305(a)–(d);

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to dilution in ground water due to well pumping, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.312. The required characteristics of the reasonably maximally exposed individual have been satisfied. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The reasonably maximally exposed individual is a hypothetical person living in the accessible environment above the highest radionuclide concentration in the plume of contamination, with a diet and living style representative of people who now live in the town of Amargosa Valley, Nevada. The reasonably maximally exposed individual has metabolic and physical characteristics, and well water usage patterns that meet the requirements of 10 CFR 63.312(a)–(e).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to dilution in ground water due to well pumping, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.332. The specific requirements for the representative volume have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The U.S. Department of Energy uses average hydrologic characteristics to determine the position and dimension of the ground-water aquifers, and projects radionuclide concentrations for the representative volume such that the highest concentration levels in the contaminant plume are included. The representative volume also contains no more that 3.715×10^9 liters (3,000 acre-feet) and meets any other requirements specified in 10 CFR 63.332(a)(1)–(3).

- To determine the dimensions of the representative volume, the U.S. Department of Energy uses one of the two alternative methods specified in 10 CFR 63.332(b)(1)–(2).

4.2.1.3.12.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.13 Redistribution of Radionuclides in Soil

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which redistribution of radionuclides in soil affects the U.S. Department of Energy safety case. Review this model abstraction considering the risk information determined in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy indicates that redistribution of radionuclides in soil has a strong effect on performance, then perform a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the dose to the reasonably maximally exposed individual, then conduct a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the individual protection standard is evaluated using Section 4.2.1.4.1, and compliance with the ground-water protection standard is evaluated using Section 4.2.1.4.3 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.13.1 Areas of Review

This section reviews redistribution of radionuclides in soil in the biosphere. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19), that is relevant to the abstraction of redistribution of radionuclides in soil.

The staff will evaluate the following parts of the abstraction of the redistribution of radionuclides in soil, using the review methods and acceptance criteria in Sections 4.2.1.13.2 and 4.2.1.3.13.3:

- Description of the geological, hydrological, pedological, and geochemical aspects of redistribution of radionuclides in soil, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;

- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;

- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;
- Approaches the U.S. Department of Energy uses to compare total system performance assessment output to process-level model outputs and empirical studies; and
- Use of expert elicitation.

4.2.1.3.13.2 Review Methods

To review the abstraction of the redistribution of radionuclides in soil, recognize that models used in the total system performance assessments may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 Model Integration

Examine the description of features, physical phenomena, and couplings between different models, and determine whether they have been appropriately incorporated in the redistribution of radionuclides in soil abstraction. Confirm that consistent and appropriate assumptions have been made throughout the abstraction.

Examine the aspects of redistribution of radionuclides in soil that have been identified as being important to repository performance, and ensure that these aspects are reasonable. Assess the technical bases for these descriptions, and for incorporating them in the total system performance assessment abstraction of redistribution of radionuclides in soil. Evaluate whether the descriptions provide transparent and traceable support for the abstraction.

Examine how the features, events, and processes related to redistribution of radionuclides in soil, have been included in the total system performance assessment abstraction.

Verify that the U.S. Department of Energy reviews follow guidance, such as NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or makes an acceptable case for using alternative approaches for peer review and data qualification.

Review Method 2 Data and Model Justification

Ensure that the data on the pedology, hydrology, and soil chemistry used in the total system performance assessment abstraction are based on a combination of techniques that may include laboratory experiments, site-specific field measurements, natural analog research, and process modeling studies. Examine how data were used, interpreted, and synthesized into parameter values, and ensure that it was done appropriately.

Evaluate the sufficiency of the data used to support conceptual models, process-level models, and alternative conceptual models considered in the total system performance assessment abstraction of redistribution of radionuclides in soil. Examine and confirm the sufficiency of the data that support the technical bases, for features, events, and processes related to redistribution of radionuclides in soil, that have been included in the total system performance assessment abstraction.

Review Method 3 Data Uncertainty

Examine the parameter values, ranges, distributions, and bounding assumptions used in conceptual models, process models, and alternative conceptual models considered in the abstraction of redistribution of radionuclides in soil, and evaluate the assessment of uncertainty and variability in these parameters. Evaluate the U.S. Department of Energy's input values by comparison with the corresponding input values in the U.S. Nuclear Regulatory Commission data set, to the extent feasible. However, direct comparison of input values may not be possible if the U.S. Nuclear Regulatory Commission and U.S. Department of Energy models are substantially different.

Examine the technical basis used to support parameter values and ranges, and confirm that the selected parameter ranges and distributions adequately represent the conditions in the Yucca Mountain region.

Assess whether uncertainty is adequately represented in parameters of conceptual models, process models, and alternative conceptual models considered in developing the abstraction of dilution of radionuclides in soil, from surface processes, either through sensitivity analyses, conservative limits, or bounding values supported by data. Assess whether correlations between parameters in the abstraction have been appropriately established.

Evaluate the U.S. Department of Energy determination of the sensitivity of the performance of the system to the parameter value or model and verify that the level of adequacy of data required for justification of parameters or models is commensurate with the impact that the parameter or model has on the performance of the system. To the extent feasible, use alternative total system performance assessment code to test the sensitivity of the repository performance to the parameter value or model.

Examine the U.S. Department of Energy use of expert elicitation, and confirm that where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of other sources, such as expert elicitation, conducted in accordance with appropriate guidance, such as NUREG–1563 (Kotra, et al., 1996).

Review Method 4 Model Uncertainty

Determine whether the U.S. Department of Energy evaluated all appropriate alternative conceptual models for redistribution of radionuclides in soil. Compare the results of alternate process models to results from process models used by the U.S. Department of Energy to assess the uncertainty, limitations, and the degree of conservatism present in the U.S. Department of Energy model. Ascertain whether any limitations identified in the

U.S. Department of Energy process model through this comparison are adequately accounted for in the U.S. Department of Energy abstraction.

Determine whether the results of appropriate alternative conceptual models have been considered in the abstraction in the context of site characterization data, laboratory experiments, field measurements, natural analog research, and process modeling studies. In particular, use an alternative total system performance assessment model to evaluate the effect of the alternative conceptual model(s) on repository performance.

Review Method 5 Model Support

Evaluate the output from the abstraction of redistribution of radionuclides in soil and compare the results with an appropriate combination of site characterization data, process modeling, laboratory testing, field measurements, and natural analog research. As appropriate, the reviewer should use an alternative total system performance assessment code to evaluate selected parts of the U.S. Department of Energy abstraction of redistribution of radionuclides in soil.

4.2.1.3.13.3 Acceptance Criteria

The following acceptance criteria are based on meeting the relevant requirements of 10 CFR 63.114(a)–(c), (e)–(g), 63.305, and 63.312, as they relate to the redistribution of radionuclides in soil abstraction. U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important features, physical phenomena and couplings between different models, and uses consistent and appropriate assumptions throughout the abstraction of redistribution of radionuclides in the soil abstraction process;

- The total system performance assessment model abstraction identifies and describes aspects of redistribution of radionuclides in soil that are important to repository performance, including the technical bases for these descriptions. For example, the abstraction should include modeling of the deposition of contaminated material in the soil and determination of the depth distribution of the deposited radionuclides;

- Relevant site features, events, and processes have been appropriately modeled in the abstraction of redistribution of radionuclides, from surface processes, and sufficient technical bases are provided; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or other acceptable approaches for peer reviews, is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- Behavioral, hydrological, and geochemical values used in the safety case are adequately justified (e.g., irrigation and precipitation rates, erosion rates, radionuclide solubility values, etc.). Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided; and

- Sufficient data (e.g., field, laboratory, and natural analog data) are available to adequately define relevant parameters and conceptual models necessary for developing the abstraction of redistribution of radionuclides in soil in the total system performance assessment.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and bounding assumptions that are technically defensible and reasonably account for uncertainties and variabilities, and are consistent with the characteristics of the reasonably maximally exposed individual in 10 CFR Part 63;

- The technical bases for the parameter values and ranges in the total system performance assessment abstraction are consistent with data from the Yucca Mountain region [e.g., Amargosa Valley survey (Cannon Center for Survey Research, 1997), studies of surface processes in the Fortymile Wash drainage basin: applicable laboratory testings: natural analogs: or other valid sources of data. For example, soil types, crop types, plow depths, and irrigation rates should be consistent with current farming practices, and data on the airborne particulate concentration should be based on the resuspension of appropriate material in a climate and level of disturbance similar to that which is expected to be found at the location of the reasonably maximally exposed individual, during the compliance time period;

- Uncertainty is adequately represented in parameters for conceptual models, process models, and alternative conceptual models considered in developing the total system performance assessment abstraction of redistribution of radionuclides in soil, either through sensitivity analyses, conservative limits, or bounding values supported by data, as necessary. Correlations between input values are appropriately established in the total system performance assessment;

- Parameters or models that most influence repository performance based on the performance measure and time period of compliance, specified in 10 CFR Part 63, are identified; and

- Where sufficient data do not exist, the definition of parameter values and conceptual models on appropriate uses of other sources, such as expert elicitation, are conducted in accordance with appropriate guidance, such as NUREG–1563 (Kotra, et al., 1996).

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data, and current scientific understanding, and the results and limitations are appropriately considered in the abstraction; and

- Sufficient evidence is provided that appropriate alternative conceptual models of features, events, and processes have been considered; that the preferred models (if any) are consistent with available data (e.g., field, laboratory, and natural analog) and current scientific understanding; and that the effect on total system performance assessment of uncertainties from these alternative conceptual models has been evaluated.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- Models implemented in the abstraction provide results consistent with output from detailed process-level models and/or empirical observations (e.g., laboratory testing, field measurements, and/or natural analogs).

4.2.1.3.13.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.13.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

These evaluation findings are only with respect to this part of the total system performance assessment model abstraction.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to redistribution of radionuclides in soil, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114. Technical requirements for conducting a performance assessment in the area of redistribution of radionuclides in soil have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effect on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to redistribution of radionuclides in soil, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.305. The required characteristics of the reference biosphere have been satisfied. In particular the U.S. Nuclear Regulatory Commission staff found that:

- The features, events, and processes used to describe the reference biosphere, the biosphere pathways, the evolution of climate, and the evolution of the geologic setting are consistent with present knowledge of the region, conditions, and past processes in the Yucca Mountain region, as required by 10 CFR 63.305(a)–(d).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to redistribution of radionuclides in soil, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.312. The required characteristics of the reasonably maximally exposed individual have been satisfied. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The reasonably maximally exposed individual is a hypothetical person living in the accessible environment above the highest radionuclide concentration in the plume of contamination, with a diet and living style representative of people who now live in the town of Amargosa Valley, Nevada. The reasonably maximally exposed individual has metabolic and physical characteristics, and well water usage patterns that meet the requirements of 10 CFR 63.312(a) and (b).

4.2.1.3.13.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

———. NUREG–1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988b.

Cannon Center for Survey Research, University of Nevada. "Identifying and Characterizing the Critical Group Results of a Pilot Study of Amargosa Valley." Las Vegas, Nevada: Cannon Center for Survey Research. 1997.

Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.2.1.3.14 Biosphere Characteristics

To review this model abstraction, evaluate the adequacy of the U.S. Department of Energy license application, relative to the degree to which biosphere characteristics affect the U.S. Department of Energy safety case. Review this model abstraction considering the risk information evaluated in the "Multiple Barriers" Section (4.2.1.1). For example, if the U.S. Department of Energy indicates that biosphere characteristics have a strong effect on performance, then conduct a detailed review of this abstraction. If, on the other hand, the U.S. Department of Energy demonstrates this abstraction to have a minor impact on the dose to the reasonably maximally exposed individual, then perform a simplified review focusing on the bounding assumptions. The review methods and acceptance criteria provided here are for a detailed review. Some of the review methods and acceptance criteria may not be necessary, in a simplified review, for those abstractions that have a minor impact on performance. The demonstration of compliance with the postclosure individual protection standard is evaluated, using Section 4.2.1.4.1 of the Yucca Mountain Review Plan.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.3.14.1 Areas of Review

This section reviews biosphere characteristics that involve application of the characteristics of the reasonably maximally exposed individual and reference biosphere to transforming estimated concentrations of radionuclides in the biosphere to a dose to the reasonably maximally exposed individual. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (15), and (19) that is relevant to the abstraction of the biosphere characteristics modeling.

The staff will evaluate the following parts of the biosphere characteristics, using review methods and acceptance criteria in Sections 4.2.1.3.14.2 and 4.2.1.3.14.3:

- Description of the ecological, behavioral, geological, hydrological, geochemical, sociological, and economic aspects of biosphere characteristics, and the technical bases the U.S. Department of Energy provides to support model integration across the total system performance assessment abstractions;

- Sufficiency of the data and parameters used to justify the total system performance assessment model abstraction;

- Methods the U.S. Department of Energy uses to characterize data uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;

- Methods the U.S. Department of Energy uses to characterize model uncertainty, and propagate the effects of this uncertainty, through the total system performance assessment model abstraction;

- Approaches the U.S. Department of Energy uses to compare output from the total system performance assessment model abstraction to process-level outputs and empirical studies; and

- Use of expert elicitation.

4.2.1.3.14.2 Review Methods

For the abstraction of biosphere characteristics, recognize that models used in the total system performance assessment may range from highly complex process-level models to simplified models, such as response surfaces or look-up tables. Evaluate model adequacy, regardless of the level of complexity.

Review Method 1 System Description and Model Integration

Determine whether the abstraction includes all important site features, physical phenomena, and couplings, and whether consistent and appropriate assumptions have been used through the abstraction;

Verify that the description is adequate, and that the conditions and assumptions in the total system performance assessment abstraction are consistent with the body of data, presented in the description. Determine whether the technical bases for these descriptions, and for incorporating them in the abstraction, are appropriate. Evaluate whether the descriptions provide transparent and traceable support for the abstraction;

Consider important physical phenomena and couplings with other abstractions, and examine them for consistency; and

Determine whether the U.S. Department of Energy has used an acceptable approach for peer reviews, such as the guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or makes an acceptable case for using alternative approaches.

Review Method 2 Data and Model Justification

Determine whether the parameter values used in the safety case are adequately justified, and consistent with the definition of the reasonably maximally exposed individual in 10 CFR 63.312. Evaluate how the data were used, interpreted, and appropriately synthesized into the parameters.

Evaluate the sufficiency of the data and parameters used to support the modeling of features, events, and processes in conceptual models, process-level models, and alternative conceptual models considered in the total system performance assessment biosphere characteristics. When evaluating alternate conceptual models of the biosphere or biosphere processes, the reviewer should recognize that 10 CFR 63.305 and 63.312 place a number of constraints on

both the biosphere and the characteristics of the reasonably maximally exposed individual. For example, 10 CFR 63.312 limits the diet and living style of the reasonably maximally exposed individual to be representative of the current population of the town of Amargosa Valley, Nevada. Therefore, evaluation of alternate conceptual models should focus on exploring the variability and uncertainty in the features, events, and processes incorporated in the biosphere abstraction , mindful of the regulatory constraints. Evaluation of behavior and characteristics of the reasonably maximally exposed individual should emphasize interpretation of survey studies of the current residents of the Town of Amargosa Valley and how uncertainty and variability in the data are used to derive mean values.

Ensure that the data used in the U.S. Department of Energy total system performance assessment abstraction are based on a combination of techniques, that may include laboratory experiments, site-specific field measurements, natural analog research, and process-level modeling studies. Investigate the effects of any differences in model and implementation approach on dose results by executing an alternative total system performance assessment code with the U.S. Department of Energy input parameters, and by comparing calculated dose results with those reported by the U.S. Department of Energy. Confirm that any differences or identified limitations in model selection and implementation, that significantly decrease dose results, are adequately justified in the U.S. Department of Energy analysis.

Review Method 3 Data Uncertainty

Examine the technical bases for parameter values and ranges used in conceptual models, process-level models, and alternative conceptual models considered in the total system performance assessment biosphere characteristics. When evaluating alternate conceptual models of the biosphere or biosphere processes, the reviewer should recognize that 10 CFR 63.305 and 63.312 put a number of constraints on both the biosphere and the characteristics of the reasonably maximally exposed individual. For example, 10 CFR 63.312 limits the diet and lifestyle of the reasonably maximally exposed individual to be representative of the current population of the Town of Amargosa Valley, Nevada. Therefore, evaluation of alternate conceptual models should focus on exploring the variability and uncertainty in the features, events, and processes incorporated in the biosphere abstraction, mindful of the regulatory constraints. Evaluation of behavior and characteristics of the reasonably maximally exposed individual should emphasize interpretation of local survey studies of the current residents of the Town of Amargosa Valley and how uncertainties and variability in the data are used to derive mean values.

Evaluate the assessment of uncertainty and variability in parameters. Verify that the U.S. Department of Energy has a technically defensible basis to support the determination that the diet and living style of the reasonably maximally exposed individual are based on the mean values of data obtained from surveys of residents of the Town of Amargosa Valley, Nevada, as specified in 10 CFR 63.312.

Evaluate whether the parameters, values, and distributions used to describe features, events, and processes of the biosphere are technically defensible, and are consistent with present knowledge of conditions in the region surrounding Yucca Mountain.

Evaluate the effects of including uncertainty and variability ranges (for important parameters) in total system performance assessment runs. Tests can provide information on the effects of including these ranges in the total system performance assessment (e.g., sensitivity and uncertainty analyses), and/or demonstrate the effects different ranges may have on dose results. Verify that any differences or identified limitations in the U.S. Department of Energy analysis that significantly decrease dose results are adequately justified.

Evaluate methods used by the U.S. Department of Energy in conducting expert elicitation to define parameter values.

Examine the sensitivity of total system performance assessment results to identify parameter differences by comparing total system performance assessment results based on the U.S. Department of Energy and the U.S. Nuclear Regulatory Commission parameter selections. Emphasize those parameters known to be important in biosphere characteristics modeling, such as consumption rates, intake-to-dose conversion factors, plant and animal transfer factors, mass-loading factors, and crop interception fractions.

Review Method 4 Model Uncertainty

Examine the model parameters in the context of available site characterization data, laboratory experiments, field measurements, natural analog research, and process-level modeling studies. To the extent practical and necessary, use an alternative total system performance assessment model to evaluate selected parts of the U.S. Department of Energy biosphere characteristics, and evaluate the effect of the alternative conceptual model(s) on repository performance. When evaluating alternate conceptual models of the biosphere or biosphere processes, the reviewer should recognize that 10 CFR 63.305 and 63.312 put a number of constraints on both the biosphere and selection of the reasonably maximally exposed individual. For example, 10 CFR 63. 312 limits the diet and living style of the reasonably maximally exposed individual to be representative of the current residents of the Town of Amargosa Valley, Nevada. Therefore, evaluation of alternate conceptual models should focus on exploring the variability and uncertainty in the features, events, and processes incorporated in the biosphere abstraction, mindful of the regulatory constraints. Evaluation of behavior and characteristics of the reasonably maximally exposed individual should emphasize interpretation of survey studies of the residents of the Town of Amargosa Valley and how uncertainty and variability in the data are used to derive mean values.

Determine whether sufficient evidence has been presented that existing alternative conceptual models of processes that are important to performance have been considered in the biosphere characteristics.

Review Method 5 Model Support

Evaluate the output from the biosphere characteristics modeling and compare the results with an appropriate combination of site characterization data, process-level modeling, laboratory testing, field measurements, and natural analog research. Examine the sensitivity analyses used to support the biosphere characteristics modeling in the total system performance assessment. To the extent practical and necessary, use an alternative total system performance assessment code to evaluate selected parts of the U.S. Department of Energy

biosphere characteristics modeling. Compare the U.S. Department of Energy biosphere dose conversion factors with the results of dose modeling using a code, such as GENII-S (Leigh, et al., 1993) and the U.S. Department of Energy input parameter data. The reviewer should conduct confirmatory runs, using alternative dose calculation codes and the U.S. Department of Energy input parameters, as necessary.

4.2.1.3.14.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.114(a)–(c), (e)–(g), 63.305, and 63.312 as they relate to biosphere characteristics modeling.

U.S. Nuclear Regulatory Commission staff should apply the following acceptance criteria, according to the level of importance established in the U.S. Department of Energy risk-informed safety case.

Acceptance Criterion 1 System Description and Model Integration Are Adequate.

- Total system performance assessment adequately incorporates important site features, physical phenomena, and couplings, and consistent and appropriate assumptions throughout the biosphere characteristics modeling abstraction process;

- The total system performance assessment model abstraction identifies and describes aspects of the biosphere characteristics modeling that are important to repository performance, and includes the technical bases for these descriptions. For example, the reference biosphere should be consistent with the arid or semi-arid conditions in the vicinity of Yucca Mountain;

- Assumptions are consistent between the biosphere characteristics modeling and other abstractions. For example, the U.S. Department of Energy should ensure that the modeling of features, events, and processes, such as climate change, soil types, sorption coefficients, volcanic ash properties, and the physical and chemical properties of radionuclides are consistent with assumptions in other total system performance assessment abstractions; and

- Guidance in NUREG–1297 and NUREG–1298 (Altman, et al., 1988a,b), or in other acceptable approaches for peer reviews, is followed.

Acceptance Criterion 2 Data Are Sufficient for Model Justification.

- The parameter values used in the safety case are adequately justified (e.g., behaviors and characteristics of the residents of the Town of Amargosa Valley, Nevada, characteristics of the reference biosphere, etc.) and consistent with the definition of the reasonably maximally exposed individual in 10 CFR Part 63. Adequate descriptions of how the data were used, interpreted, and appropriately synthesized into the parameters are provided; and

- Data are sufficient to assess the degree to which features, events, and processes related to biosphere characteristics modeling have been characterized and incorporated in the abstraction. As specified in 10 CFR Part 63, the U.S. Department of Energy should demonstrate that features, events, and processes, which describe the biosphere, are consistent with present knowledge of conditions in the region, surrounding Yucca Mountain. As appropriate, the U.S. Department of Energy sensitivity and uncertainty analyses (including consideration of alternative conceptual models) are adequate for determining additional data needs, and evaluating whether additional data would provide new information that could invalidate prior modeling results and affect the sensitivity of the performance of the system to the parameter value or model.

Acceptance Criterion 3 Data Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Models use parameter values, assumed ranges, probability distributions, and bounding assumptions that are technically defensible and reasonably account for uncertainties and variabilities, and are consistent with the definition of the reasonably maximally exposed individual in 10 CFR Part 63;

- The technical bases for the parameter values and ranges in the abstraction, such as consumption rates, plant and animal uptake factors, mass-loading factors, and biosphere dose conversion factors, are consistent with site characterization data, and are technically defensible;

- Process-level models used to determine parameter values for the biosphere characteristics modeling are consistent with site characterization data, laboratory experiments, field measurements, and natural analog research;

- Uncertainty is adequately represented in parameter development for conceptual models and process-level models considered in developing the biosphere characteristics modeling, either through sensitivity analyses, conservative limits, or bounding values supported by data, as necessary. Correlations between input values are appropriately established in the total system performance assessment, and the implementation of the abstraction does not inappropriately bias results to a significant degree;

- Where sufficient data do not exist, the definition of parameter values and conceptual models is based on appropriate use of expert elicitation, conducted in accordance with appropriate guidance, such as NUREG–1563 (Kotra, et al., 1996). If other approaches are used, the U.S. Department of Energy adequately justifies their uses; and

- Parameters or models that most influence repository performance, based on the performance measure and time period of compliance specified in 10 CFR Part 63, are identified.

Acceptance Criterion 4 Model Uncertainty Is Characterized and Propagated Through the Model Abstraction.

- Alternative modeling approaches of features, events, and processes are considered and are consistent with available data and current scientific understanding, and the results and limitations of alternative modeling approaches are appropriately considered in the abstraction. Staff should evaluate alternate conceptual models of the biosphere or biosphere processes, recognizing that 10 CFR 63.305 and 63.312 place a number of constraints on both the biosphere and the characteristics of the reasonably maximally exposed individual. Alternate conceptual models focus on exploring the variability and uncertainty in the physical features, events, and processes, mindful of the regulatory constraints. Evaluation of behavior and characteristics of the reasonably maximally exposed individual emphasizes understanding the characteristics of the current residents of the Town of Amargosa Valley, and uncertainty and variability in the data used to derive mean values; and

- Sufficient evidence is provided that existing alternative conceptual models of features and processes that are important to performance, such as plant uptake of radionuclides from soil, soil resuspension, and the inhalation dose model for igneous events, have been considered.

Acceptance Criterion 5 Model Abstraction Output Is Supported by Objective Comparisons.

- Dose calculations pertaining to this total system performance assessment abstraction provide results consistent with output from detailed process-level models and/or empirical observations (e.g., laboratory testing, field measurements, and/or natural analogs).

4.2.1.3.14.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.3.14.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.114, regarding biosphere characteristics modeling in performance assessment. In particular, the U.S. Nuclear Regulatory Commission staff found reasonable expectation that:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternative conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f); and

- Adequate technical bases have been provided for models used in the performance assessment, as required by 10 CFR 63.114(h).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.305. The required characteristics of the reference biosphere have been justified. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The features, events, and processes used to describe the reference biosphere, the biosphere pathways, the evolution of climate, and the evolution of the geologic setting are consistent with present knowledge of the region, conditions, and past processes in the Yucca Mountain region, as required by 10 CFR 63.305(a); and

- Biosphere pathways are consistent with arid or semi-arid conditions as required by 10 CFR 63.305(b);

- Climate evolution is consistent with the geologic record of natural climate change in the region surrounding the Yucca Mountain site as required by 10 CFR 63.305(c); and

- Changes in society, the biosphere (other than climate), human biology, or increases or decreases in human knowledge or technology are assumed constant at the time of license application and changes are not projected into the future as required in 10 CFR 63.305(d).

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to biosphere characteristics modeling and the characteristics of the reasonably maximally exposed individual, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.312. The required characteristics of the reasonably maximally exposed individual have ben satisfied. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The reasonably maximally exposed individual is a hypothetical person living in the accessible environment above the highest radionuclide concentration in the plume of contamination, with a diet and living style representative of people who now live in the Town of Amargosa Valley, Nevada. The reasonably maximally exposed individual has metabolic and physical characteristics, and well water usage patterns that meet the requirements of 10 CFR 63.312(a)–(e).

4.2.1.3.14.5 References

Altman, W.D., J.P. Donnelly, and J.E. Kennedy. NUREG–1297, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988a.

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Kotra, J.P., et al. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

Leigh, C.D., et al. "User's Guide for GENII-S: A Code for Statistical and Deterministic Simulation of Radiation Doses to Humans from Radionuclides in the Environment." SAND 91-0561. Albuquerque, New Mexico: Sandia National Laboratories. 1993.

4.2.1.4 Demonstration of Compliance with the Postclosure Public Health and Environmental Standards

4.2.1.4.1 Demonstration of Compliance with the Postclosure Individual Protection Standard

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.4.1.1 Areas of Review

This section reviews the analysis of repository performance that demonstrates compliance with the postclosure individual protection standard. Reviewers will also evaluate the information, required by 10 CFR 63.21(c)(11) and (12). The review of compliance with the standards for ground-water protection as required by 10 CFR 63.331 and 63.332 will be conducted using Section 4.2.1.4.3 of the Yucca Mountain Review Plan.

The staff will evaluate the following parts of the analysis of repository performance that demonstrates compliance with the postclosure individual protection standard, using the review methods and acceptance criteria in Sections 4.2.1.4.1.3 and 4.2.1.4.1.4:

- Scenario classes that have been included in a set of total system performance assessment calculations;
- Calculations of the annual dose curve; and
- Credibility of the total system performance assessment results, based on an understanding of assumptions and parameters of the total system performance assessment and consideration of uncertainties of the analysis.

4.2.1.4.1.2 Review Methods

Review Method 1 Scenarios Used in the Calculation of the Annual Dose as a Function of Time

Confirm that the estimates of the annual dose, as a function of time, include all scenario classes that have been determined to be sufficiently probable or to have a sufficient effect on overall performance, that they could not be screened from the total system performance assessment analyses, based on the results of the review conducted using Section 4.2.1.2 of the Yucca Mountain Review Plan.

Confirm that the U.S. Department of Energy calculation of the annual dose curve appropriately sums the contribution of each of the scenario classes. Verify that the contribution to the annual dose from each scenario class calculation properly accounts for the effects that the time of occurrence of the disruptive events comprising the scenario class has on the consequences. Also, verify that the annual probability of occurrence of the events used to calculate the contribution to the annual dose is consistent with the results of the review conducted, using Section 4.2.1.2.2 of the Yucca Mountain Review Plan. The probabilities of occurrence of all scenario classes included in the annual dose curve should sum to one.

Review Method 2 Demonstration That the Annual Dose to the Reasonably Maximally Exposed Individual in Any Year During the Compliance Period Does Not Exceed the Postclosure Individual Protection Standard

Confirm that the U.S. Department of Energy has conducted a sufficient number of realizations for each scenario class using their total system performance assessment computer code to ensure that the results of the total system performance assessment are statistically stable. Use simulations with an alternative total system performance assessment code to help confirm that the appropriate number of realizations were performed to achieve stable results.

Confirm that repository performance and the performance of individual components or subsystems are consistent and reasonable. Verify that results of alternative total system performance assessment code analyses confirm estimates of repository performance. The results should be consistent with the results examined, using Section 4.2.1.1 "System Description and Demonstration of Multiple Barriers" of the Yucca Mountain Review Plan.

Confirm that the total system performance assessment results show that the repository performance results in an annual dose, to the reasonably maximally exposed individual in any year during the compliance period, which does not exceed the postclosure individual protection standard.

Review Method 3 Credibility of the Total System Performance Assessment Code Representation of Repository Performance

In coordination with the reviewers of the model abstractions (using Section 4.2.1.3 of the Yucca Mountain Review Plan), ensure that assumptions and parameters used in the total system performance assessment are acceptable. Verify that assumptions made within the total system

performance assessment are consistent among different modules of the U.S. Department of Energy total system performance assessment code. Confirm that the use of assumptions and parameter values that differ among modules of the U.S. Department of Energy total system performance assessment code is adequately documented.

Confirm that the total system performance assessment code is properly verified, such that there is confidence that the code is modeling the physical processes in the repository system in the manner that was intended (i.e., individual modules of the total system performance assessment code produce results consistent with the results of the reviews of Sections 4.2.1.1, 4.2.1.2, and 4.2.1.3 of the Yucca Mountain Review Plan). Verify that the transfer of data between modules of the code is conducted properly (i.e., units are the same in both modules and the data are assigned to proper variables). Confirm the results from the outputs of individual models using an alternative total system performance assessment code.

Examine the U.S. Department of Energy estimate of the uncertainty in the performance assessment results (i.e., timing and magnitude of the annual dose), and confirm that it is reasonable, considering the uncertainties in modeling assumptions and parameter values reviewed, using Sections 4.2.1.2 and 4.2.1.3 of the Yucca Mountain Review Plan. Use an alternative total system performance assessment code to help confirm the results for the individual modules.

Confirm that the U.S. Department of Energy has used an appropriate approach for sampling parameters in the total system performance assessment code across their ranges of uncertainty.

4.2.1.4.1.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.113(b) and 63.114, relating to the analysis of repository performance, that demonstrates compliance with the postclosure individual protection standard.

Acceptance Criterion 1 Scenarios Used in the Calculation of the Annual Dose as a Function of Time Are Adequate.

- The annual dose as a function of time includes all scenario classes that have been determined to be sufficiently probable, or to have a sufficient effect on overall performance that they could not be screened from the total system performance assessment analyses; and

- The calculation of the annual dose curve appropriately sums the contribution of each of the disruptive event scenario classes. The contribution to the annual dose from each scenario class calculation properly accounts for the effects that the time of occurrence of the disruptive events comprising the scenario class has on the consequences. The annual probability of occurrence of the events used to calculate the contribution to the annual dose is consistent with the results of the scenario analysis. The probabilities of occurrence of all scenario classes, included in calculating the annual dose curve, sum to one.

Acceptance Criterion 2 An Adequate Demonstration Is Provided That the Annual Dose to the Reasonably Maximally Exposed Individual in Any Year During the Compliance Period Does Not Exceed the Exposure Standard.

- A sufficient number of realizations has been obtained, for each scenario class, using the total system performance assessment code, to ensure that the results of the calculations are statistically stable;
- The annual dose curve includes confidence intervals (e.g., 95th and 5th percentile) to represent the uncertainty in the dose calculations;
- Repository performance and the performance of individual components or subsystems are consistent and reasonable; and
- The total system performance assessment results confirm that the repository performance results in annual dose, to the reasonably maximally exposed individual, in any year, during the compliance period, that does not exceed the postclosure individual protection standard.

Acceptance Criterion 3 The Total System Performance Assessment Code Provides a Credible Representation of Repository Performance.

- Assumptions made within the total system performance assessment code are consistent among different modules of the code. The use of assumptions and parameter values that differ among modules of the code is adequately documented;
- The total system performance assessment code is properly verified, such that there is confidence that the code is modeling the physical processes in the repository system in the manner that was intended. The transfer of data between modules of the code is conducted properly;
- The estimate of the uncertainty in the performance assessment results is consistent with the model and parameter uncertainty; and
- The total system performance assessment sampling method ensures that sampled parameters have been sampled across their ranges of uncertainty.

4.2.1.4.1.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.4.1.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable expectation, that they satisfy the

requirements of 10 CFR 63.113(b). The performance objectives for the geologic repository after permanent closure have been met. In particular:

- The engineered barrier system is designed so that, working in combination with the natural barriers, the annual dose to the reasonably maximally exposed individual meets the postclosure individual protection standard during the first 10,000 years after permanent closure, as required by 10 CFR 63.113(b); and

- The ability of the geologic repository to limit radiological exposures has been demonstrated, through a performance assessment, meeting the requirements of 10 CFR 63.114, and uses the reference biosphere defined in 10 CFR 63.305(a)–(e), the reasonably maximally exposed individual as defined in 10 CFR 63.312(a)–(e), and excludes the effects of human intrusion.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found that they satisfy the requirements of 10 CFR 63.114(a). Technical requirements for conducting a performance assessment have been met. In particular:

- Appropriate data from the site and surrounding region, uncertainties and variabilities in parameter values, and alternate conceptual models have been used in the analyses, in compliance with 10 CFR 63.114(a)–(c);

- The U.S. Department of Energy has considered those events that have at least one chance in 10,000 of occurring over 10,000 years, in compliance with 10 CFR 63.114(d);

- Specific features, events, and processes have been included in the analyses, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(e);

- Specific degradation, deterioration, and alteration processes have been included in the analyses, taking into consideration their effects on annual dose, and appropriate technical bases have been provided for inclusion or exclusion, in compliance with 10 CFR 63.114(f).

- Adequate technical bases are provided for models used in the performance assessment, as required by 10 CFR 63.114(g).

4.2.1.4.1.5 References

None.

4.2.1.4.2 Demonstration of Compliance with the Human Intrusion Standard

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.4.2.1 Areas of Review

This section reviews the analysis of performance in the event of limited human intrusion. Reviewers will also evaluate the information, required by 10 CFR 63.21(c)(13).

The staff will evaluate the following parts of the analysis of performance, in the event of limited human intrusion, using the review methods and acceptance criteria in Sections 4.2.1.4.2.2 and 4.2.1.4.2.3:

- Results of the separate total system performance assessment performed for human intrusion;
- Technical bases and associated analyses used to determine the time of occurrence of human intrusion without recognition by the drillers; and
- Credibility of the evaluation of human intrusion based on an understanding of assumptions and parameters of the total system performance assessment, characteristics of the intrusion event, and consideration of uncertainties in the analysis.

4.2.1.4.2.2 Review Methods

Review Method 1 Evaluation of the Time of Occurrence of an Intrusion Event

Verify that the technical bases and associated analyses used to determine the time of occurrence of human intrusion without recognition by the drillers are adequate and appropriate. For example, the technical bases include analyses of the time to which the engineered barrier system has degraded to the point at which a driller can intercept the repository but not recognize it.

Review Method 2 Evaluation of An Intrusion Event That Demonstrates That the Annual Dose to the Reasonably Maximally Exposed Individual in Any Year During the Compliance Period Is Acceptable

If intrusion occurs within the regulatory timeframe, confirm that the total system performance assessment for human intrusion is performed separately from the overall total system performance assessment, and meets the requirements for performance assessments, specified in 10 CFR 63.114.

Verify that the total system performance assessment for human intrusion is identical to the total system performance assessment for individual protection, except that it assumes the occurrence of a postulated human intrusion event with characteristics, as defined in 10 CFR 63.322 and excludes the consideration of unlikely (Commission will define in future rulemaking) natural features, events, and processes.

Confirm that a sufficient number of realizations has been run, for each scenario class, using the total system performance assessment code to ensure that the results of the calculations are statistically stable.

Verify that the estimated repository performance is reasonable and consistent with the results evaluated during the review, using Section 4.2.1.4 of the Yucca Mountain Review Plan, and with the characteristics of the postulated intrusion event. Use results of an alternative total system performance assessment code to confirm repository performance with the postulated intrusion event.

Verify that the annual dose curve for limited human intrusion confirms that the repository system meets performance objectives, specified in 10 CFR 63.321, for limited human intrusion events.

Review Method 3 The Total System Performance Assessment Code Representation of the Intrusion Event

In coordination with the reviewers of the model abstractions (using Section 4.2.1.3 of the Yucca Mountain Review Plan), ensure that assumptions made within the total system performance assessment for evaluating the postulated intrusion event are consistent among different modules of the code. Verify that any use of assumptions and parameter values that differ among modules of the code is adequately documented.

Confirm that the total system performance assessment code is properly verified, such that there is confidence that the code is modeling the physical processes in the repository system in the manner that is consistent with the characteristics of the postulated intrusion event. Verify that the transfer of data between modules of the code is conducted properly (i.e., units are the same in both modules and the data are assigned to proper variables). Use an alternative total system performance assessment code to confirm the U.S. Department of Energy results for the outputs of individual modules.

Verify that the estimate of the uncertainty in the performance assessment results (i.e., timing and magnitude of annual dose) is consistent with the uncertainties considered in the characteristics of the postulated intrusion event and the uncertainties (i.e., model and parameter uncertainty) evaluated, using Sections 4.2.1.2 and 4.2.1.3 of the Yucca Mountain Review Plan.

Confirm that the total system performance assessment sampling method ensures that sampled parameters of the postulated intrusion event have been sampled across their ranges of uncertainty.

4.2.1.4.2.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.113(d), relating to analysis of performance in the event of limited human intrusion.

Acceptance Criterion 1 Evaluation of the Time of an Intrusion Event.

- The technical basis and associated analyses adequately support the selection of time of occurrence of human intrusion, as specified in 10 CFR 63.321.

Acceptance Criterion 2 Evaluation of an Intrusion Event Demonstrates That the Annual Dose to the Reasonably Maximally Exposed Individual in Any Year During the Compliance Period Is Acceptable.

- The total system performance assessment for human intrusion is performed separately from the overall total system performance assessment, and meets the requirements for performance assessments, specified in 10 CFR 63.114.

- The total system performance assessment for human intrusion is identical to the total system performance assessment for individual protection, except that it assumes the occurrence of a postulated human intrusion event with characteristics, as defined in 10 CFR 63.322;

- A sufficient number of realizations has been run using the total system performance assessment code, to ensure that the results of the calculations are statistically stable;

- The estimated repository performance is reasonable and consistent with the analysis of overall repository performance, and with the characteristics of the postulated intrusion event; and

- The annual dose curve for limited human intrusion confirms that the repository system meets performance objectives, specified in 10 CFR 63.321, for limited human intrusion events.

Acceptance Criterion 3 The Total System Performance Assessment Code Provides a Credible Representation of the Intrusion Event.

- Assumptions made within the total system performance assessment for evaluating the postulated intrusion event are consistent among different modules of the code. The use of assumptions and parameter values that differ among modules of the code is adequately documented;

- The total system performance assessment code for evaluating human intrusion is properly verified, such that there is confidence that the code is modeling the physical processes in the repository system in the manner that is consistent with the characteristics of the postulated intrusion event. The transfer of data between modules of the code is conducted properly;

- The estimate of the uncertainty in the performance assessment results is consistent with the uncertainties considered in the characteristics of the postulated intrusion event, and with model and parameter uncertainty; and

- The sampling method used in the total system performance assessment ensures that sampled parameters of the postulated intrusion event have been sampled across their ranges of uncertainty.

4.2.1.4.2.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.4.2.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable expectation, that they satisfy the requirements of 10 CFR 63.113(d). The requirements for demonstrating repository performance, in the event of limited human intrusion, have been met.

4.2.1.4.2.5 References

None.

4.2.1.4.3 Analysis of Repository Performance that Demonstrates Compliance with the Separate Ground-Water Protection Standards

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.2.1.4.3.1 Areas of Review

This section reviews analysis of repository performance that demonstrates compliance with the separate ground-water protection standards. Reviewers will also evaluate information, required by 10 CFR 63.21(c)(1), (9), (14), and (15).

The staff will evaluate the following parts of the analysis of repository performance that demonstrate compliance with the separate ground-water protection standards, using the review methods and acceptance criteria in Sections 4.2.1.4.3.2 and 4.2.1.4.3.3:

- Calculations of the concentrations of specified radionuclides and doses as functions of time; and
- Credibility and consistency of the methods and assumptions used to identify the location of highest concentration of radionuclides in the accessible environment and to estimate the physical dimensions of the 3,000 acre-feet representative volume of ground water.

4.2.1.4.3.2 Review Methods

Review Method 1 Demonstration that the Ground-Water Radioactivity and Doses at Any Year During the Compliance Period Do Not Exceed the Separate Ground-Water Protection Standard

Confirm that the U.S. Department of Energy has provided an estimate of ground-water radioactivity for the representative volume of ground water that includes combined radium-226

and radium-228, gross alpha activity (including radium-226 but excluding radon and uranium), and combined beta and photon emitting radionuclides.

Verify that the average level of radioactivity in the representative volume of ground water is calculated using methods, assumptions, models, and data that are consistent with the performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal (the separate ground-water protection standard does not consider unlikely events). Ensure that the calculated ground-water radioactivity is supported by adequate technical bases that are consistent with those evaluated in the performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8), "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9), and the "Representative Volume" (Section 4.2.1.3.12).

Compare the calculated level of ground-water radioactivity at any year during the 10,000-year compliance period to the limits established in 10 CFR 63.331.

Review Method 2 Methods and Assumptions used to Determine the Location and Shape of the Representative Volume of Ground Water

Verify that the representative volume of ground water is located along the radionuclide migration path from the proposed repository at Yucca Mountain to the accessible environment.

Compare the hydrologic and transport parameters used to determine the location of the representative volume of ground water. Confirm that assumptions, methods, models, and data are consistent with those used in repository performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal. Verify that the calculations are supported by an adequate technical basis that is consistent with performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8) and "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9).

Confirm that the representative volume of ground water is located in such a way that it includes the highest concentration level in the plume of contamination. Verify that the location of the highest concentration of radionuclides in the plume of contamination used for the location of the representative volume of ground water is consistent with the requirements used to define characteristics of the reasonably maximally exposed individual in 10 CFR 63.312(a). Confirm that the locations of the representative volume of ground water and the highest concentration level in the plume of contamination are consistent with the performance assessment model abstraction "Representative Volume" (Section 4.2.1.3.12).

Review Method 3 Methods and Assumptions Used in Calculating the Physical Dimensions of the Representative Volume of Ground Water

Confirm that the representative volume of ground water is drawn from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water, and contains no more than 3,000 acre-feet (3.714×10^9 liters).

Verify that the physical dimensions of the representative volume are determined using one of the methods defined in 10 CFR 63.332. Depending on the method selected, confirm that

information such as well characteristics, pumping rates, ground-water flow direction, and screening intervals are consistent with those used in repository performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal, and the calculations are supported by an adequate technical basis. For example, evaluate whether the levels of ground-water radioactivity in the representative volume of ground water are determined using modeling approaches and parameters that are consistent with those used in the performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8) and "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9).

Ensure that the representative volume of ground water is consistent with the water usage characteristics of the reasonably maximally exposed individual defined in 10 CFR 63.312(c) and 63.312(d). For example, verify that the representative volume of ground water is consistent with that used in analyses in "Representative Volume" (Section 4.2.1.3.12).

4.2.1.4.3.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.331, relating to compliance with the separate standards for protection of ground water, and 10 CFR 63.332, relating to the representative volume of ground water.

Acceptance Criterion 1 An Adequate Demonstration is Provided That the Expected Concentration of Combined Radium-226 and Radium-228, Expected Concentration of Specified Alpha-emitting Radionuclides, and Expected Whole Body or Organ-specific Doses from any Photon- or Beta-emitting Radionuclides at Any Year During the Compliance Period Do Not Exceed the Separate Ground-Water Protection Standards.

- The U.S. Department of Energy has provided an estimate of ground-water radioactivity for the representative volume of ground water that includes combined radium-226 and radium-228, gross alpha activity (including radium-226 but excluding radon and uranium), and combined beta- and photon-emitting radionuclides.

- The level of ground-water radioactivity in the representative volume of ground water is calculated using methods, assumptions, models, and data that are consistent with the repository performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal, and the calculations are supported by an adequate technical basis. For example, the level of ground-water radioactivity in the representative volume of ground water is determined using modeling approaches and parameters that are consistent with those evaluated in the performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8) and "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9), and using dilution analyses consistent with those in the "Representative Volume" (Section 4.2.1.3.12) model abstraction.

- The average level of ground-water radioactivity at any year during the 10,000-year compliance period meets the limits specified in 10 CFR 63.331.

Acceptance Criterion 2 The Methods and Assumptions Used to Determine the Position of the Representative Volume of Ground Water are Credible and Consistent, and the Representative Volume of Ground Water Includes the Highest Concentration Level in the Plume of Contamination in the Accessible Environment.

- The representative volume of ground water is located along the radionuclide migration path from the proposed repository at Yucca Mountain to the accessible environment as defined in 10 CFR 63.302.

- The location of the representative volume of ground water is determined using average hydrologic parameters that are consistent with those used in repository performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal, and the calculations are supported by an adequate technical basis. For example, the levels of ground-water radioactivity in the representative volume of ground water are determined using modeling approaches and parameters that are consistent with those evaluated in the performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8) and "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9).

- The representative volume of ground water is located in such a way that it includes the highest concentration level in the plume of contamination. In this respect, the location of the highest concentration of radionuclides in the plume of contamination used for the location of the representative volume of ground water is consistent with the requirements used to define characteristics of the reasonably maximally exposed individual in 10 CFR 63.312(a). For example, the locations of the representative volume of ground water and the highest concentration level in the plume of contamination are consistent with those used in analyses in "Representative Volume" (Section 4.2.1.3.12).

Acceptance Criterion 3 The Methods and Assumptions Used to Calculate the Physical Dimensions of the Representative Volume of Ground Water are Credible and Consistent.

- The representative volume of ground water is drawn from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water, and contains no more than 3,000 acre-feet (3.714×10^9 liters).

- The physical dimensions of the representative volume are determined using one of the methods defined in 10 CFR 63.332. Depending on the method selected, information including, but not limited to, well characteristics, pumping rates, ground-water flow direction, and screening intervals are consistent with those used in repository performance assessment calculations for the undisturbed case over the period of 10,000 years after disposal, and the calculations are supported by an adequate technical basis. For example, the levels of ground-water radioactivity in the representative volume of ground water are determined using modeling approaches and parameters that are consistent with those evaluated in the performance assessment abstractions for "Flow Paths in the Saturated Zone" (Section 4.2.1.3.8) and "Radionuclide Transport in the Saturated Zone" (Section 4.2.1.3.9).

- The representative volume of ground water is consistent with the water usage characteristics of the reasonably maximally exposed individual defined in 10 CFR 63.312(c) and 63.312(d). For example, the representative volume of ground water is consistent with that used in analyses in "Representative Volume" (Section 4.2.1.3.12).

4.2.1.4.3.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.2.1.4.3.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found that they satisfy the requirements of 10 CFR 63.331 and 10 CFR 63.332. The requirements for demonstrating compliance with the ground-water protection standards have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The average concentrations of combined radium-226 and radium-228, gross alpha activity (including radium-226 but excluding radon and uranium) and combined beta and photon emitting radionuclides meet the limits required by 10 CFR 63.331.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, relevant to dilution in ground water due to well pumping, and has found that they satisfy the requirements of 10 CFR 63.332. The specific requirements for the representative volume of ground water have been met. In particular, the U.S. Nuclear Regulatory Commission staff found that:

- The representative volume of ground water is drawn from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water to meet a given water demand. Average hydrologic characteristics that are consistent with the repository performance assessment calculations are used to determine the position and dimension of the ground-water aquifers, and projects average radionuclide concentrations for the representative volume such that the highest concentration levels in the contaminant plume are included. The representative volume should also contain no more than 3,000 acre-feet (3.714×10^9 liters) and meet any other requirements specified in 10 CFR 63.332(a)(1)–(3).

- The dimensions of the representative volume of ground water are calculated using one of the alternative methods specified in 10 CFR 63.332(b)(1)–(2).

4.2.1.4.3.5 References

None.

4.3 RESEARCH AND DEVELOPMENT PROGRAM TO RESOLVE SAFETY QUESTIONS

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.3.1 Areas of Review

This section reviews the research and development program for resolving safety questions related to structures, systems, and components important to safety and engineered or natural barriers important to waste isolation. Reviewers will evaluate the information, required by 10 CFR 63.21(c)(16). The program is required to identify, describe, and discuss those safety features or components for which further technical information is required, to confirm the adequacy of site characterization, design, or natural barriers.

The staff will evaluate the following parts of the research and development program to resolve safety questions, using the review methods and acceptance criteria in Sections 4.3.2 and 4.3.3:

- Identification and description of safety questions;
- Identification and description of the research and development programs that will be conducted to resolve any safety questions for structures, systems, and components important to safety and the engineered and natural barriers important to waste isolation;
- A schedule for completion of the program, as related to the projected startup date of repository operation; and
- The design alternatives or operational restrictions available, if the results of the program do not demonstrate acceptable resolution of the safety question problem(s).

4.3.2 Review Methods

Review Method 1 Identification and Description of Safety Questions

Verify that the license application identifies safety questions. If there are deficiencies, examine the rationale for them to determine whether it is adequate.

Review Method 2 Identification and Detailed Description of the Research and Development Programs to Resolve Any Safety Questions for Structures, Systems, and Components Important to Safety and the Engineered and Natural Barriers Important to Waste Isolation

Verify that for each safety question identified, a detailed research and development program has been established. Verify there is a description of the specific technical information that must be obtained to demonstrate acceptable resolution of the safety question. The description of the program should be of sufficient detail to show how the information will be obtained. Verify that criteria described in the research and development program to resolve safety

questions incorporate appropriate scientific or engineering techniques to address the scope of the issues. Examine the specific programs to ensure that appropriate analyses, experiments, data collection, field tests, or other techniques have been identified, and that the timing and sequence of these activities have been specified.

Review Method 3 Schedule for Completion of the Program as Related to the Projected Startup Date of Repository Operation, and Commitment to Include Resolved Questions in Amendments to the License Application

Verify schedules for resolution of safety questions and specify a date by which the issues should be resolved. Schedules should include intermediate dates or events at which decisions relating to the issue resolution program implementation will be made. The program and schedule should be detailed enough to show the interface with the repository design, construction activities, schedule proposed for receipt and emplacement of wastes, and any other related activities. In conducting this verification, consider the accessibility of underground locations, conditions that are likely to exist at the geologic repository operations area, and other interferences that might exist during construction. Evaluate the research and development program for compatibility with other site activities and any schedule proposed for receipt and emplacement of wastes. The schedule must be compatible with: (i) other site activities and schedules, including the performance confirmation program (10 CFR Part 63, Subpart F); (ii) repository design; and (iii) site characteristics. It should also satisfy the requirements of any license conditions, established under 10 CFR 63.32 and 63.42.

Verify a commitment in the license application to include resolved questions in amendments to the license application.

Review Method 4 Design Alternatives or Operational Restrictions Available in the Event That the Results of the Program Do Not Demonstrate Acceptable Resolution of the Problem.

Verify there is an alternative plan to demonstrate acceptable resolution of the safety questions. Design alternatives or operational restrictions should be discussed in the alternative plan. Ensure there is a discussion of any programs that will be conducted during operation to demonstrate the acceptability of contemplated future changes in design or operation.

4.3.3 Acceptance Criteria

The following acceptance criteria meet the requirements of 10 CFR 63.21(c)(16).

Acceptance Criterion 1 The Identification and Descriptions of Safety Questions Are Adequate.

Acceptance Criterion 2 The U.S. Department of Energy Adequately Identifies, and Describes in Detail, a Research and Development Program That Will Be Conducted to Resolve Any Safety Questions, in a Reasonable Time Period, for Structures, Systems, and Components Important to Safety, and the Engineered and Natural Barriers Important to Waste isolation.

Acceptance Criterion 3 The U.S. Department of Energy Provides a Reasonable Schedule for the Completion of the Program, as Related to the Projected Startup Date of Repository Operation, and the Date When Items Are Expected to Be Resolved. The U.S. Department of Energy Makes a Commitment to Include Resolved Questions in Requested Amendments to the License Application, as Appropriate.

Acceptance Criterion 4 The U.S. Department of Energy Provides the Design Alternatives or Operational Restrictions Available, If the Results of the Program Do Not Demonstrate Acceptable Resolution of the Problem.

4.3.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.3.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material, and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(16). Requirements for identification and description of safety questions related to structures, systems, and components and the engineered and natural barriers have been met. The U.S. Department of Energy has provided a detailed description of the programs designed to resolve safety questions, including a schedule indicating when these questions would be resolved. The design alternatives or operational restrictions available, if the results of the program do not demonstrate acceptable resolution of the problem, have been provided. Repository construction can proceed, considering the scope of the safety questions and the programs and schedules for their resolution.

4.3.5 References

None.

4.4 PERFORMANCE CONFIRMATION PROGRAM

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.4.1 Areas of Review

Subpart F of 10 CFR Part 63 provides the requirements for the performance confirmation program. The staff defines performance confirmation as the program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in Subpart E (refer to 10 CFR 63.2). The need for a performance confirmation program is unique to high-level radioactive waste. This reflects the uncertainties in estimating geologic repository performance over thousands of years. At permanent closure, 10 CFR 63.51(a)(1) requires the U.S. Department of Energy to present an update of the postclosure performance assessment. The updated assessment includes any performance confirmation data collected and relevant to postclosure performance. The U.S. Nuclear Regulatory Commission will then decide whether the U.S. Department of Energy comprehensive program of testing, monitoring, and confirmation suggests the repository will work as planned. Unless the U.S. Department of Energy designs the repository to preserve the option to retrieve the waste before permanent closure, an action reserved to the U.S. Nuclear Regulatory Commission could be foreclosed, and an unsafe condition could be transmitted to future generations. Therefore, the broad reference to the performance objectives under Subpart E in the performance confirmation definition reflects the need to consider retrievability when monitoring subsurface conditions, and that preserving the retrieval option is a preclosure performance requirement. The general requirements for the performance confirmation program do not require testing and monitoring to confirm preclosure performance in other contexts (that is, testing and monitoring structures, systems, and components important to safety). The general requirements at 10 CFR 63.131 focus on subsurface conditions, as well as the natural and engineered systems and components required for repository operation and that are designed or assumed to operate as barriers after permanent closure. The bases for the acceptance criteria are the requirements for performance confirmation, in 10 CFR Part 63, that are performance-based. Where suitable, the acceptance criteria are also risk-informed, because performance confirmation focuses on those parameters and natural and engineered barriers important to performance.

The staff will determine whether the submittal complies with the requirements for tests, specified by 10 CFR 63.74(b) and 10 CFR Part 63, Subpart F, "Performance Confirmation Program." The staff will evaluate the information that is relevant to the performance confirmation program and is in the Safety Analysis Report, as required by 10 CFR 63.21(c)(17).

The staff will evaluate the following parts of the performance confirmation program, using the review methods and acceptance criteria in Sections 4.4.2 and 4.4.3:

- General requirements for the performance confirmation program, including:
  - Objectives of the performance confirmation program to acquire data by identified *in situ* monitoring, laboratory, and field testing, and *in situ* experiments, to

indicate whether: (i) actual subsurface conditions (i.e., specific geotechnical and design parameters, including natural processes, pertaining to the geologic setting) encountered and changes in those conditions (including any interactions between natural and engineered systems) during construction and waste emplacement operations are within the limits assumed in the licensing review; and (ii) natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure are functioning as intended and anticipated;

— Overall schedule for performance confirmation;

— Plans to implement the performance confirmation program, so the program: (i) does not adversely affect the ability of the geologic and engineered elements of the geologic repository to meet the performance objectives; (ii) provides baseline information and analysis of that information on those parameters and natural processes of the geologic setting that may change because of site characterization, construction, and operations; and (iii) monitors and analyzes changes from the baseline condition of parameters that could affect the performance of the geologic repository; and

— Administrative procedures.

- Confirmation of geotechnical and design parameters, including:

  — Technical measuring, testing, and geologic mapping program during repository construction and operation to confirm geotechnical and design parameters;

  — Technical program to monitor natural systems and components that are designed or assumed to operate as barriers after permanent closure, to ensure they are functioning, as intended and expected;

  — Technical program to monitor, *in situ*, the thermomechanical response of the underground facility until permanent closure to ensure the performance of the geologic and engineering features is within design limits; and

  — Surveillance program to evaluate subsurface conditions against design assumptions, including procedures to: (i) compare measurements and observations with original design bases and assumptions; (ii) determine the need for changes to the design or construction methods, if significant differences exist between the measurements and observations and the original design bases and assumptions; and (iii) report significant differences between measurements and observations and the original design bases and assumptions, their significance to repository performance, and recommended changes, to the U.S. Nuclear Regulatory Commission.

- Design testing including
  - Technical program to test engineered systems and components, other than waste packages, used in the design during the early or developmental stages of construction. This includes, for example, borehole and shaft seals, backfill, and drip shields;
  - Technical program to evaluate the thermal and chemical interaction effects of waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water;
  - Schedule for starting tests of engineered systems and components used in the design;
  - Plan to conduct a test, before permanent backfill placement begins, to evaluate the effectiveness of backfill placement and compaction procedures against design requirements, if the U.S. Department of Energy includes backfill in the repository design; and
  - Plan for conducting tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing.
- Monitoring and testing waste packages, including:
  - Plan for monitoring the condition of waste packages at the geologic repository operations area, including an evaluation of the: (i) representativeness of those waste packages chosen for monitoring, and (ii) representativeness of the waste package environment of the waste packages chosen for monitoring;
  - Plan for laboratory experiments that focus on the internal condition of the waste packages, including an evaluation of the degree the environment experienced by the emplaced waste packages within the underground facility is duplicated in the laboratory experiments;
  - Duration of the waste package monitoring and testing program; and
  - Plans for testing the fabrication of containers, including closure welding and any post-weld heat treatment.

4.4.2 Review Methods

Review Method 1 Compliance with General Requirements for the Performance Confirmation Program

- Verify that the U.S. Department of Energy performance confirmation plan provides the program objectives. Determine whether those objectives are sufficient to meet the general requirements for the performance confirmation program. This includes verifying that enough technical information exists, and plans for specific *in situ* monitoring,

laboratory, and field testing, and *in situ* experiments are identified to carry out stated objectives. Specifically, verify that the U.S. Department of Energy performance confirmation plan:

- Identifies the geotechnical and design parameters, including natural processes, pertaining to the geologic setting the U.S. Department of Energy selected to monitor and analyze;

- Includes the method used to select the geotechnical and design parameters, including natural processes, pertaining to the geologic setting the U.S. Department of Energy will monitor and analyze;

- Identifies the natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure, including their specific functions, the U.S. Department of Energy selected to monitor and test, to ensure they are functioning as intended and expected;

- Includes the method used to select the natural and engineered systems and components, that are designed or assumed to operate as barriers after permanent closure; the U.S. Department of Energy will monitor and test to ensure they are functioning as intended and expected;

- Identifies specific geotechnical and design parameters, including any interactions between natural and engineered systems and components, the U.S. Department of Energy has selected to measure or observe;

- Includes the method used to select specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components;

- Includes specific *in situ* monitoring, laboratory and field testing, and *in situ* experiments to acquire needed data;

- Specifies which *in situ* monitoring, laboratory and field testing, or *in situ* experimental methods the U.S. Department of Energy will apply to the selected: (i) geotechnical and design parameters, including natural processes, pertaining to the geologic setting; (ii) natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure; and (iii) interactions between natural and engineered systems and components;

- Includes the expected changes (that is, design bases and assumptions) from baseline for the selected geotechnical and design parameters, including natural processes, pertaining to the geologic setting that will result from construction and waste emplacement operations; and

- Includes the intended and expected performance limits (i.e., design assumptions) for the selected natural and engineered systems and components, which are designed or assumed to operate as barriers after permanent closure.

- Verify the U.S. Department of Energy performance confirmation plan includes a schedule for planned activities, and assess whether the schedule is sufficient to meet the general requirements for the performance confirmation program;

- Assess the U.S. Department of Energy approach to implement the performance confirmation program. This includes verifying that the U.S. Department of Energy performance confirmation plan includes the information necessary to determine whether the U.S. Department of Energy will implement the program, as required, and to complete the detailed technical reviews, using Review Methods 2, 3, and 4 of this section. Specifically, verify the U.S. Department of Energy performance confirmation plan includes:

  — Procedures to ensure that performance confirmation activities do not adversely affect the ability of the natural and engineered elements of the geologic repository to meet the performance objectives;

  — Baseline information for selected geotechnical and design parameters, including natural processes, pertaining to the geologic setting;

  — Methods used to establish the baseline information for selected geotechnical and design parameters, including natural processes, pertaining to the geologic setting;

  — A commitment to monitor and analyze changes from the baseline condition of selected geotechnical and design parameters, including natural processes, pertaining to the geologic setting that could affect the performance of a geologic repository;

  — A commitment to monitor natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure to indicate whether they are functioning as intended and expected; and

  — Terms for periodic assessment and update of the performance confirmation plan.

- Verify the U.S. Department of Energy performance confirmation plan includes administrative procedures related to records and reports, construction records, reports of deficiencies, and inspections. Determine whether the U.S. Department of Energy administrative procedures to implement the performance confirmation program are adequate.

Review Method 2 Compliance with Requirements to Confirm Geotechnical and Design Parameters

- Determine whether the U.S. Department of Energy performance confirmation plan provides an acceptable program of measuring, testing, and geologic mapping, during

repository construction and operation, to confirm geotechnical and design parameters (including natural processes) pertaining to the geologic setting. Specifically:

— Evaluate the adequacy of the method the U.S. Department of Energy used to select the geotechnical and design parameters to monitor and analyze;

— Determine whether the U.S. Department of Energy list of selected geotechnical and design parameters is reasonable and complete;

— Evaluate the adequacy of the method the U.S. Department of Energy used to establish the baseline values of the selected geotechnical and design parameters;

— Determine whether the baseline values of the selected geotechnical and design parameters, established by the U.S. Department of Energy, are reasonable;

— Determine whether the U.S. Department of Energy estimates of the expected changes (that is, original design bases and assumptions) from baseline for the selected geotechnical and design parameters are reasonable; and

— Determine whether the monitoring, testing, or experimental methods are suitable for each geotechnical or design parameter the U.S. Department of Energy will monitor and analyze.

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate technical program to monitor or test natural systems and components, that are designed or assumed to operate as barriers after permanent closure, to ensure they are functioning as intended and expected. Specifically:

  — Evaluate the adequacy of the method the U.S. Department of Energy used to select the natural systems and components, that are designed or assumed to operate as barriers after permanent closure, to be monitored or tested;

  — Determine whether the U.S. Department of Energy list of selected natural systems and components is reasonable and complete;

  — Determine whether the monitoring or testing methods are suitable for each natural system or component the U.S. Department of Energy will monitor or test; and

  — Determine whether the intended and expected performance limits (that is, design assumptions) for the selected natural systems and components are reasonable.

- Verify the U.S. Department of Energy performance confirmation program includes plans to monitor, *in situ*, the thermomechanical response of the underground facility until permanent closure, and evaluate the adequacy of those plans. Specifically:

  — Evaluate the adequacy of the method the U.S. Department of Energy used to select the *in situ* thermomechanical response parameters to monitor and analyze;

- — Determine whether the U.S. Department of Energy list of selected *in situ* thermomechanical response parameters is reasonable and complete;

- — Evaluate the adequacy of the method the U.S. Department of Energy used to establish the baseline values of the selected *in situ* thermomechanical response parameters;

- — Determine whether the baseline values of *in situ* thermomechanical response parameters, established by the U.S. Department of Energy, are reasonable;

- — Determine whether the U.S. Department of Energy estimates of the anticipated changes (i.e., original design bases and assumptions) from baseline for the selected *in situ* thermomechanical response parameters are reasonable; and

- — Determine whether the monitoring, testing, or experimental methods are suitable for each *in situ* thermomechanical response parameter the U.S. Department of Energy will monitor and analyze.

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate surveillance program to monitor and evaluate subsurface conditions against design assumptions. Specifically:

  - — Verify the U.S. Department of Energy performance confirmation plan includes procedures to compare measurements and observations with original design bases and assumptions. Evaluate the adequacy of those procedures;

  - — Verify the U.S. Department of Energy performance confirmation plan includes procedures to determine the need for modifications to the design or construction methods, if significant differences exist between the measurements and observations and the original design bases and assumptions. Evaluate the adequacy of those procedures; and

  - — Verify the U.S. Department of Energy performance confirmation plan includes procedures to report significant differences between measurements and observations and the original design bases and assumptions, their significance to repository performance, and recommended changes to the U.S. Nuclear Regulatory Commission. Evaluate the adequacy of those procedures.

Review Method 3 Compliance with Requirements for Design Testing

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate program of testing engineered systems and components, other than waste packages, used in the design. Specifically:

  - — Evaluate the adequacy of the method the U.S. Department of Energy used to select the engineered systems and components, that are designed or assumed to operate as barriers after permanent closure, that the U.S. Department of Energy will monitor and test;

- — Determine whether the U.S. Department of Energy list of selected engineered systems and components is reasonable and complete;

- — Determine whether the monitoring, testing, or experimental methods are suitable for each engineered system or component the U.S. Department of Energy will monitor or test; and

- — Determine whether the intended and expected performance limits (that is, design assumptions) for the selected engineered systems and components are reasonable.

- Verify whether the U.S. Department of Energy included thermal and chemical interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components in the design testing program. Determine whether the testing program for thermal interaction effects is adequate. Specifically:

  - — Evaluate the adequacy of the method the U.S. Department of Energy used to select the thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components in the design testing program;

  - — Determine whether the U.S. Department of Energy list of selected thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components is reasonable and complete;

  - — Determine whether the monitoring, testing, or experimental methods are suitable for each thermal interaction effect of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components the U.S. Department of Energy will monitor or test; and

  - — Determine whether the intended and expected performance limits (that is, design assumptions) for the selected thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components are reasonable.

- Determine whether the schedule for testing engineered systems and components used in the design is sufficient to meet the requirements for the design testing program;

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate program of tests to evaluate the effectiveness of backfill placement and compaction procedures against design requirements (only if the U.S. Department of Energy included backfill in the repository design). Specifically:

  - — Evaluate the adequacy of the method the U.S. Department of Energy used to select the backfill placement and compaction procedures in the design testing program;

— Determine whether the U.S. Department of Energy list of selected backfill placement and compaction procedures is reasonable and complete;

— Determine whether the monitoring, testing, or experimental methods are suitable for the backfill placement and compaction procedures the U.S. Department of Energy will monitor or test; and

— Determine whether the intended and expected performance limits (i.e., design assumptions) for the selected backfill placement and compaction procedures are reasonable.

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing (only if the U.S. Department of Energy included seals for borehole, shaft, and ramp in the repository design). Specifically:

  — Evaluate the adequacy of the method the U.S. Department of Energy used to select the program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing in the design testing program;

  — Determine whether the U.S. Department of Energy program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing is reasonable and complete;

  — Determine whether the monitoring, testing, or experimental methods are suitable for the program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing; and

  — Determine whether the intended and expected performance limits (that is, design assumptions) for the selected program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing are reasonable.

Review Method 4 Compliance with Requirements for Monitoring and Testing Waste Packages

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate program for monitoring the condition of waste packages at the geologic repository operations area. Verify the plan requires an evaluation of the:
  (i) representativeness of those waste packages chosen for monitoring; and
  (ii) representativeness of the waste package environment of the waste packages chosen for monitoring. Specifically:

  — Evaluate the waste packages the U.S. Department of Energy will monitor and test to ensure that they are representative of those to be emplaced in terms of materials, design, structure, fabrication, and inspection methods;

  — Determine whether the environment of the waste packages the U.S. Department of Energy will monitor and test is representative of the emplacement

environment, consistent with safe operations, and includes variations in environmental factors that encompass the range of expected uncertainties;

— Ensure the environmental conditions the U.S. Department of Energy will monitor and evaluate include, but are not limited to, those describing water chemistry;

— Determine whether monitoring and testing includes evaluation of fabrication defects and post-fabrication damage, in particular damage that may occur during handling operations; and

— Verify the program is technically feasible, taking into consideration whether the methods proposed are suitable and practicable, and the sensors and devices to be used are either able to sustain the prevailing environmental conditions (e.g., temperature, humidity, radiation) during the required period of repository operation or will be replaceable.

- Determine whether the U.S. Department of Energy performance confirmation plan provides an adequate program of laboratory experiments that focus on the internal condition of the waste packages. Verify the plan includes an evaluation of the degree the environment experienced by the emplaced waste packages within the underground facility is duplicated in the laboratory, as well as determine whether this evaluation is adequate. Specifically:

  — Determine whether the program and plan provide data needed to design the waste package and confirm performance assessment models and assumptions;

  — Verify that experiments will incorporate scale-model waste package testing that includes the effects of welding and other fabrication processes (e.g., stress relief treatment); and

  — Determine whether corrosion monitoring and testing includes, but is not limited to, the use of corrosion coupons.

- Verify adequate testing of fabrication processes, including closure welds and post-weld heat treatment; and

- Determine whether the schedule for the waste package monitoring and testing program is sufficient to meet the requirements for such a program.

4.4.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.131, 63.132, 63.133, and 63.134 for the performance confirmation program.

Acceptance Criterion 1 The Performance Confirmation Program Meets the General Requirements Established for Such a Program.

- The objectives of the performance confirmation program are consistent with the general requirements in that the program will provide data to indicate whether: (i) actual

subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review; and (ii) natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure are functioning as intended and expected. The performance confirmation plan provides sufficient technical information and plans for *in situ* monitoring, laboratory and field testing, and *in situ* experiments to carry out the objectives in that:

— It identifies the geotechnical and design parameters, including natural processes, pertaining to the geologic setting selected for monitoring and analysis;

— It includes the method used to select the geotechnical and design parameters, including natural processes, pertaining to the geologic setting the U.S. Department of Energy will monitor and analyze;

— It identifies the natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure, including their specific functions, the U.S. Department of Energy selected to monitor and test, to ensure they are functioning as intended and expected;

— It includes the method used to select the natural and engineered systems and components, which are designed or assumed to operate as barriers after permanent closure, the U.S. Department of Energy will be monitor and test, to ensure they are functioning as intended and expected;

— It identifies specific geotechnical and design parameters, including any interactions between natural and engineered systems and components, the U.S. Department of Energy selected to be measured or observed;

— It includes the method used to select including any interactions between natural and engineered systems and components, the U.S. Department of Energy will measure or observe;

— It includes specific *in situ* monitoring, laboratory and field testing, and *in situ* experiments to acquire needed data;

— It specifies which *in situ* monitoring, laboratory and field testing, or *in situ* experimental methods the U.S. Department of Energy will apply to the selected: (i) geotechnical and design parameters, including natural processes, pertaining to the geologic setting; (ii) natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure; and (iii) interactions between natural and engineered systems and components;

— It includes the expected changes (i.e., design bases and assumptions) from baseline for the selected geotechnical and design parameters, including natural processes, pertaining to the geologic setting that will result from construction and waste emplacement operations; and

- It includes the intended and expected performance limits (i.e., design assumptions) for the selected natural and engineered systems and components, which are designed or assumed to operate as barriers after permanent closure.

- The schedule for the performance confirmation program is consistent with the general requirements. The program started during site characterization and will continue until permanent closure.

- The U.S. Department of Energy will implement the performance confirmation program in a manner consistent with the general requirements in that:

  - Procedures require the U.S. Department of Energy to consider adverse effects on the ability of the natural and engineered elements of the geologic repository to meet the performance objectives before initiating any *in situ* monitoring, tests, or experiments to acquire data;

  - It provides baseline information and analysis of that information on those parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operations;

  - It commits to monitoring and analyzing changes from the baseline condition for those parameters that could affect the performance of a geologic repository. Exceptions from this commitment for any particular parameter are identified and technically justified (refer to Acceptance Criterion 2 of this section);

  - It commits to monitoring natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure to indicate whether they are functioning as intended and expected. Exceptions from this commitment for any particular system or component are identified and technically justified (refer to Acceptance Criterion 2 of this section); and

  - It provides terms for periodic assessment and update of the performance confirmation plan.

- The performance confirmation plan includes procedures to manage the program. These procedures meet the requirements for records and reports, construction records, reports of deficiencies, and inspections, specified at 10 CFR 63.71, 63.72, 63.73, and 63.75, respectively.

Acceptance Criterion 2 The Performance Confirmation Program to Confirm Geotechnical and Design Parameters Meets the Requirements Established for Such a Program.

- The performance confirmation plan establishes a program for measuring, testing, and geologic mapping to confirm geotechnical and design parameters. The

U.S. Department of Energy will implement the program during repository construction and operation. The program is consistent with the requirements in that:

— Geotechnical and design parameters the U.S. Department of Energy will monitor and analyze are selected using a performance-based method that focuses on those parameters that could affect the performance of the geologic repository. The U.S. Department of Energy also considered the need to preserve the retrieval option;

— Results of performance assessments confirm the list of selected geotechnical and design parameters is reasonable and complete. The U.S. Department of Energy has justified excluding any geotechnical and design parameter that is important to performance. Acceptable justification factors include the certainty provided by existing baseline information and the low likelihood of changes in that parameter as a result of construction, waste emplacement operations, or interactions between natural and engineered systems;

— The baseline "value" of selected geotechnical and design parameters was determined using analytical or statistical methods appropriate for the particular parameter;

— The baseline "value" of selected geotechnical and design parameters considered all data available at the time of the submittal;

— The effects of construction, waste emplacement operations, and interactions between natural and engineered systems are considered in the original design bases and assumptions for the geotechnical and design parameters; and

— Monitoring, testing, and experimental methods are suitable for the nature of individual parameters in terms of time, space, resolution, and technique. Instrumentation reliability and replacement requirements are considered;

- The performance confirmation plan establishes a technical program to monitor natural systems and components, that are designed or assumed to operate as barriers after permanent closure, to ensure they are functioning as intended and expected. The program is consistent with the requirements in that:

— Natural systems and components the U.S. Department of Energy will monitor or test are selected using a performance-based method that focuses on those systems and components important to performance;

— Results of performance assessments confirm the list of selected natural systems is reasonable and complete. The U.S. Department of Energy has justified excluding any natural system and component that is designed or assumed to operate as a barrier after permanent closure from this program. Acceptable justification factors include the certainty in the natural system or component(s) capacity to perform its intended function or the degree the system and

component is represented by parameter(s) being confirmed under the geotechnical and design parameter monitoring program.

— Monitoring and testing methods are suitable for the nature of individual natural systems and components in terms of time, space, resolution, and technique. Instrumentation reliability and replacement requirements are considered; and

— The effects of construction, waste emplacement operations, and interactions between natural and engineered systems are considered in estimates of the intended and anticipated performance limits (i.e., design assumptions).

- The program includes adequate plans to monitor, *in situ*, the thermomechanical response of the underground facility until permanent closure. The program is consistent with the requirements in that:

  — *In situ* thermomechanical response parameters that the U.S. Department of Energy will monitor and analyze are selected using a performance-based method that focuses on those parameters that could affect the performance of the geologic repository. The U.S. Department of Energy also considered the need to preserve the retrieval option;

  — Results of performance assessments confirm that the list of selected *in situ* thermomechanical response parameters is reasonable and complete. The U.S. Department of Energy has justified excluding any *in situ* thermomechanical response parameter that is important to performance. Acceptable justification factors include the certainty provided by existing baseline information and the low likelihood of changes in that parameter as a result of construction, waste emplacement operations, or interactions between natural and engineered systems;

  — The baseline "value" of selected *in situ* thermomechanical response parameters was determined using analytical or statistical methods appropriate for the particular parameter;

  — The baseline "value" of selected *in situ* thermomechanical response parameters considered all data available at the time of the submittal;

  — The effects of construction, waste emplacement operations, and interactions between natural and engineered systems are considered in the original design bases and assumptions for the *in situ* thermomechanical response parameters; and

  — Monitoring, testing, and experimental methods are suitable for the nature of individual parameters in terms of time, space, resolution, and technique. Instrumentation reliability and replacement requirements are considered.

- The performance confirmation plan sets up a surveillance program to evaluate subsurface conditions against design assumptions. The program is consistent with the requirements in that:

  — It includes procedures for comparing measurements and observations with original design bases and assumptions. Comparisons are done routinely and in a timely manner to ensure that if any significant differences exist between the measurements and observations and the original design bases and assumptions, their significance to repository performance, and the need for design changes can be determined quickly and efficiently;

  — It includes procedures for determining the need for modifications to the design or construction methods if significant differences exist between measurements and observations and original design bases and assumptions. Acceptable variations in the design bases and assumptions the design would accommodate without an adverse impact on performance have been provided. If construction methods or design needs to be modified to address changed conditions, the U.S. Department of Energy design control process used in the design phase may be used; and

  — It includes procedures to report significant differences between measurements and observations and the original design bases and assumptions, their significance to repository performance and recommended changes to the Commission. These procedures meet the requirements for reports of deficiencies specified at 10 CFR 63.73.

Acceptance Criterion 3 The Performance Confirmation Program for Design Testing Meets the Requirements Established for Such a Program.

- The performance confirmation plan establishes a program for design testing. The program is consistent with the requirements in that:

  — Engineered systems and components the U.S. Department of Energy will test are selected using a performance-based method that focuses on those systems and components important to performance;

  — Results of performance assessments confirm that the list of selected engineered systems and components is reasonable and complete. The U.S. Department of Energy has justified excluding any engineered system or component that is important to performance from this program. An acceptable justification factor is the certainty that the system or component can perform its intended function;

  — Testing methods are suitable for the particular engineered system or component being tested in terms of time, space, resolution, and technique. Testing methods are selected, in part, by considering the data needed to design the engineered systems and components. Test locations are selected considering compatibility with the environment in which the components or systems are to function.

Instrumentation reliability and replacement requirements have been considered; and

— The effects of waste emplacement operations and interactions between natural and engineered systems are considered in estimates of the intended and expected performance limits (i.e., design assumptions).

- Thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components used in the design are included in the design testing program. The program is consistent with the requirements in that:

  — Thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components the U.S. Department of Energy will test are selected using a performance-based method that focuses on those systems and components important to performance;

  — Results of performance assessments confirm that the list of selected thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components is reasonable and complete. The U.S. Department of Energy has justified excluding any thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components that are important to performance from this program. An acceptable justification factor is the certainty that the system or component can perform its intended function;

  — Testing methods are suitable for the particular thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components being tested in terms of time, space, resolution, and technique. Testing methods are selected, in part, by considering the data needed to design the thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components. Test locations are selected considering compatibility with the environment in which the components or systems are to function. Instrumentation reliability and replacement requirements have been considered; and

  — The effects of waste emplacement operations and interactions between natural and engineered systems are considered in estimates of the intended and anticipated performance limits (that is, design assumptions).

- Design testing will begin during the early or developmental stages of construction. The testing schedule allows the results to be available in time for use in the design of engineered systems and components;

- The design testing program requires that the effectiveness of backfill placement and compaction procedures against design requirements be demonstrated in an *in situ* test if

backfill is included in the design. The importance of the contribution of the backfill to the long-term performance of the repository is considered in specifying testing requirements such as backfill material, gradation, and placement density, which are an indication of the water tightness or permeability of the backfill. Specifically:

— Backfill placement and compaction procedures the U.S. Department of Energy will test are selected using a performance-based method that focuses on those systems and components important to performance;

— Results of performance assessments confirm that the list of selected backfill placement and compaction procedures is reasonable and complete. The U.S. Department of Energy has justified excluding any backfill placement and compaction procedures that are important to performance from this program. An acceptable justification factor is the certainty that the backfill and compaction can perform its intended function;

— Testing methods are suitable for the particular backfill placement and compaction procedures being tested in terms of time, space, resolution and technique. Testing methods are selected, in part, by considering the data needed to design the backfill placement and compaction procedures. Test locations are selected considering compatibility with the environment in which the components or systems are to function. Instrumentation reliability and replacement requirements have been considered; and

— The effects of waste emplacement operations and backfill placement and compaction procedure interactions between natural and engineered systems are considered in estimates of the intended and anticipated performance limits (i.e., design assumptions);

- The design testing program requires that the effectiveness of borehole, shaft, and ramp seals be demonstrated in a test before full-scale sealing. The importance of seals to the long-term performance of the repository is considered in planning the seal test program. Specifically:

  — The program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing was selected, using a performance-based method that focuses on those systems and components important to performance;

  — Results of performance assessments confirm that the program of tests to evaluate the effectiveness of borehole, shaft, and ramps seals, before full-scale sealing, is reasonable and complete. The U.S. Department of Energy has justified excluding any tests to evaluate the effectiveness of borehole, shaft, and ramp seals, before full-scale sealing, that are important to performance, from this program. An acceptable justification factor is the certainty that the seals can perform their intended function;

  — Testing methods are suitable for the particular program of tests to evaluate the effectiveness of borehole, shaft, and ramps seals before full-scale sealing, in

terms of time, space, resolution and technique. Testing methods are selected, in part, by considering the data needed to design the program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale sealing. Test locations are selected considering compatibility with the environment in which the components or systems are to function. Instrumentation reliability and replacement requirements have been considered; and

— The effects of waste emplacement operations, and the program of tests to evaluate the effectiveness of borehole, shaft, and ramp seals, before full-scale sealing, on interactions between natural and engineered systems, are considered in estimates of the intended and anticipated performance limits (i.e., design assumptions).

Acceptance Criterion 4 The Performance Confirmation Program for Monitoring and Testing Waste Packages Meets the Requirements Established for Such A program.

- The performance confirmation plan establishes a program for monitoring and testing the condition of waste packages at the geologic repository operations area. Further, the program is adequate because:

  — The waste packages the U.S. Department of Energy will monitor and test are representative of those to be emplaced in terms of materials, design, structure, fabrication, and inspection methods.

  — The environment of the waste packages the U.S. Department of Energy will monitor and test is representative of the emplacement environment, consistent with safe operations, and includes variations in environmental factors that encompass the range of expected uncertainties;

  — The environmental conditions the U.S. Department of Energy will monitor and evaluate include, but are not limited to, those describing water chemistry;

  — Monitoring and testing include evaluation of fabrication defects and post-fabrication damage, in particular damage that may occur during handling operations; and

  — The program is technically feasible, taking into consideration that the methods proposed are suitable and practicable and the sensors and devices to be used are either able to sustain the prevailing environmental conditions (e.g., temperature, humidity, radiation) during the required period of repository operation, or are replaceable.

- The performance confirmation plan establishes a program of laboratory experiments that focuses on the internal condition of the waste packages. The environment

experienced by the emplaced waste packages is duplicated in the laboratory experiments to the extent practicable. The laboratory experiments are adequate because:

— They provide data needed to design the waste package and confirm performance assessment models and assumptions;

— Experiments will incorporate scale-model waste package testing that includes the effects of welding and other fabrication processes (e.g., stress relief treatment); and

— Corrosion monitoring and testing include, but are not limited to, the use of corrosion coupons.

- An adequate testing of fabrication processes, including fabrication and post-weld heat treatment, will be conducted; and

- The schedule for the waste package program requires monitoring and testing to begin as soon as practicable. Monitoring and testing will continue up to the time of permanent closure.

4.4.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.4.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.74(b) and 10 CFR Part 63, Subpart F—"Performance Confirmation Program." The performance objectives of Subpart E are met. In particular, the staff found reasonable assurance that an acceptable performance confirmation program will be conducted to evaluate the adequacy of information supporting the granting of the license.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.131. The general requirements for a performance confirmation program will be met. In particular, the staff found that:

- The performance confirmation program will provide data to indicate whether: (i) actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement are within limits assumed in the licensing review; and (ii) natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure are functioning as intended and expected;

- The performance confirmation program will include *in situ* monitoring, laboratory and field testing, and *in situ* experiments, as appropriate;

- The performance confirmation program was started during site characterization and will continue until permanent closure; and

- The performance confirmation program will be implemented such that it: (i) does not adversely affect the performance of the geologic and engineered elements of the repository; (ii) provides adequate baseline information on parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operational activities; (iii) monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository; and (iv) monitors natural and engineered systems and components that are designed or assumed to operate as barriers after permanent closure.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.132. The requirements to confirm geotechnical and design parameters will be met. In particular, the staff found that:

- An adequate continuing program of measuring, testing, and geologic mapping, during repository construction and operation, will be conducted to confirm geotechnical and design parameters (including natural processes) pertaining to the geologic setting;

- An adequate program to monitor or test natural systems and components that are designed or assumed to operate as barriers after permanent closure will be conducted, to ensure they are functioning as intended and expected;

- An adequate program to monitor, *in situ*, the thermomechanical response of the underground facility will be conducted until permanent closure; and

- An adequate surveillance program will be conducted to monitor and evaluate subsurface conditions against design assumptions. The surveillance program will: (i) compare measurements and observations with original design bases and assumptions: (ii) determine the need for modifications to the design or construction methods if significant differences exist between measurements and observations and the original design bases and assumptions: and (iii) report significant differences between measurements and observations and the original design bases and assumptions, their significance to repository performance, and recommended changes to the Commission.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.133. The requirements for design testing will be met. In particular, the staff found that:

- An adequate program for testing engineered systems and components will be conducted.

- An adequate program for evaluating the thermal interaction effects of waste packages, rock, unsaturated zone and saturated zone water, and other engineered systems and components used in the design will be conducted;

- Testing will begin during the early or developmental stages of construction;

- Backfill placement and compaction procedures will be tested against design requirements before permanent backfill placement begins; and

- The effectiveness of borehole, shaft, and ramp seals will be tested before full-scale sealing proceeds.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.134. The requirements for monitoring and testing waste packages will be met. In particular, the staff found that:

- An adequate program for monitoring and testing the condition of waste packages at the geologic repository operations area will be conducted. Waste packages will be representative of those to be emplaced and the environment will be representative of the emplacement environment;

- The waste package monitoring and testing program will include appropriate laboratory experiments that focus on the internal condition of the waste packages. The laboratory experiments will duplicate the environment of the emplaced waste packages to the extent practicable; and

- The waste package monitoring program will begin as soon as practicable and continue up to the time of permanent closure.

4.4.5 References

None.

4.5 Administrative and Programmatic Requirements

4.5.1 Quality Assurance Program

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

Quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, and components important to safety, the design and characterization of engineered and natural barriers important to waste isolation, and activities related thereto will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, system, or component that provide a means to control the quality of the material, structure, system, or component to predetermined requirements.

The purpose of this review is to determine whether the U.S. Department of Energy has a quality assurance program that complies with the requirements of 10 CFR Part 63. Additionally, this Section (4.5.1) of the Yucca Mountain Review Plan will be used to determine if changes to the U.S. Nuclear Regulatory Commission-approved quality assurance program meet the specific quality assurance program change control requirements of 10 CFR 63.144. The basis for these determinations is a review and evaluation of the U.S. Department of Energy quality assurance program and changes to it submitted in accordance with 10 CFR Part 63. The results of the review and evaluation will be documented in the safety evaluation report.

This review plan is written to accommodate the use of graded quality assurance controls for structures, systems, and components and barriers, important to safety or waste isolation, that have been categorized as low-safety-risk-significant. If a graded quality assurance process is selected, the review provisions contained in this Yucca Mountain Review Plan section must be applied to structures, systems, and components and barriers categorized as high-safety-risk-significant. As provided for in Acceptance Criterion 2 of this Section (4.5.1.2), the U.S. Department of Energy may propose reduced quality assurance controls for selected elements of the quality assurance program, for structures, systems, and components and barriers categorized as low-safety-risk-significant. This categorization process must be risk-informed. If graded quality assurance is not used, the review provisions contained in this Section (4.5.1) of the Yucca Mountain Review Plan would apply to all structures, systems, and components and barriers subject to the quality assurance requirements contained in 10 CFR Part 63. As provided for in this section (4.5.1) of the Yucca Mountain Review Plan, the U.S. Department of Energy may propose alternatives to these review provisions.

4.5.1.1 Areas of Review

This section addresses review of the U.S. Department of Energy quality assurance program. In determining compliance with the requirements specified in 10 CFR 63.21(c)(20) and 10 CFR Part 63, Subpart G (10 CFR 63.141–144), the reviewers will evaluate information specified in 10 CFR 63.21(c)(20).

Review Plan for Safety Analysis Report

The following elements of the quality assurance program will be evaluated using the review methods and acceptance criteria in Sections 4.5.1.2 and 4.5.1.3.

- Quality Assurance Organization;
- Quality Assurance Program;
- Design Control;
- Procurement Document Control;
- Instructions, Procedures, and Drawings;
- Document Control;
- Control of Purchased Material, Equipment, and Services;
- Identification and Control of Materials, Parts, and Components;
- Control of Special Processes;
- Inspection;
- Test Control;
- Control of Measuring and Test Equipment;
- Handling, Storage, and Shipping;
- Inspection, Test, and Operating Status;
- Nonconforming Materials, Parts, or Components;
- Corrective Action;
- Quality Assurance Records;
- Audits;
- Software;
- Sample Control;
- Scientific Investigation; and
- Field Surveys.

4.5.1.2 Review Methods

The review should be conducted as follows.

Each element of the quality assurance program description will be reviewed against the acceptance criteria specified in Section 4.5.1.3 of the Yucca Mountain Review Plan and the documents and positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan. The assigned High-Level Waste Branch quality assurance program reviewer will interface with the other High-Level Waste Branch reviewers to ensure that they have documented the acceptability of the identification of structures, systems, and components and barriers covered by the quality assurance program (e.g., the identification of these structures, systems, and components and barriers is typically compiled in a list referred to as the Q-List). Further, if the graded quality assurance process is used, the assigned reviewer will interface with other High-Level Waste Branch reviewers to ensure that they have documented the acceptability of any safety-risk-significance categorization process used to support the graded quality assurance process.

If required, the High-Level Waste Branch will process the necessary request(s) for additional information to the U.S. Department of Energy and coordinate the response with the appropriate branches for acceptance. Changes to the quality assurance program will be evaluated to assure at a minimum that such changes have not degraded the previously approved program. Consideration should be given to the current regulatory position(s) in the area of the change in determining acceptability of the change. The reviewer's judgment during the evaluation process is to be based on an assessment of the material presented. Any exceptions or proposed alternatives to the Yucca Mountain Review Plan section, including the documents and positions cited in Section 4.5.1.5 of the Yucca Mountain Review Plan, will be carefully reviewed to assure that they are clearly defined and that an adequate basis exists for acceptance.

The acceptability of the quality assurance program is determined by the following review procedures:

- The quality assurance program description should be reviewed in detail to determine if each of the criteria of 10 CFR 63.142 has been acceptably addressed (by the quality assurance program describing how the applicable criteria are satisfied) and if there is an adequate commitment to comply with the documents and positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan. The quality assurance program description should also be reviewed to ensure that the U.S. Department of Energy approach to meeting the quality assurance criteria and commitments is acceptable;

- The measures described to implement 10 CFR 63.142 should be evaluated to determine if management support exists (e.g., does it appear that the quality assurance program controls have adequate review, approval, and endorsement of management?);

- The duties, responsibilities, and authority of personnel performing quality assurance functions should be reviewed to assure that they provide sufficient independence to effectively perform these functions;

- Based on: (i) review of information provided in the license application and any subsequent quality assurance program changes; (ii) meetings with the U.S. Department of Energy; (iii) assessment of the ongoing quality assurance program activities; and (iv) the results of inspections, a judgment is made and documented in the safety evaluation report that the U.S. Department of Energy is capable of implementing quality assurance responsibilities in accordance with an effective quality assurance program; and

- The review of program commitments and descriptions of how the commitments will be met, organizational arrangements, and capabilities to fulfill quality assurance requirements should lead to a conclusion regarding acceptability of the program, as described in Subsection 4.5.1.4.

  The review will assure that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

4.5.1.3 Acceptance Criteria

General Acceptance Criteria

The criteria in the following introductory paragraphs and the 22 numbered acceptance criteria are based on meeting the relevant requirements of 10 CFR Parts 21, 63.21(c)(20), 63.44, 63.73, and 63.141–144, as they relate to the quality assurance program.

The U.S. Department of Energy quality assurance program description document must describe how the applicable requirements of 10 CFR 63.142 will be satisfied.

The U.S. Department of Energy quality assurance program and associated quality assurance program controls and implementing procedures regarding activities performed must be in place before activities begin.

It is not sufficient for the U.S. Department of Energy documents to assert that particular requirements are met or provided for. The description of the quality assurance program submitted in the license application and any subsequent quality assurance program changes must identify individuals and organizations that are responsible for meeting particular requirements, in order to allow the reviewer to understand the process by which the U.S. Department of Energy expects to meet specific requirements and to determine whether or not following that process would lead to compliance with requirements. Defining a process involves establishing authorities, assigning responsibilities, and issuing instructions and procedures.

The U.S. Department of Energy shall establish a quality assurance program for site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities in accordance with 10 CFR 63.21(c)(20) and 63.142. Applicable provisions contained in the U.S. Department of Energy quality assurance program must be incorporated into the quality

assurance programs of the principal contractors as related to their applicable scope of work. The U.S. Department of Energy quality assurance program must describe how each criterion of 10 CFR 63.142 will be met. Further, if the U.S. Department of Energy chooses to implement a graded quality assurance program, the specific graded quality assurance controls for each quality assurance program element would need to be identified. The acceptance criteria used by the High-Level Waste Branch to evaluate this quality assurance program are specified in this section (4.5.1.3) of the Yucca Mountain Review Plan.

Acceptance Criteria 1 through 18 are organized to reflect the 18 criteria contained in 10 CFR 63.142. Acceptance criteria for certain subelements of the 18 criteria that are considered important are also provided as Acceptance Criteria 19 through 22. Each of the 22 listed acceptance criteria specifies the relevant area of review. The subelement Acceptance Criterion links to 10 CFR 63.142 are as follows: Acceptance Criterion 19, "Software"—10 CFR 63.142(d), "Design Control;" Acceptance Criterion 20, "Sample Control"—10 CFR 63.142(i), "Identification and Control of Material, Parts, and Components;" Acceptance Criterion 21, "Scientific Investigation"—10 CFR 63.142(d), "Design Control;" and Acceptance Criterion 22, "Field Surveys"—10 CFR 63.142(k), "Inspection."

The acceptance criteria include a commitment to comply with the documents and positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan. Where appropriate, the quality assurance program description may reference a commitment to comply with certain provisions of a document identified in Section 4.5.1.5 of the Yucca Mountain Review Plan and not repeat the text of the document in the quality assurance program. For example, it may be appropriate for the U.S. Department of Energy to indicate compliance with NQA–1–1983 and the exceptions noted in Acceptance Criterion17 of this Section (4.5.1) of the Yucca Mountain Review Plan for the section of its quality assurance program that addresses records. In certain instances, when the quality assurance program description section references other documents (e.g., NQA–1–1983) as commitments, additional text may be needed because there may be provisions of the Yucca Mountain Review Plan section that are not addressed in the referenced documents. Thus, the commitment constitutes an integral part of the quality assurance program description and requirements.

Exceptions and alternatives to these acceptance criteria and the documents and positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan may be adopted by the U.S. Department of Energy, provided adequate justification is given. The High-Level Waste Branch review allows for flexibility in defining methods and controls while still satisfying pertinent regulations. If the quality assurance program description meets the applicable acceptance criteria of this Section (4.5.1.3) of the Yucca Mountain Review Plan and the commitments contained in Section 4.5.1.5 of the Yucca Mountain Review Plan or provides acceptable exceptions or alternatives, then the program will be considered to be in compliance with pertinent U.S. Nuclear Regulatory Commission regulations.

Specific Acceptance Criteria

Acceptance Criterion 1 The organizational elements responsible for the quality assurance program are acceptable provided that:

- Responsibility for the overall quality assurance program is retained and exercised by the U.S. Department of Energy.

- The U.S. Department of Energy identifies and describes major delegation of work involved in establishing and implementing the quality assurance program or any part thereof to other organizations;

- When major portions of the U.S. Department of Energy quality assurance program are delegated:

  — The U.S. Department of Energy describes how responsibility is exercised for the overall program. The extent of management oversight is addressed, including the location, qualifications, and number of personnel performing these functions, and the bases for them;

  — The U.S. Department of Energy evaluates the performance (frequency and method stated once per year, although a longer cycle may be acceptable with other evaluations of individual elements) of work by the delegated organization; and

  — Qualified individual(s) or organizational element(s) are identified within the U.S. Department of Energy organization as responsible for the quality of the delegated work before initiation of activities.

- Clear management controls and effective lines of communication exist for quality assurance activities among the U.S. Department of Energy and the principal contractors to assure proper management, direction, and implementation of the quality assurance program.

- Organization charts clearly identify all on-site and off-site organizational elements that function under the cognizance of the quality assurance program (e.g., design, engineering, procurement, shipping, receiving, storage, manufacturing, construction, inspection, auditing, testing, instrumentation and control), engineering, maintenance and preclosure (operations), modifications, dismantling, etc.; the lines of responsibility; and a description of the bases for determining the size of the quality assurance organization, including the inspection staff;

- The U.S. Department of Energy (and principal contractors) describe the quality assurance responsibilities of each of the organizational elements noted on the organization charts. The authorities and duties of individuals and organizations performing activities important to safety or waste isolation are clearly established and delineated in writing;

- The U.S. Department of Energy (and principal contractors) identify a management position that retains overall authority and direct responsibility for the definition, direction, and effectiveness of the overall quality assurance program. (Normally, this position is the quality assurance manager.) This position has the following characteristics:

  — Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as engineering,

procurement, construction, and operation) and is sufficiently independent from cost and schedule;

— Has effective communication channels with other senior management positions;

— Has responsibility for approval of quality assurance manual(s);

— Has no other duties or responsibilities, unrelated to quality assurance, that would prevent his/her full attention to quality assurance matters;

— Has sufficient authority to effectively implement responsibilities; and

— Is sufficiently free from cost and schedule responsibilities.

Qualification requirements for this position are established in a position description that includes the following prerequisites: management experience through assignments to responsible positions; in-depth knowledge of quality assurance regulations, policies, practices, and standards; and appropriate experience working in quality assurance or related activity in nuclear-related design, construction, or operation or in a similar technically based industry. The qualifications for this position should be at least equivalent to those described in American National Standards Institute/American Nuclear Society, American Nuclear Society–3.1–1993, "Selection and Training of Nuclear Power Plant Personnel" [American National Standards Institute/American Nuclear Society, as endorsed by the regulatory positions in Regulatory Guide 1.8, Revision 3 (U.S. Nuclear Regulatory Commission, 2000)].

- Verification of conformance to established requirements is accomplished by individuals or groups, within the quality assurance organization, that do not have direct responsibility for performing the work being verified, or by individuals or groups trained and qualified in quality assurance concepts and practices and independent of the organization responsible for performing the task;

- Individuals and organizations performing quality assurance functions have direct access to management levels that will assure the ability to identify quality problems; initiate, recommend, or provide solutions through designated channels; and verify implementation of solutions;

- The individuals and organizations with the above authority are identified, procedures for reporting are described, and clear lines of authority are provided;

- Designated quality assurance personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming material until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred;

- The organizational positions with stop-work authority are identified;

- Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between quality assurance personnel and other department (e.g., engineering, procurement, construction, etc.) representatives;

- Designated quality assurance individuals are involved in day-to-day facility activities important to safety or important to waste isolation. For example, the quality assurance organization routinely attends and participates in daily work schedule and status meetings to assure that it is kept abreast of day-to-day work assignments. There is adequate quality assurance coverage relative to procedural and inspection controls, acceptance criteria, and quality assurance staffing and qualification of personnel to carry out quality assurance assignments;

- Policies regarding the implementation of the quality assurance program are documented and made mandatory. These policies are established at the U.S. Department of Energy Office of Civilian Radioactive Waste Management level; and

- If the quality assurance organizational structure of the U.S. Department of Energy or its principal contractors identifies a position for an individual, at the construction site, or the geologic repository operations area, that is responsible for directing and managing the site quality assurance program, there must be controls identified for this position in the quality assurance program. These controls must assure that the individual assigned to this position has: (i) an appropriate level within the organizational structure, (ii) identified responsibilities, and (iii) authority to exercise proper control over the quality assurance program. These controls must also assure that this individual is free from non-quality assurance duties and can thus give full attention to ensuring that the quality assurance program at the repository site is being effectively implemented;

Acceptance Criterion 2 The activities related to the quality assurance program are acceptable provided that:

- The scope of the quality assurance program includes:

  — A commitment that structures, systems, and components important to safety, design and characterization of engineered and natural barriers important to waste isolation, and activities related thereto, will be subject to the applicable controls of the quality assurance program. Such activities include, but are not limited to: site characterization; acquisition and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantlement of surface facilities. The structures, systems, and components, barriers, and related consumables covered by the quality assurance program are identified in the Q-list as addressed in Section 4.1.1.6,—"Identification of Structures, Systems, and Components Important to Safety, Safety Controls, and Measures to Ensure Availability of the Safety Systems"—and Section 4.2.1, "Performance Assessment," of the Yucca Mountain Review Plan;

— A commitment that the preoperational test program (before the start of preclosure operations) will be conducted in accordance with the quality assurance program and a description of how the quality assurance program will be applied;

— A commitment that the development, control, and use of computer software will be conducted in accordance with the quality assurance program and a description of how the quality assurance program will be applied; and

— A commitment that special equipment, environmental conditions, skills, or processes will be provided as necessary.

- A brief summary of the U.S. Department of Energy Office of Civilian Radioactive Waste Management quality assurance policies is given. The organizational group or individual having responsibility for each policy statement is identified;

- Provisions are established to assure that quality-affecting procedures required to implement the quality assurance program are: (i) consistent with quality assurance program commitments and corporate policies, (ii) are properly documented and controlled, and (iii) made mandatory through a policy statement or equivalent document signed by the responsible official;

- The quality assurance organization reviews and documents concurrence with these quality-related procedures;

- The quality-affecting procedural controls of the principal contractors should be provided with documented agreement of acceptance before initiation of activities affected by the quality assurance program;

- Provisions are included for notifying the U.S. Nuclear Regulatory Commission of changes for review and acceptance of the accepted description of the quality assurance program, in accordance with 10 CFR 63.144. Changes to the U.S. Nuclear Regulatory Commission-approved quality assurance program must be processed in accordance with the applicable requirements of 10 CFR 63.144, and revisions to the U.S. Department of Energy quality assurance program documentation should be forwarded to the U.S. Nuclear Regulatory Commission;

  The U.S. Department of Energy should inform the High-Level Waste Branch of changes in the quality assurance program organizational elements, when possible, within 30 days after announcement.

- The U.S. Department of Energy (and its principal contractors) commit to comply with: (i) the requirements in 10 CFR 63.44, 63.73, and 63.141–144; and (ii) the documents and regulatory positions and documents contained in Section 4.5.1.5 of the Yucca Mountain Review Plan and any exceptions contained in the acceptance criteria. Further, the U.S. Department of Energy (and its principal contractors) commit to conduct activities under 10 CFR 63.73 and 10 CFR Part 21 commercial-grade-item dedication activities, in accordance with the quality assurance program;

The quality assurance organization and the necessary technical organizations should participate early in the quality assurance program definition stage to determine and identify the extent that quality assurance controls are to be applied to specific structures, systems, and components and barriers important to waste isolation. This effort may involve applying a defined graded approach to certain structures, systems, and components in accordance with their safety/risk significance and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, and audits.

- The Graded Quality Assurance Process: A graded application of quality assurance, if used, requires U.S. Department of Energy justification and U.S. Nuclear Regulatory Commission reviewer acceptance. A graded quality assurance program is structured to apply quality assurance measures and controls to all items and activities in proportion to their importance to safety or importance to waste isolation. The graded approach for the application of quality assurance controls must be adequately described. The quality assurance program should identify items and activities that are important to safety or important to waste isolation and their degree of importance based on the safety/risk significance of the items and activities. High-safety-risk-significant items and activities should have a high level of control (e.g., the full application of the quality assurance controls), and less-safety-risk-significant items and activities may have reduced quality assurance controls applied. However, the U.S. Department of Energy may chose to apply the highest level of quality assurance controls to all items and activities.

  If the U.S. Department of Energy decides to apply quality assurance controls in a graded manner, its quality assurance program must address the various elements of the graded quality assurance process. The activities related to the graded quality assurance process include:

  — The safety-risk-significance categorization process is adequately described and is subject to review in accordance with Section 4.1.1.6 (for preclosure) and Section 4.2.1 (for postclosure) of the Yucca Mountain Review Plan (U.S. Nuclear Regulatory Commission, 2001). Although this review is performed using other sections of the Yucca Mountain Review Plan, the quality assurance program should describe, at a high level, the safety-risk-significance categorization process;

    Provisions for reassessing the safety-risk-significance categorization when new information becomes available should be appropriately described.

  — The U.S. Department of Energy may select two or more safety-risk-significance categories (e.g., high, low, or medium). The quality assurance program describes each safety-risk-significance category selected;

  — The selection of graded quality assurance controls to be applied to each safety-risk-significant category must be described in adequate detail. Section 3.2, "Potential Areas for Implementing Graded Quality Assurance Program Controls," of Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decision-Making: Graded Quality Assurance" (U.S. Nuclear

Regulatory Commission, 1998), provides guidance on acceptable application of graded quality assurance controls. In proposing reduced quality assurance controls, the following two basic objectives should be kept in mind: (i) the graded quality assurance program should be sufficient to reasonably ensure the design integrity and ability of the SSC or barrier to successfully perform its intended important-to safety or waste-isolation function, and (ii) the graded quality assurance -program should include processes and documentation that support an effective corrective action program. The selection of graded quality assurance controls may be applied to any element of the quality assurance program;

— Provisions for a feedback process to adjust graded quality assurance controls should be described. Provisions for reassessing the quality assurance controls when new information becomes available through adverse trends or nonconformance reporting should be described;

The U.S. Department of Energy quality assurance program description should discuss elements specifically related to effective corrective actions and causal analysis. Because it is not completely understood at the onset of the graded quality assurance program how changes will ultimately affect SSC fabrication, construction, installation, testing, and performance, and given that the categorization process cannot address these changes in a quantitative manner, it is important that the U.S. Department of Energy have an effective process in place so that adjustments can be made in the graded quality assurance program on the basis of repository and industry experiences. Within this area, the U.S. Department of Energy process controls should have the capability to determine whether structures, systems, and components have been treated properly in the graded quality assurance program. Failures, or adverse performance degradations, of low-safety-risk-significant structures, systems, and components should be identified in accordance with the U.S. Department of Energy corrective action programs, so that the U.S. Department of Energy can ascertain whether the reduction of the quality assurance controls has resulted in excessive nonconformances and an unacceptable decrease in performance of structures, systems, and components and barriers.

The U.S. Department of Energy should employ techniques such as monitoring, surveillance, and trend analysis to identify when a structure, system, and component is found to be unacceptable or the reliability and availability of low-safety-risk-significant structures, systems, and components are trending toward unacceptable levels. Structure, system, and component monitoring approaches should be used to accomplish this goal.

— Provisions for an effective root-cause analysis and corrective action as a result of the feedback process should be described. Provisions should also be described for evaluating common cause/mode failures. The U.S. Department of Energy corrective action efforts should determine, as a minimum, the apparent cause of repetitive failures of structures, systems, and components under the graded quality assurance controls so that it can be decided whether graded

quality assurance controls should be adjusted. In some instances, a failure may result in an unanticipated event and may cause the categorization of the structures, systems, and components to be changed;

— Provisions should also be in place for the U.S. Department of Energy to obtain documented U.S. Nuclear Regulatory Commission approval before implementing any quality assurance program changes that reduce previous commitments; and

— The use of reduced sampling plans for low-safety-risk-significant structures, systems, and components and related activities is required to be documented in accordance with Acceptance Criterion 3 of this section.

- Existing or proposed quality assurance procedures are identified that reflect the documents and regulatory positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan. The requirements in 10 CFR Parts 21 and 63.73, and each criterion of 10 CFR 63.142 will be met by documented procedures. In addition, activities conducted under 10 CFR 63.73 and commercial-grade-item-dedication activities conducted under 10 CFR Part 21 must conform to the applicable provisions of the quality assurance program;

- A description is provided that emphasizes how the docketed quality assurance program description controls, particularly the requirements in 10 CFR 63.21(c)(20), 63.44, 63.73, and 63.141–144 and the regulatory positions and documents contained in Section 4.5.1.5 of the Yucca Mountain Review Plan, will be implemented properly;

- A description is provided of how management (either above or outside the quality assurance organization) regularly assesses the scope, status, and adequacy of the quality assurance program and its compliance with 10 CFR Part 63, Subpart G. These measures should include: (i) frequent contact with program status through reports, meetings, and/or audits and observations; and (ii) performance of an annual assessment that is preplanned and documented, with corrective action identified and tracked;

- Quality-related activities (such as design and procurement) initiated before the U.S. Nuclear Regulatory Commission issuance of the license are controlled under a U.S. Nuclear Regulatory Commission-approved quality assurance program in accordance with the requirements of 10 CFR Part 63, Subpart G. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the quality assurance program before the initiation of the activity;

- A summary description is provided on how responsibilities and control of quality-related activities are transferred from principal contractors to the U.S. Department of Energy during any phase out of principal contractor activities;

- A provision is included to establish any additional quality assurance program provisions for preclosure operations and to establish that such provisions should be implemented before commencement of startup activities and startup testing;

- Confirmation is provided to: (i) commit to continued implementation of the quality assurance program for any design or site modification or construction activities that occur during preclosure: and (ii) commit that the preoperational test program or an acceptable alternative will continue to be applied during preclosure after site modification or construction activities;

- Indoctrination, training, and qualification programs are established such that:

  — Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of quality-related manuals, instructions, and procedures;

  — Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed;

  — For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance;

  — Proficiency tests are given to personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified;

  — A certificate of qualifications clearly delineates: (i) the specific functions personnel are qualified to perform; and (ii) the criteria used to qualify personnel in each function;

  — Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment;

  — Appropriate management personnel monitor the performance of individuals involved in activities affecting quality and determine the need for retraining. A system of annual appraisal and evaluation can satisfactorily accomplish this;

  — Qualified personnel, when required, are certified in accordance with applicable codes and standards; and

  — For the qualification of inspection and test personnel, Appendix 2A–1 of NQA–1–1983, "Nonmandatory Guidance on the Qualification of Inspection and Test Personnel" (American Society of Mechanical Engineers, 1983), provides guidance. The provisions of Appendix 2A–1 (or acceptable alternatives) must be met as part of Supplement 2-1, "Supplementary Requirements for the Qualification of Inspection and Test Personnel."

- A readiness review program has been established and procedures are in place to assure that the program is executed at appropriate major milestones to complement the inspection program; and

- Provisions are established that effectively demonstrate through a matrix system or alternative means that each criterion of 10 CFR 63.142 is properly documented, described, and addressed by implementing procedures and/or instructions.

Acceptance Criterion 3 The activities related to design control are acceptable provided that:

- The scope of the design control program includes design activities associated with the preparation and review of design documents, including the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents. Included in the scope are such activities as field design engineering; physics (including criticality physics), seismic, stress, thermal, and hydraulic analyses; radiation shielding; compatibility of materials; delineation of acceptance criteria for inspections and tests; the Safety Analysis Report accident analyses; associated computer software; features to facilitate decontamination; suitability and compatibility of materials; accessibility for in-service inspection, maintenance, and repair; and quality standards;

- The term "design" includes specifications; drawings; design criteria; design bases; structures, systems, and components performance requirements for preclosure; and natural and engineered barriers of the repository system. It also includes inputs and outputs at each stage of design development (e.g., from conceptual design to final design). Design information and design activities also refer to data collection and analyses and computer software that are used in supporting design development and verification. Design information and activities include general plans and detailed procedures for data collection and analyses and related information such as test and analyses results. Data analyses include the initial step, data reduction, as well as broad system analyses (such as performance assessments), that integrate other data and analyses for individual parameters;

- The design control program provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents;

- Measures are established to assure that applicable regulatory requirements, design bases, and design features developed through the site characterization phase activities for structures, systems, and components and software are correctly translated into specifications, drawings, instructions, and plans;

- Design control measures are established and are applied to: (i) the design of structures, systems, and components that are important to safety; (ii) engineered and natural barriers that are important to waste isolation; (iii) the description of the geologic setting and the plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in licensing and performance confirmation; and (iv) computer software used in such activities. These design measures must apply to the design inputs, outputs, and site characterization activities and performance-confirmation activities.

- Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, related computer software, specifications, and procedures.

- Errors and deficiencies in approved design documents, including design methods (such as computer software), that could adversely affect structures, systems, and components important to safety or waste isolation are documented, and action is taken to assure that all errors and deficiencies are corrected;

- Deviations from specified quality standards are identified and formally documented, and procedures are established to assure their control;

- Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to assure that structures, systems, and components are compatible geometrically, functionally, and with processes and environment;

- Procedures are established and described, requiring a documented check to verify the dimensional accuracy and completeness of design drawings and specifications;

- Procedures are established and described, requiring that design drawings and specifications be reviewed by the quality assurance organization to assure that the documents: (i) are prepared, reviewed, and approved in accordance with the U.S. Department of Energy procedures; and (ii) contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented;

- Guidelines or criteria are established and described for determining the method of design verification (e.g., design review, alternate calculations, or tests);

- Procedures are established and described, for design verification activities, that assure the following:

  — The verifier is qualified and is not directly responsible for the design (i.e., neither the performer nor his/her immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided: the supervisor is the only technically qualified individual; the need is individually documented and approved in advance by the supervisor's management; and quality assurance audits cover frequency and effectiveness of the use of supervisors as design verifiers, to guard against abuse;

  — Design verification, if other than by qualification testing of a prototype, is completed before release: (i) for procurement, manufacturing, or construction; or (ii) to another organization for use in other design activities. In cases where this timing cannot be satisfied, the design verification may be deferred, providing

that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled. Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework). In all cases, the design verification must be complete before waste package placement in the repository, or before reliance on the structure, system, or component to perform its function.

— Procedural control is established for design documents that reflect the commitments of the Safety Analysis Report; this control differentiates between documents that receive formal design verification by interdisciplinary or multiorganizational teams and those that can be reviewed by a single individual (a signature and date are acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, associated computer software, system descriptions, parts of the Safety Analysis Report when used as a design document, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant; and

— The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

- The following provisions are included if the design verification method is by test only:

  — Procedures provide criteria that specify when verification should be by test;

  — Prototype, component, or feature testing is performed as early as possible before installation of facility equipment, before the installation would become irreversible; and

  — Verification by test is performed under conditions that simulate the full range, including the most adverse anticipated, design conditions, as determined by analysis.

- Procedures are established to assure that verified computer software is certified for use in design and that such use is specified;

- Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design;

- Measures are provided to assure that responsible repository site personnel are notified of design changes/modifications that may affect performance of their duties;

- Sampling: The basis, including any supporting analyses, for the use of sampling plans for structures, systems, and components and barriers and activities related thereto, such as inspection and commercial-grade item dedication, is required to be documented. The following apply for the use of sampling plans: (i) sampling plans used for high-safety-risk significant -activities are expected to use criteria that provide 95 percent confidence that there are only 5 percent defective items in a lot (95/5); (ii) reduced sampling plans may be used for low-safety-risk-significant activities; and (iii) lots sampled are essentially homogenous;

- The applicable change control requirements of 10 CFR 63.44 are described; and

- Procedures are established describing methods of reviewing and qualifying data used in design that were collected without a fully implemented 10 CFR Part 63 quality assurance program [NUREG–1298 (U.S. Nuclear Regulatory Commission, 1987)].

Acceptance Criterion 4 The activities related to procurement document control are acceptable provided that:

- Procedures are established for the review of procurement documents, to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with quality assurance program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by independent personnel trained and qualified in quality assurance practices and concepts;

- Procedures are established to assure that procurement documents include a statement of work to be performed by the contractor and identify requirements such as: (i) applicable regulatory, design, technical, administrative, and reporting requirements; (ii) drawings; (iii) specifications; (iv) codes and industry standards; (v) test and inspection and acceptance requirements; (vi) access for audit or inspection by the purchaser; (vii) identification of documentation to be submitted to the purchaser or retained by the supplier (including any retention times); (viii) requirements for reporting and disposition of nonconformances; and (ix) special process instructions that should be complied with by suppliers; and

- Organizational responsibilities are described for: (i) procurement planning; (ii) the preparation, review, approval, and control of procurement documents; (iii) supplier selection; (iv) bid evaluations; and (v) review and concurrence of supplier quality assurance programs before initiation of activities affected by the program. The involvement of the quality assurance organization is described.

Acceptance Criterion 5 The activities related to instructions, procedures, and drawings are acceptable provided that:

- Organizational responsibilities are described for ensuring that activities affecting quality are: (i) prescribed by documented instructions, procedures, and drawings; and (ii) accomplished through implementation of these documents;

- Procedures are established to assure that instructions, procedures, and drawings include quantitative (e.g., dimensions, tolerances, operating limits) and qualitative (e.g., workmanship samples) acceptance criteria for determining that important activities have been satisfactorily accomplished; and

- Procedures are established for controlling changes to field and laboratory procedures associated with exploratory investigations for site characterization and performance confirmation to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel.

Acceptance Criterion 6 The activities related to document control are acceptable provided that:

- The scope of the document control program is described, and the types of controlled documents are identified. Controlled documents are required to include, as a minimum, design documents (e.g., calculations, drawings, specifications, analyses), including documents related to computer software; procurement documents; instructions and procedures for such activities as fabrication, construction, modification, installation, testing, and inspection; as-built documents; quality assurance and quality control manuals and quality-affecting procedures; Safety Analysis Reports; nonconformance/deficiency reports; and corrective action reports, including changes thereto;

- Procedures for the review, approval, and issuance of documents and changes thereto are established and described to assure technical adequacy and inclusion of appropriate quality requirements before implementation. The quality assurance organization, or an individual other than the one who generated the document, but qualified in quality assurance, reviews and concurs with these documents with respect to quality assurance-related aspects;

- Procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the U.S. Department of Energy;

- Procedures are established to assure that documents are available at the location where the activity will be performed before commencing the work;

- Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner;

- A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. When such a list is used, it should be updated and distributed to predetermined responsible personnel;

- Procedures are established and described to provide for the preparation of as-built drawings and related documentation in a timely manner to accurately reflect the actual repository design; and

- Maintenance, modification and inspection procedures are reviewed by qualified personnel knowledgeable in the quality assurance discipline (normally the quality assurance organization) to determine: (i) the need for inspection, identification of inspection personnel, and documentation of inspection results; and (ii) that the necessary inspection requirements, methods, and acceptance criteria have been identified.

Acceptance Criterion 7 The activities related to control of purchased material, equipment, and services are acceptable provided that:

- Organizational responsibilities are described for the control of purchased material, equipment, software, and services including interfaces between design, procurement, and quality assurance organizations;

- Verification of suppliers' activities during fabrication, inspection, testing, and shipment of material, equipment, and components is planned and performed with quality assurance organization participation in accordance with written procedures to assure conformance to the purchase order requirements. These procedures, as applicable to the method of procurement, provide for:

  — Specification of the characteristics or processes to be witnessed, inspected, or verified, and accepted; the method of surveillance and the extent of documentation required; and individuals responsible for implementing these procedures; and

  — Audits, surveillance, or inspections that assure that the supplier complies with the quality requirements. The quality assurance program requires that the effectiveness of quality control by contractors and subcontractors be assessed.

- Selection of suppliers is documented, filed, and maintained as a record; and

- Procurement of spare or replacement parts for structures, systems, and components and parts thereof important to safety and engineered barriers important to waste isolation are subject to present quality assurance program controls, codes and standards, and technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects.

- Receiving inspection is performed to assure that:

  — Material, components, and equipment are properly identified, in correspondence to identification on purchase documents and receiving documentation;

  — Material, components, equipment, and acceptance records satisfy inspection instructions before installation or use; and

— Specified inspection, testing, and other records (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements) are available at the facility before installation or use.

- Items accepted and released are identified as to their inspection status before forwarding them to a controlled storage area or releasing them for installation or further work;

- The supplier furnishes the following records to the purchaser:

  — Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item;

  — Documentation identifying any procurement requirements that have not been met; and

  — A description of nonconformances from the procurement requirements that are dispositioned "accept as is" or "repair."

  The review and acceptance of these documents should be described in the purchaser's quality assurance program.

- Commercial-Grade Item Dedication: For commercial "off-the-shelf" items, where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements must be established and described to provide the necessary assurance of an acceptable item by the purchaser;

  For procurement of commercial-grade items, Section 10, "Commercial Grade Items," of Supplement 7S–1 of NQA–1–1983, "Supplementary Requirements for Control of Purchased Items and Services" (American Society of Mechanical Engineers, 1983), does not adequately address commercial-grade item dedication. The guidance provided in this acceptance criteria should be used for commercial-grade item dedication.

  Where the U.S. Department of Energy elects to purchase commercial-grade items and dedicate the items for use as basic components, as permitted by the requirements contained in 10 CFR Part 21, the quality assurance program must provide for the following to assure that the dedicated item will perform its intended safety or waste-isolation function:

  — When applied to facilities licensed pursuant to 10 CFR Part 63, commercial-grade item means an item that is: (i) not subject to design or specification requirements that are unique to that facility or activities; (ii) used in applications other than that facility or activities; and (iii) to be ordered from the manufacturer/ supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., catalog). This definition must meet the requirements specified in 10 CFR Part 21;

— Important terms having specific meaning that are used in the dedication process, such as "critical characteristics," "dedication," "dedicating entity," "commercial-grade item," etc., are defined. The U.S. Department of Energy should use the following definitions when dedicating commercial-grade items for use as basic components (it is noted that additional definitions such as "commercial-grade survey" may also need to be defined):

  - "Critical characteristics" are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety or waste-isolation function;

  - "Dedicating entity" means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the U.S. Department of Energy itself. The dedicating entity pursuant to 10 CFR 21.21(c) is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedicating process; and

  - "Dedication" is an acceptance process undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety or waste-isolation function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 63, Subpart G, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspection, tests, or analyses performed by a purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witnessing at hold points at the manufacturer's facilities; and analyses of historical records for acceptable performance. In all cases, the dedication process should be conducted in accordance with the applicable requirements of 10 CFR Part 63, Subpart G. Final dedication of an item occurs after receipt and final acceptance by the U.S. Department of Energy or its contractor, when the item is designated for use as a basic component.

— If these definitions are used, the U.S. Department of Energy commits to comply with all the provisions associated with the definitions.

— Additional definitions are contained, in 10 CFR 21.3, that are specifically applicable to 10 CFR Part 63 and are required to be applied to U.S. Department of Energy commercial-grade-item dedication activities.

— It is preferred that the above definitions be used. However, additional definitions and guidance for commercial-grade item dedication are provided in Electric Power Research Institute (1988), NP–5652, as endorsed by U.S. Nuclear Regulatory Commission Generic Letter 89-02 (U.S. Nuclear Regulatory

Commission, 1989) and Generic Letter 91-05 (U.S. Nuclear Regulatory Commission, 1991). Although these documents are applicable for 10 CFR Part 50 licensees, certain elements of these documents may be appropriate for 10 CFR Part 63 commercial-grade-item-dedication activities.

- Sampling plans used for commercial-grade-item dedication activities are required to satisfy the requirements for sampling under Acceptance Criterion 3 of this section.

- Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure that they are valid, and the results are documented;

- The quality assurance program describes the responsibilities for, and requires instructions and procedures for, accepting services such as third-party audits and inspections; engineering and consulting services; installation, repair, overhaul, or maintenance work; commercial grade item dedication; and testing. It may be necessary for the acceptance methods to include one or more activities similar to the following: (i) technical verification of data; (ii) surveillance, auditing, or source inspection; and (iii) review of certifications and reports from approved suppliers;

- For the purchase of American Society of Mechanical Engineers Section III Code items, the U.S. Nuclear Regulatory Commission considers the referenced edition of NQA–1 in the endorsed versions of the Code to be acceptable only for the construction of American Society of Mechanical Engineers Section III items when the referenced edition of NQA–1 is used in conjunction with the other quality assurance, administrative, and reporting requirements contained in the American Society of Mechanical Engineers Section III Code. Further, applicable provisions contained in the U.S. Department of Energy quality assurance program and requirements contained in the regulations also need to be met and must be used in conjunction with the American Society of Mechanical Engineers Section III Code; and

- For audits of American Society of Mechanical Engineers Section III Code suppliers, the U.S. Nuclear Regulatory Commission Information Notice 86-21 and its two supplements discuss the U.S. Nuclear Regulatory Commission recognition of the American Society of Mechanical Engineers accreditation program for N Stamp Holders, and the guidance provided therein should be used by the U.S. Department of Energy. U.S. Department of Energy audits of American Society of Mechanical Engineers Section III Code suppliers shall confirm that the suppliers are satisfactorily implementing: (i) their accredited American Society of Mechanical Engineers quality assurance program (as approved by the U.S. Department of Energy, (ii) the technical and quality provisions specified in the U.S. Department of Energy purchase order, (iii) the applicable provisions of the U.S. Department of Energy quality assurance program, and (iv) the applicable requirements contained in the regulations.

Acceptance Criterion 8 The activities related to identification and control of materials, parts, and components (including samples) are acceptable provided that:

- Controls are established and described to identify and control materials (including consumables), software, parts, and components, including samples and partially fabricated subassemblies. The description should include organizational responsibilities;

- Procedures are established that assure identification is maintained either on the item, software, or sample, or in records traceable to them, to preclude use of incorrect or defective items;

- Identification of materials and parts important to the function of structures, systems, and components important to safety can be traced to the appropriate documentation such as drawing;, specifications; purchase orders; technical reports; drilling locations and logs (including well bore and depth); test records; installation and use records; manufacturing and inspection documents; deviation reports; and physical and chemical mill test reports;

- Correct identification of materials, parts, and components is verified and documented before release for fabrication, assembling, shipping, and installation;

- Correct identification of samples is verified and documented before release for use or analysis;

- Procedures are established for providing traceability of items (when required by codes, standards, or specifications) to: (i) applicable specification and grade of material; (ii) heat, batch, lot, part, or serial number; and (iii) specified inspection, test, or other records such as drawings, purchase orders, deviation reports, or reports of nonconformance and their disposition;

- Responsibilities are assigned and procedures or instructions are issued for maintaining identification of items in prolonged storage or storage under adverse conditions by: (i) protecting markings and identification records of items in storage from deterioration caused by environmental exposure or adverse storage conditions; and (ii) restoring or replacing markings or identification records that are damaged because of aging or storage conditions.

- Responsibilities are assigned and procedures or instructions are issued for: (i) identifying items with limited calendar or operating life cycles; (ii) establishing records of shelf life or operating life or cycles remaining; (iii) preventing the use of items whose shelf lives have expired; and (iv) preventing further use of items, components, or materials that have reached the ends of their operating lives or cycles; and

- Controls are established to preclude the inadvertent use of incorrect or defective items, software, or samples.

Acceptance Criterion 9 The activities related to control of special processes are acceptable provided that:

- The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Examples of special processes include welding, heat treating, nondestructive examination, and chemical cleaning;

- Organizational responsibilities, including those for the quality assurance organization, are described for qualification of special processes, equipment, and personnel;

- Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, procedures, and specifications. The quality assurance organization is involved in the qualification activities to assure they are satisfactorily performed;

- Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel;

- Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and maintained to be current;

- When no applicable codes, standards, or specifications address methods for qualifying special processes associated with scientific investigations, the following methods may be considered: (i) the conducting of a prototype test, if possible, that demonstrates that the process maintains quality or produces a quality product; and (ii) a combination of methods such as peer reviews, technical reviews, models, and testing that provides reasonable assurance that the process maintains quality or produces a quality product;

  In all cases, measures are established to assure that special processes associated with scientific investigations are controlled and accomplished by qualified personnel using qualified procedures.

- Special processes associated with nondestructive evaluation should be performed in accordance with American Society for Nondestructive Testing–TC–1A (American Society for Nondestructive Testing, 1980). In all cases, the qualification and certification of nondestructive evaluation personnel includes a performance demonstration as part of the practical examination. In lieu of the 3-year recertification interval specified in American Society for Nondestructive Testing–TC–1A, Level III nondestructive examination personnel may be recertified on a 5-year interval.

Acceptance Criterion 10 The activities related to inspection are acceptable, provided that:

- The scope of the inspection program is described that indicates that an effective inspection program has been established for verifying conformance of items or activities to specified requirements. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when

inspections are required and defining how and when inspections are performed. The quality assurance organization participates in the above functions;

- Organizational responsibilities for inspection are adequately described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individuals performing inspections are not part of the quality assurance organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found acceptable by the quality assurance organization before the initiation of the activity;

- A qualification program for inspectors (including nondestructive examination personnel) is established and documented, and the qualifications and certifications of inspectors are maintained to be current;

- Inspection procedures, instructions, or checklists provide for the following: identification of characteristics and activities to be inspected; description of the method of inspection; identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of the second bullet under this acceptance criteria; acceptance and rejection criteria; identification of required procedures, drawings, specifications, and revisions thereof; records of the identity of the inspector or data recorder and the results of the inspection operation; and specification of necessary measuring and test equipment, including accuracy requirements;

- Procedures are established and described to identify, in pertinent documents, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector;

- Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual or group;

- When inspections associated with normal operations of the site (e.g., routine maintenance, surveillance, tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are required: (i) the qualification criteria for the inspection personnel are reviewed and found acceptable by the quality assurance organization before initiating the inspection; and (ii) the quality of the work can be objectively demonstrated through a functional test when the activity involves breaching a pressure-retaining item; and

- Sampling plans used for inspection activities are required to meet the requirements for sampling under Acceptance Criterion 3 of this section.

Acceptance Criterion 11 The activities related to test control are acceptable provided that:

- The scope of the test control program is described that indicates that an effective program has been established for testing activities for verifying conformance of items or

activities to specified requirements and demonstrating that items will perform satisfactorily in service. The test control program encompasses, but is not limited to, such testing activities as: acquiring data from samples; prototype qualifications tests; production tests; proof tests before installation; preoperational tests; tests supporting site characterization; tests supporting scientific investigations; tests of software; construction phase tests; and operational tests. Program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when tests are required and defining how and when testing activities are performed. Tests must be performed in accordance with written test procedures that identify test acceptance criteria and that incorporate, as appropriate, requirements and acceptance limits contained in applicable design documents;

- Test procedures or instructions provide, as required, for the following:
  - The requirements and acceptance limits contained in applicable design and procurement documents;
  - Instructions for performing the test;
  - Test prerequisites such as calibrated instrumentation, adequate test equipment, and instrumentation, including their accuracy requirements, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage;
  - Mandatory inspection hold points for witnessing by the U.S. Department of Energy, contractor, or inspector (as required);
  - Acceptance and rejection criteria; and
  - Methods of documenting or recording test data and results, and provisions for ensuring that test prerequisites have been met.
- Test results, including computer software and supporting data, are documented and evaluated, and their acceptability is determined by a responsible individual or group.

Acceptance Criterion 12 The activities related to control of measuring and test equipment are acceptable provided that:

- The scope of the program for the control of measuring and test equipment is adequately described and the types of equipment to be controlled are established;
- Responsibilities of quality assurance and other organizations are adequately described for establishing, implementing, and ensuring effectiveness of the calibration program;
- Procedures are established and described in sufficient detail for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and

nondestructive test equipment) that is used in the measurement, inspection, and monitoring of structures, systems, and components;

- The review and documented concurrence of these procedures is described and the organization responsible for these functions is identified;

- Measuring and test equipment is identified and traceable to the calibration test data;

- Measuring and test equipment is labeled or tagged or "otherwise controlled" to indicate the due date of the next calibration, and such methods of control should be adequately described;

- Measuring and test equipment is calibrated at specified intervals, based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, that have an accuracy that assures that the equipment being calibrated will be within required tolerance. The basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified;

- Calibration standards have greater accuracy than the standards being calibrated. Calibration standards with the same accuracy may be used if this level of accuracy can be demonstrated to be adequate for the requirements and provided that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified;

- Reference and transfer standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document the basis for calibration;

- When measuring and test equipment is found to be out of calibration, measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration. Inspections or tests are repeated on items determined to be suspect; and

- Procedures are established for selecting measuring and test equipment, for use in processes, inspections, and tests, that: (i) is of the type appropriate for measuring specified characteristics of items being processed, inspected, or tested; and (ii) has sufficient range, accuracy, and tolerance to determine conformance to specified requirements.

Acceptance Criterion 13 The activities related to handling, storage, and shipping are acceptable provided that:

- Special handling, preservation, storage, cleaning, packaging, and shipping requirements and procedures are established and accomplished by suitably trained and, when

appropriate, qualified individuals, in accordance with predetermined work and inspection instructions;

- Procedures are established and described to control the cleaning, handling, storage, packaging, and shipping of items, samples, materials, components, and systems, in accordance with design and procurement requirements, to preclude damage, loss, or deterioration from environmental conditions such as temperature or humidity;

- Provisions are described for the storage (including the control of shelf life) of chemicals, reagents, lubricants, and other consumable materials;

- Provisions are described for identifying special handling tools and equipment that are required for safe handling of items. Provisions are established for inspection and testing of such tools and equipment, including specification of procedures to be implemented at specified intervals to verify that such tools and equipment are adequately maintained; and

- Provisions are described for marking or labeling items being shipped, handled, or stored, for the purpose of identifying the items and any special environments or controls required by such items.

Acceptance Criterion 14 The activities related to inspection, test, and operating status are acceptable provided that:

- Procedures are established to indicate the inspection, test, and operating status of structures, systems, and components and software throughout fabrication, installation, testing, and operation.

- The status of inspection, test activities, and software controls should be identified either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

- Inspection, test, and operating status of structures, systems, and components and software should be identified by status indicators, such as physical location tags, markings, labels, travelers, stamps, inspection records, or other suitable means;

- Procedures and authority are established and described to control the application and removal of inspection and welding stamps and status indicators such as those listed in the previous bullet;

- Procedures are established and described to control alteration of the sequence of required tests, inspections, and other operations important to waste isolation or important to safety. Such actions should be subject to the same controls as the original review and approval;

- The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is clearly identified; and

- Procedures are established to prevent inadvertent use or operations of a structure, system, or component that is out of service, by indicating its operating status, by the use of tags or markings on control panels, switches, breakers, and other locations where its use or operation can be initiated.

Acceptance Criterion 15 The activities related to nonconforming materials, parts, or components are acceptable provided that:

- Procedures are established and described for identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, structures, systems, and components, and services (as applicable), including computer software, if disposition is other than disposal. The procedures provide identification of authorized individuals for independent review of nonconformances, including disposition and closeout;

- Procedures are established for preventing the inadvertent use or installation of nonconforming items;

- Quality assurance and other organizational responsibilities are described for the definition and implementation of activities related to nonconformance control, including identification of individuals or groups with authority for the disposition of nonconforming items;

- Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved before initiation of the preoperational test program on the item;

- Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives. Design control measures commensurate with those applied to the original design are applied when dispositioning nonconformance as "use-as-is" or "repair," and the technical bases for such dispositions are documented;

- Nonconformance reports are periodically analyzed by the quality assurance organization to show quality trends, and the significant results are reported to upper management for review and assessment; and

- Items reworked or repaired are retested or reinspected against the original acceptance criteria unless the disposition of the nonconforming item established alternate acceptance criteria. (If the latter is the case, then a design change may be required to support the disposition.)

Acceptance Criterion 16 The activities related to corrective action are acceptable provided that:

- Procedures are established and described indicating an effective corrective action program has been established. The quality assurance organization reviews and documents concurrence with the procedures;

- Corrective action is documented and initiated after the determination of a condition adverse to quality, such as a nonconformance, failure, malfunction, deficiency, deviation, or defect in material, equipment, or samples, and procedures and records are established to preclude recurrence. Conditions adverse to quality should be identified promptly and corrected as soon as practical. The quality assurance organization is involved in the documented concurrence of the adequacy of the corrective action. Followup action is taken by the quality assurance organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

- Significant conditions adverse to quality, the cause of the conditions, and the corrective actions taken to preclude repetition are documented and reported to immediate management and upper levels of management, for review and assessment;

- A program for determining adverse quality trends is established and includes: (i) evaluation of nonconformance and other related documents to identify adverse quality trends and assist in identifying root causes; (ii) prompt identification of adverse trends; and (iii) prompt reporting of adverse trends to management.

- Significant conditions adverse to quality include repetitive conditions that are less significant, but when taken collectively: (i) indicate a programmatic failure to properly implement the quality assurance program; (ii) may be precursors for a significant technical deficiency or problem; or (iii) may reduce the margin of safety; and

  In addition, significant conditions adverse to quality also include, but are not limited to: (i) loss of or potential loss, of a safety or waste-isolation function, to the extent that there is a reduction in the degree of protection provided to the public health and safety; (ii) loss, or potential loss of a safety or waste-isolation function to the extent that there is a major reduction in the degree of protection provided for worker safety, (iii) programmatic or technical adverse-quality trends; (iv) common-cause failures; and (v) adverse trends.

Acceptance Criterion 17 The activities related to quality assurance records are acceptable provided that:

- Quality assurance records that furnish documentary evidence of quality must be specified, prepared, and maintained. These records must be legible, identifiable, and retrievable. Requirements and responsibilities for quality assurance record transmittal, distribution, retention, maintenance, and disposition must be established and documented.

- The scope of the quality assurance records program is described. Quality assurance records include scientific, engineering, and operational data and logs; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; maintenance and modification procedures and related inspection results; reportable occurrences; computer software; qualification of personnel, procedures, and equipment; and other documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, as-built drawings, and other records required by preclosure and postclosure operating conditions;

- Quality assurance and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to quality assurance records, particularly in the retention and duration of record storage;

- Criteria are established and described in procedures for determining when a document becomes a quality assurance record, subject to the controls of this section, and the retention period for such records;

- Procedures are established describing methods for documenting/recording, reviewing, and confirming the accuracy of quality assurance records, including laboratory and field notebooks and logbooks, data sheets, data-reduction documents, and software.

- Inspection and test records contain the following, where applicable: a description of the type of observation; date and results of the inspection or test; information related to conditions adverse to quality; identification of inspector or data recorder; evidence as to the acceptability of the results; and action taken to resolve any discrepancies noted;

- Provisions are made for the disposition of quality assurance records, including: ensuring that disposition of records is governed by the most stringent regulatory requirements that apply to records (this may be an agency other than the U.S. Nuclear Regulatory Commission); ensuring that suppliers' nonpermanent records are properly controlled and retained for required periods; and ensuring that quality assurance records are protected against damage, deterioration, or loss;

- Suitable controls are established and described for controlling, protecting, and maintaining quality assurance records before they are entered and stored in a quality assurance record storage area;

- Suitable facilities for the storage, preservation, and safekeeping of quality assurance records are described and satisfy the provisions contained in Section 4, "Storage, Preservation, and Safekeeping," of Supplement 17S–1 of NQA–1–1983 (American Society of Mechanical Engineers, 1983), "Supplementary Requirements for Quality Assurance Records;"

- Guidance for storing quality assurance records, using electronic media, is provided in Regulatory Issue Summary 2000-18 (U.S. Nuclear Regulatory Commission, 2000);

- The additional records provisions referenced in Subsection 4.5.1.5 of the Yucca Mountain Review Plan are described;

- For quality assurance records, Section 2.8, "Retention of Records," of Supplement 17S–I of NQA–1–1983 (American Society of Mechanical Engineers, 1983), "Supplementary Requirements for Quality Assurance Records," states that the retention period for non-permanent records is required to be established in writing. Programmatic non-permanent records should be retained for at least 10 years or the life of the item if less than 10 years. For programmatic non-permanent records, the retention period should be considered to begin on completion of the activity. For product non-permanent records generated before facility licensing, the retention period should be considered to begin on completion of delivery. In addition, product and programmatic non-permanent records should be retained at least until the date of the start of preclosure site operational activities. Table 1 of Regulatory Guide 1.28, Revision 3 (U.S. Nuclear Regulatory Commission, 1985), provides a list of non-permanent and lifetime records and their respective retention times. Records similar to those identified in Table 1 of Regulatory Guide 1.28 are required to be maintained for the repository for the durations identified. Although Table 1 is intended to be a comprehensive list, it is the U.S. Department of Energy responsibility to assure itself, in accordance with the Records Section of 10 CFR 63.142, that sufficient records are maintained to furnish evidence of activities affecting quality. Table 1 is not applicable for preoperational test or operational phase records at this time because the final design and operating practices have not been developed. Further, Table 1 does not address site characterization records. It should be recognized that the nomenclature of these records may vary. For records not listed in Table 1, the type of record most nearly describing the record in question should be followed with respect to its retention period. The following definitions apply to the records:

  — Programmatic nonpermanent records are those documents that were used to prescribe activities affecting quality, but that are not considered permanent records. Such records include documents prescribing the planning, execution, and auditing of activities affecting quality. Records such as audit checklists, audit results, and actual examinations used to qualify inspection and test personnel are included in this category; and

  — Product nonpermanent records document that specific structures, systems, and components of the repository site have been designed and constructed in accordance with applicable requirements, but are such that is it not necessary to retain them as lifetime records. These records include design, verification data, receiving records, calibration records, maintenance records, inspection records, radiographs not associated with in-service inspection, and test records that are not otherwise designated as lifetime records.

- This acceptance criterion (i.e., Acceptance Criterion 17 relating to quality assurance records) may be updated to address records for site characterization, preoperational testing, and operations. This update is contingent on the level of detail of records included in the U.S. Department of Energy quality assurance program for these activities. [Note: potential licensing condition.]

Acceptance Criterion 18 The activities related to audits are acceptable provided that:

- Responsibilities and procedures are established for audits, for documenting and reviewing audit results, and for designating management levels to review and assess audit results;

- Internal and external audits to assure that procedures and activities comply with all aspects of the overall quality assurance program are performed by:

  — The quality assurance organization, to provide a comprehensive independent verification and evaluation of quality-related procedures and activities; and

  — The U.S. Department of Energy (and principal contractors), to verify and evaluate the quality assurance programs, procedures, and activities of suppliers. [Note: Internal and external audits are carried out by the U.S. Department of Energy and its contractors to verify that products, services, and activities comply with all aspects of the overall quality assurance program and to determine the effectiveness of the quality assurance program.] The U.S. Department of Energy and its contractors should perform audits of the prime contractor and subcontractors, consultants, vendors, and laboratories.

- The audit program should address planning and performance of audits to: (i) verify compliance with drawings, instructions, specifications, and other requirements affecting quality; and (ii) determine the effectiveness of the quality assurance program;

- An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits should be regularly scheduled based on the status and safety importance of the activities being performed and should be initiated early enough to assure effective quality assurance during design, procurement, manufacturing, construction, installation, inspection, testing, and performance confirmation. For scheduling audits, Section 2, "Scheduling," of Supplement 18S–1 of NQA–1–1983 (American Society of Mechanical Engineers, 1983), "Supplementary Requirements for Audits," requires audits to be scheduled in a manner that provides coverage and coordination with ongoing quality assurance program activities. The guidelines provided in Regulatory Position C.3.1, "Internal Audits," and C.3.2, "External Audits," of Regulatory Guide 1.28, Revision 3 (U.S. Nuclear Regulatory Commission, 1985), are considered acceptable and should be used for scheduling audits and related audit activities;

- Audits include: (i) an objective programmatic and technical evaluation of quality-related practices, procedures, instructions, activities, and items; and (ii) a review of documents and records, including software and test data from samples. Audits are conducted to assure that the abovementioned in (i) and (ii) are acceptable and to assure that the quality assurance program is effective and properly implemented;

- Provisions are established requiring that audits be performed in all areas where the requirements of 10 CFR Part 63, Subpart G are applicable. However, the results of the

audit process indicate that the following areas have either been omitted or not emphasized to the extent necessary;

— The determination of site features that affect site safety (e.g., site characterization, performance confirmation, core sampling, site and foundation preparation, and methodology);

— The preparation, review, approval, and control of early procurements;

— Indoctrination and training programs;

— Interface control among the U.S. Department of Energy and principal contractors;

— Corrective action, calibration, and nonconformance control systems;

— Safety Analysis Report commitments;

— Activities associated with computer software;

— The purchase of American Society of Mechanical Engineers Section III Code items. For the purchase of such items, the U.S. Nuclear Regulatory Commission has only endorsed certain editions and addenda of the American Society of Mechanical Engineers Section III Code (American Society of Mechanical Engineers, 1998) and in doing so has indirectly endorsed quality assurance standards referenced in the Code. The U.S. Nuclear Regulatory Commission considers the referenced edition of NQA–1 (American Society of Mechanical Engineers, 1983) in the endorsed versions of the Code to be acceptable only for the construction of American Society of Mechanical Engineers Section III items when the referenced edition of NQA–1 is used in conjunction with the other quality assurance, administrative, and reporting requirements contained in the American Society of Mechanical Engineers Section III Code. Applicable provisions contained in the U.S. Department of Energy quality assurance program and requirements contained in the regulations also need to be met; and

— Audits of American Society of Mechanical Engineers Section III Code suppliers. U.S. Nuclear Regulatory Commission Information Notice 86-21 (U.S. Nuclear Regulatory Commission, 1986) discusses the U.S. Nuclear Regulatory Commission recognition of the American Society of Mechanical Engineers accreditation program for N Stamp Holders, and the guidance provided therein should be used by the U.S. Department of Energy.

- Audit data are analyzed by the quality assurance organization and, as appropriate, the technical staff. The resulting reports describing any quality problems and the effectiveness of the quality assurance program, including the need for an audit of deficient areas, are reported to management for review and assessment;

- Audits are performed in accordance with preestablished written procedures or checklists and are conducted by trained, qualified, competent quality assurance and technical personnel having expertise that encompasses the area being audited. Audit team members must not have been directly involved with the work being audited;

- Where the on-site quality assurance organization does not report to the off-site organization:

  — The off-site quality assurance organization conducts audits sufficient to verify adequacy of activities conducted by the on-site quality assurance organization;

  — The off-site quality assurance organization reviews and concurs in the schedule and scope of audits performed by the on-site quality assurance organization; and

  — Results of audits performed by the on-site quality assurance organization are provided to the off-site quality assurance organization for review and assessment.

- A tracking system for audit findings is established to help assure that all findings are appropriately addressed, prioritized, and trended;

- The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and responsible management of the audited organization; and

- Provisions are established and described to assure that the cause of each finding is identified, resulting corrective action is described, and followup action is accomplished to assure proper closeout of deficiencies.

Acceptance Criterion 19 The activities related to software are acceptable provided that:

- Software is defined as computer programs, procedures, rules, and associated documentation;

- Software should perform all intended functions, provide correct solutions, and not perform or cause any adverse unintended functions;

- Controls should be established to permit authorized access and prevent unauthorized access to computer systems;

- Software verification and validation activities are planned, documented, and performed for each item of software, software changes, and system configurations that are determined to affect software. Specifically:

  — Software verification of the various software life cycle phases (e.g., the requirement, design, implementation, and testing life cycle phases, as discussed below) is performed to assure that the products of a given life cycle phase are

traceable and fulfill the requirements of the previous phase and/or previous phases;

— Verification reviews identify reviewers and their specific review responsibilities; and

— Individuals not directly involved with the development of the software perform software verification and validation activities. In cases where this level of independence may not be achieved, an individual associated with the development of the software may perform these activities with a higher level of management approval and documented justification;

- A plan or similar document addressing software quality assurance is in existence for each new software project at the start of the software life cycle. The plan for software identifies:

  — A description of the overall nature and purpose of the software;

  — The software products to which it applies;

  — The organization responsible for performing the work and achieving software quality and the tasks and responsibilities of that organization;

  — Required documentation;

  — Standards, conventions, techniques, or methodologies that should guide the software activity;

  — Required software reviews; and

  — Methods for error reporting and corrective action.

- The software development and maintenance process should proceed in a planned, traceable, and orderly manner, using a defined software life-cycle methodology, which should address the following phases:

  — Requirement Phase

    – Software requirements such as functionality, performance, design constraints, attributes, and external interfaces are specified, documented, and reviewed;

  — Design Phase

    – Software design is developed, documented, and reviewed based on the requirements depicted in the requirements document;

— Implementation Phase

  - The design is translated into source code and resulting executables necessary to perform the functions required.

  - The source code and resulting executables should adhere to the design specifications.

  - User information is developed, documented, and reviewed in accordance with the design to delineate how the software is to be used.

— Testing Phase

  - Software activities are performed, documented, and verified at the end of the implementation phase to assure that the software installs properly and satisfies the requirements for its intended use.

  - Testing to an approved plan or process is the primary method of software validation to assure adherence to requirements and to assure that the software produces correct results for test cases.

  - Software validation documentation describes the task and specifies criteria for accomplishing the validation of the software at the end of the development cycle.

  - Modifications to released software are subjected to regression testing to detect errors introduced during modification of the software, to verify that modifications have not caused unintended adverse affects, and to verify that modified software still meets specified requirements.

— Operations and Maintenance Phase

  - On acceptable validation of the software, the software is designated as baselined and placed under configuration management controls.

— Installation and Checkout Phase

  - Software installation and checkout activities are performed and documented when the software is installed on a computer, or when there are changes in the operating system, to assure that the software installs properly and satisfies requirements for its intended use.

— Retirement Phase

  - The support for a software product is terminated and use of the software is prevented.

- A software configuration management system should be established that consists of the following:
  - A configuration identification that includes:
    - A definition of the baseline elements of each software baseline;
    - A unique identification of each software item, including version or revision, to be placed under software configuration management; and
    - Assignment of unique identifiers that relate baseline documents to their associated software items. Cross-references between baseline documents and associated software should be maintained.
  - A configuration change control that includes:
    - A release and control process for baseline elements;
    - A formal process to control and document changes to baseline elements;
    - A formal evaluation of the baseline element or change to the baseline element, and approval by the organization responsible for approving the baseline element;
    - A process of transmitting information concerning approved changes to all organizations affected by the changes; and
    - A software verification and validation process to assure that software changes are appropriately reflected in software documentation and to assure that document traceability is maintained.
  - A configuration status accounting that includes:
    - A listing of approved baseline elements and unique identifiers;
    - The status of proposed, in-process, or approved changes to baseline elements; and
    - A history of changes to software items, including descriptions of changes between versions of software items.
- Requirements controlling software procurement and services are established to assure proper verification and validation support, software maintenance, configuration control, and performance of software audits, assessments, or surveys. Requirements for the supplier's reporting of software errors to the purchaser and, as appropriate, the purchaser's reporting of software errors to the supplier are identified;

- Software engineering elements must define the baseline documents that are to be maintained as records; and

- Provisions for defect reporting and resolution specify that:

  — A software defect reporting and resolution system is implemented for software errors and failures, to assure that problems are promptly reported to affected organizations and to assure formal processing of problem resolutions; and

  — If a defect is identified in software that adversely affects previous applications, the condition adverse to quality is documented and controlled in accordance with Acceptance Criterion 16 of this section.

- Provisions for control of the use of software specify that:

  — Affected organizations control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process;

  — Use of software is independently reviewed and approved to assure that the software selected is suitable to the problem being solved; and

  — Documentation for the receipt of software is obtained from software configuration management and maintained for all software in operation or use.

- Procedures are established describing the quality assurance controls for software that satisfy the above review provisions and additional provisions contained in Subpart 2.7 of American Society of Mechanical Engineers NQA–1–2000.

- As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the control of software.

Acceptance Criterion 20 The activities related to the control of physical samples for activities such as scientific investigations, performance confirmation, material testing, and similar activities are acceptable provided that:

- Identification requirements include the following:

  — Samples are identified and controlled in a manner consistent with their intended use;

  — Identification is maintained on the samples or in a manner that assures identification is established and maintained;

  — Samples are identified from their initial collection through final use;

- — Sample identification is documented and checked before release of samples for use.
- — Sample identification methods include use of physical markings; and
- — If physical markings are either impractical or insufficient, other appropriate means should be employed, such as physical separation, labels or tags attached to bags, containers, or procedural control.

- Traceability requirements include the following provisions:
  - — Sample identification methods assure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents; and
  - — Sample traceability assures that the sample can be traced at all times from its collection through final use and any post-test retention that may be appropriate.
- Requirements are established to control the physical markings of samples.
  - — Physical markings are applied using materials and methods that provide clear and legible identification;
  - — Physical markings do not detrimentally affect sample content or form;
  - — Physical markings are transferred to each identified sample portion when the sample is subdivided; and
  - — Physical markings are not obliterated or hidden by surface treatments or sample preparations, unless other means of identification are substituted.
- Implementing documents specify the representative samples to be archived if the need to archive samples is identified; and
- Handling, storage, and shipping requirements include the following:
  - — Handling, storage, cleaning, packaging, shipping, and preserving samples are conducted in accordance with established implementing documents or other specified documents;
  - — Specific measures for handling, storage, cleaning, packaging, shipping, and preserving are identified and used for critical, sensitive, perishable, or high-value samples;
  - — Measures are established for the marking and labeling for packaging, shipping, handling, and storing samples, as necessary, to adequately identify, maintain, and preserve samples;

- — Markings and labels indicate the presence of special environments or the necessity for special controls;
- — Special equipment (e.g., containers) and special protective environments (e.g., inert gas, moisture and temperature limits) should be required for particular samples;
- — Special handling tools and equipment are used and controlled, as necessary, to assure safe and adequate handling;
- — Special handling tools and equipment are inspected and tested in accordance with implementing documents, and at specified time intervals, to verify that the tools and equipment are adequately maintained; and
- — Experience and training are specified for operators of special handling and lifting equipment.

- Samples that do not meet requirements specified in work controlling documents (such as job packages, travelers, or work requests) are documented, evaluated, and segregated in accordance with Acceptance Criterion 15 of this section;
- The disposition for nonconforming samples is identified and documented and should be limited to "use-as-is," "discard," or, where appropriate, "rework;" and
- As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the control of samples.

Acceptance Criterion 21 The activities related to scientific investigation are acceptable provided that:

- Scientific notebooks include:
  - — Statement of objective and description of work performed;
  - — Identification of method(s) and computer software used;
  - — Identification of samples and measuring and test equipment used;
  - — Description of work as it was performed, results obtained, names of individuals performing the work, and dated initials or signatures, as appropriate, of individuals making entries; and
  - — Description of changes made to methods used, as appropriate.
- Independent review of scientific notebooks is performed;
- Data are identified in a manner that facilitates traceability to: (i) associated documentation and (ii) qualification status of the data;

- Identification and traceability are maintained throughout the lifetime of the data;
- Requirements for data reduction are described in sufficient detail, to permit independent reproducibility by another qualified individual;
- Data that are directly relied on to address safety or waste-isolation issues must be qualified from origin or classified as accepted data. Procedures are established describing methods of reviewing and qualifying data that were collected without a fully implemented 10 CFR Part 63 quality assurance program [NUREG–1298 (U.S. Nuclear Regulatory Commission, 1988)];
- Unqualified data directly relied on to address safety or waste-isolation issues must be qualified or it can not be used in the license application;
- Model development and approaches to validation are planned, controlled, and documented. Procedures are established for model validation [NUREG–1636 (U.S. Nuclear Regulatory Commission, 1999)];
- Documentation is transparent and identifies principal lines of investigation considered;
- Documentation is legible and in a form suitable for reproduction, filing, and retrieval;
- Computer software used to develop or execute models is qualified in accordance with the requirements under Acceptance Criterion19 of this section, and such models are used and validated;
- As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the control of scientific investigations;
- Procedures are established describing the use of expert elicitation. The procedure complies with NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program" (U.S. Nuclear Regulatory Commission,1996) as addressed in Section 4.5.4 of this review plan; and
- Procedures are established describing the use of per review [NUREG–1297 (U.S. Nuclear Regulatory Commission, 1988)].

Acceptance Criterion 22 The activities related to field surveys are acceptable provided that:

- The field survey system:
  - Is a permanent system of horizontal and vertical controls;
  - Is used in accordance with implementing documents to obtain the accurate location and relocation of designated features, including locations of sample or data collection; and

— Is subject to proper administrative controls and program requirements.

- Pertinent survey documents are identified, maintained, and verified for completeness as work progresses;
- As applicable, other requirements of the U.S. Department of Energy quality assurance program apply to the control of field surveys; and
- Procedures are established describing methods of reviewing and qualifying data that were collected without a fully implemented 10 CFR Part 63 quality assurance program [NUREG–1298 (U.S. Nuclear Regulatory Commission, 1987)].

4.5.1.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.1.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

The reviewer will prepare evaluation findings based on satisfying the applicable regulatory requirements relating to the U.S. Department of Energy quality assurance program. If the reviewer concludes that information provided with the initial application or a subsequent quality assurance program change submittal shows that the quality assurance program meets the acceptance criteria (or acceptable alternative) provided, the quality assurance program should be considered acceptable. During the review process, clarification may be obtained by the U.S. Department of Energy providing additional information in response to requests by the reviewer. The reviewer will verify that sufficient information has been provided and that the review is sufficiently complete and adequate to support conclusions of the following type to be included in the safety evaluation report.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 21.3. Applicable definitions have been appropriately applied to U.S. Department of Energy commercial-grade item dedication.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.44. Adequate procedures for control of changes, tests, and experiments have been provided.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.73. Adequate procedures have been established for reporting deficiencies.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.21(c)(20). Requirements for the content of the license application have been met in

that an adequate description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation has been provided, including a discussion of how the applicable requirements of 10 CFR 63.142 will be satisfied.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.141. The description of the quality assurance program provided is within the proper scope and includes quality control.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.142. The quality assurance program described in the license application satisfies requirements of applicability and specified criteria and applies to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.143. The description of the quality assurance program satisfies requirements for the implementation of a program based on the criteria required by 10 CFR 63.142.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed materials and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.144. The description of the quality assurance program satisfies requirements and follows procedures for implementation of changes to a previously accepted quality assurance program for cases in which U.S. Nuclear Regulatory Commission approval either is or is not required.

Based on detailed review and evaluation of the quality assurance program description contained in the U.S. Department of Energy license application, the U.S. Nuclear Regulatory Commission staff finds, with reasonable assurance, that:

- The organizations and individuals performing quality assurance functions have the required independence and authority to effectively carry out the quality assurance program without undue influence from those directly responsible for costs and schedules; and

- The quality assurance program describes requirements, procedures, and controls that, when properly implemented, comply with the requirements of 10 CFR Part 63, Subpart G; the requirements of 10 CFR 63.73; the criteria contained in this Section (4.5.1) of the Yucca Mountain Review Plan; and the regulatory requirements, documents, and positions presented in Section 4.5.1 of the Yucca Mountain Review Plan;

  A brief description of the U.S. Department of Energy quality assurance program may be provided, along with the more important aspects of the program.

- The quality assurance program covers activities affecting structures, systems, and components important to safety and barriers important to waste isolation as identified in the Safety Analysis Report. Accordingly, the staff concludes that the U.S. Department of Energy description of the quality assurance program is in compliance with applicable U.S. Nuclear Regulatory Commission regulations and industry standards and that the quality assurance program can be implemented for the (specify: design, procurement, construction, operation, etc.) phases of the repository life cycle; and

- The U.S. Department of Energy quality assurance program description is in compliance with applicable U.S. Nuclear Regulatory Commission regulations.

4.5.1.5 References

Commitments

The U.S. Department of Energy is expected to commit to the use of the staff positions and provisions contained in the following documents in conjunction with any exceptions or clarifications provided in the acceptance criteria. However, as provided for in Section 4.5.1 of the Yucca Mountain Review Plan, exceptions and alternatives to these acceptance criteria and the documents and positions contained in Section 4.5.1.5 of the Yucca Mountain Review Plan may be adopted by the U.S. Department of Energy, provided adequate justification is given.

American Society of Mechanical Engineers. "Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications." *Quality Assurance Requirements for Nuclear Facility Applications.* NQA–1–2000. New York, New York: American Society of Mechanical Engineers.

———. "Quality Assurance Program Requirements for Nuclear Power Plants." NQA–1–1983. New York, New York: American Society of Mechanical Engineers. July 1983. Note: The exceptions to, and the U.S. Nuclear Regulatory Commission positions on, the use of NQA–1–1983, provided in the acceptance criteria in Section 4.5.1.3 of the Yucca Mountain Review Plan, apply. Also, the U.S. Nuclear Regulatory Commission positions provided in Section C of U.S. Nuclear Regulatory Commission Regulatory Guide 1.28, Revision 3, apply.

American National Standards Institute/American Nuclear Society. "Selection and Training of Nuclear Power Plant Personnel." American National Standards Institute/American Nuclear Society–3.1–1993. New York, New York: American National Standards Institute. 1993, as endorsed by the regulatory positions in Regulatory Guide 1.8, Revision 3, May 2000. Note: The exceptions to, and U.S. Nuclear Regulatory Commission positions on, the use of NQA–1–1983, provided in the acceptance criteria in Section 4.5.1.3 and in Section 4.5.1.5 of the Yucca Mountain Review Plan apply.

American Society for Nondestructive Testing. "Recommended Practice for Nondestructive Testing Personnel Qualification and Certification." TC–1A–1980. Columbus, Ohio: American Society for Nondestructive Testing. June 1980. Note: The exceptions to, and U.S. Nuclear Regulatory Commission positions on, the use of American Society for Nondestructive Testing–TC–1A, provided in the acceptance criteria in Section 4.5.1.3 of the Yucca Mountain Review Plan, apply.

U.S. Nuclear Regulatory Commission. Regulatory Guide 1.8, "Personnel Selection and Training." Revision 3. Washington, DC: U.S. Nuclear Regulatory Commission. May 2000.

———. NUREG–1636, "Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI White Paper." Washington, DC: U.S. Nuclear Regulatory Commission. March 1999.

———. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

———. NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

———. "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders." Information Notice 86-21. Washington, DC: U.S. Nuclear Regulatory Commission. March 31, 1986. Including Supplement 1, December 4, 1986, and Supplement 2, April 16, 1991.

———. NUREG–1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1988.

———. NUREG–1297, "Generic Technical Position: Peer Review for High-Level Nuclear Waste Repositories." Washington, DC: U.S. Nuclear Regulatory Commission. 1987.

———. U.S. Nuclear Regulatory Commission Regulatory Positions C.1, C.2, C.3, C.3.1, C.3.2 (1,2,and 3) contained in Section C, "Regulatory Position;" Regulatory Guide 1.28, "Quality Assurance Requirements (Design and Construction)," Revision 3. Washington, DC: U.S. Nuclear Regulatory Commission. August 1985.

Noncommitments

Where applicable, the U.S. Department of Energy should be aware of and should consider the guidance contained in the following documents. It is recognized that the U.S. Department of Energy quality assurance program description may not address the subjects included in these documents. However, if they are addressed, the following documents should also be used by the staff in performing its review.

Electric Power Research Institute. "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG–07)." EPRI NP–5652. Palo Alto, California: Electric Power Research Institute. June 1988. [Endorsed by U.S. Nuclear Regulatory Commission Generic Letter 89-02 and 91-05.]

U.S. Nuclear Regulatory Commission. "U.S. Nuclear Regulatory Commission Staff Review of the U.S. Department of Energy's Proposed Approach to Risk Significance Categorization of Structures, Systems, and Components Important to Safety." Letter: C. William Reamer (September 28, 2001) to S. Brocoum (U.S. Department of Energy). Washington, DC: U.S. Nuclear Regulatory Commission. 2001.

———. "Guidance on Managing Quality Assurance Records in Electronic Media." Regulatory Issue Summary 2000-18. Washington, DC: U.S. Nuclear Regulatory Commission. October 13, 2000.

———. Regulatory Guide 1.176, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance." Washington, DC: U.S. Nuclear Regulatory Commission. August 1998.

———. "Licensee Commercial-Grade Procurement and Dedication Programs." Generic Letter 91-05. Washington, DC: U.S. Nuclear Regulatory Commission. 1991.

———. "Actions to Improve Detection of Counterfeit and Fraudulently Marketed Products." Generic Letter 89-02. Washington, DC: U.S. Nuclear Regulatory Commission. 1989.

4.5.2 Records, Reports, Tests, and Inspections

Although the U.S. Department of Energy is not expected to have prepared procedures and plans for records, reports, tests and inspections at the time of the application for the license, the U.S. Department of Energy should commit to developing and implementing these plans and procedures to meet or exceed the acceptance criteria in this section.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.2.1 Areas of Review

This section reviews procedures for records, reports, tests, and inspections. Reviewers will evaluate the information required by 10 CFR 63.21(c)(23).

The staff will evaluate the following parts of U.S. Department of Energy procedures for managing records, reports, tests, and inspections using the review methods and acceptance criteria in Sections 4.5.2.2 and 4.5.2.3.

- Proposed records of receipt, handling, and disposition of radioactive waste;
- Records of construction;
- Ways to ensure use of records by future generations;
- Means to evaluate and notify the U.S. Nuclear Regulatory Commission of deficiencies found in the characteristics, design, and construction of the site and the geologic repository operations area;
- Means to support tests needed to administrate Commission regulations;
- Programs to support Commission inspections;
- Availability of records for licensed activities; and

- Provisions for Commission office space at the geologic repository operations area.

4.5.2.2 Review Methods

Review Method 1 Records and Reports

Confirm that the U.S. Department of Energy has committed to maintain records and reports required by conditions of the license or rules, regulations, and orders of the Commission.

Determine that records of receipt, handling, and disposition of radioactive waste at the geologic repository operations area will contain enough information to provide a complete history of waste movement from the shipper through all phases of storage and disposal.

Determine that records of construction of the geologic repository operations area at the Yucca Mountain site will contain enough information to adequately describe the construction and the resulting as-built configuration. Verify construction records will include the following, as a minimum:

- Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to easily identified surface features or monuments;
- A description of the geologic materials and structures encountered;
- Geologic maps and geologic cross sections;
- Locations and amounts of seepage;
- Details of construction equipment, methods, progress, and sequence of work;
- Descriptions of construction problems;
- Anomalous conditions encountered;
- Instrument locations, readings, and analyses;
- Locations and descriptions of structural support systems;
- Locations and descriptions of dewatering systems;
- Details, methods of emplacement, and location of monuments used to identify the site after permanent closure;
- Details, methods of emplacement, and location of seals used; and
- Geologic repository operations area design records such as specifications and as-built drawings.

Determine that records of construction of the geologic repository operations area and receipt, handling, and disposition of radioactive waste will be kept in a way to ensure their use by future generations in accordance with 10 CFR 63.51(a)(3).

Review Method 2 Reports of Deficiencies

Verify that the U.S. Department of Energy will establish a program to evaluate and report deviations and failures to comply with requirements of 10 CFR 50.55(e). This applies to the construction and design of the geologic repository operations area. Confirm that deficiencies to be reported are those that, should they remain uncorrected, could result in:

- Substantial safety hazard;
- Significant deviation from the conditions stated in the license, including license conditions and technical specifications; and
- Deviation from the design criteria and design bases stated in the license application.

Verify that the U.S. Department of Energy will implement a program, to report specific events and conditions, that is the same as specified in 10 CFR 72.75.

Determine that the U.S. Department of Energy will document deficiencies in a written report as specified in the applicable regulation. The deficiencies may include substantial safety hazards, significant deviations from conditions and technical specifications in the license and design criteria, and bases. Copies will be sent to the U.S. Nuclear Regulatory Commission Operations Center, Document Control Desk, U.S. Nuclear Regulatory Commission; the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission; and to the U.S. Nuclear Regulatory Commission on-site representative.

Review Method 3 Ability of the Commission to Conduct Tests

Verify either that the U.S. Department of Energy will perform tests or the Commission will be allowed to perform tests necessary to administer the regulations at 10 CFR Part 63. Tested items may include:

- Radioactive waste;
- Geologic setting and the repository structures, systems, and components;
- Radiation detection and monitoring instruments;
- Equipment and devices used for the receipt, handling, or storage of radioactive waste; and
- Aspects of the performance confirmation program.

Review Method 4 Commission Access to the Geologic Repository Operations Area and Adjacent Areas

Confirm the Commission will be allowed to inspect the premises of the geologic repository operations area and adjacent areas where the U.S. Department of Energy has rights of access. Verify that U.S. Nuclear Regulatory Commission inspectors will have immediate and unfettered access to the geologic repository operations area, equivalent to the access provided regular U.S. Department of Energy employees, after proper identification and compliance with access control measures for security, radiation protection, and personal safety.

Verify that records related to activities licensed under 10 CFR Part 63 will be available for Commission inspection on reasonable notice.

Confirm that the U.S. Department of Energy will provide adequate rent-free office space for the exclusive use of the Commission inspection team. Verify that:

- Heat, air-conditioning, light, electrical outlets, and janitorial services will be furnished;
- Office space will be conveniently located, with full access to the geologic repository operations area;
- Office space will provide visual and acoustic privacy; and
- Office space will accommodate two U.S. Nuclear Regulatory Commission full-time inspectors and other transient U.S. Nuclear Regulatory Commission personnel and will be commensurate with other office facilities at the geologic repository operations area. {A space of 23.23-square meters [250-square feet] will be acceptable.}

4.5.2.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.71, 63.72, 63.73, 63.74, and 63.75 relating to records, reports, tests, and inspections.

Acceptance Criterion 1 The U.S. Department of Energy Will Maintain Adequate Records and Reports Required by the Conditions of the License or by Rules, Regulations, and Orders of the Commission.

- The U.S. Department of Energy commits to maintain adequate records and reports that may be required by conditions of the license or rules, regulations, and orders of the Commission;
- The records of receipt, handling, and disposition of radioactive waste at the geologic repository operations area will contain enough information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal;
- The records of construction of the geologic repository operations area at the Yucca Mountain site will contain enough information to give an adequate description of the

construction and the resulting as-built configuration. The construction records will include the following, as a minimum:

— Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;

— A description of the geologic materials and structures encountered;

— Geologic maps and geologic cross sections;

— Locations and amounts of seepage;

— Details of construction equipment, methods, progress, and sequence of work;

— Descriptions of construction problems;

— Anomalous conditions encountered;

— Instrument locations, readings, and analyses;

— Locations and descriptions of structural support systems;

— Locations and descriptions of dewatering systems;

— Details, methods of emplacement, and location of monuments used to identify the site after permanent closure;

— Details, methods of emplacement, and location of seals used; and

— Facility design records such as specifications and as-built drawings.

- The U.S. Department of Energy will retain the records of construction of the geologic repository operations area and receipt, handling, and disposition of radioactive waste in a way that ensures their use by future generations in accordance with 10 CFR 63.51(a)(3).

Acceptance Criterion 2 The U.S. Department of Energy Will Submit Adequate Reports of Deficiencies Found in the Characterization, Design, and Construction of the Yucca Mountain Site.

- The U.S. Department of Energy has an adequate program to evaluate and report deviations and failures to comply with applicable requirements of 10 CFR 50.55(e). This applies to the construction and design of the geologic repository operations area. Deficiencies to be reported are those that, should they remain uncorrected, could result in:

— Substantial safety hazard;

- — Significant deviation from the conditions stated in the license, including license conditions and technical specifications; and
- — Deviation from the design criteria and design bases stated in the license.

- The U.S. Department of Energy will implement a program, to report specific events and conditions, that is the same as specified in 10 CFR 72.75; and
- The U.S. Department of Energy will document deficiencies in a written report as specified in the applicable regulation. The deficiencies may include substantial safety hazards, significant deviations from conditions and technical specifications in the license, and design criteria and bases. Copies will be sent to the U.S. Nuclear Regulatory Commission Operations Center, Document Control Desk, U.S. Nuclear Regulatory Commission; the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission; and to the U.S. Nuclear Regulatory Commission on-site representative.

Acceptance Criterion 3 The Commission Will Be Able to Conduct Tests to Administer Regulations at the Yucca Mountain Site.

- The U.S. Department of Energy will perform tests or the Commission will be allowed to perform tests deemed necessary to administer the regulations at 10 CFR Part 63. Tested items may include:
  - — Radioactive waste;
  - — Geologic setting and the repository structures, systems, and components;
  - — Radiation detection and monitoring instruments;
  - — Equipment and devices used along with the receipt, handling, or storage of radioactive waste; and
  - — Aspects of the performance confirmation program.

Acceptance Criterion 4 The Commission Is Allowed to Inspect the Premises of the Geologic Repository Operations Area and Adjacent Areas Where the U.S. Department of Energy Has Rights of Access.

- The Commission will be allowed to inspect the premises of the geologic repository operations area and adjacent areas where the U.S. Department of Energy has rights of access. U.S. Nuclear Regulatory Commission inspectors will have immediate and unfettered access to the geologic repository operations area, equivalent to the access provided regular U.S. Department of Energy employees, after proper identification and compliance with applicable access control measures for security, radiation protection, and personal safety;

- On reasonable notice, the U.S. Department of Energy will make available records pertaining to activities licensed under 10 CFR Part 63; and
- The U.S. Department of Energy will provide adequate rent-free office space for the exclusive use of the Commission inspection team.

4.5.2.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.2.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.71. The U.S. Department of Energy has provided an adequate description of the record keeping and reporting programs for receipt, handling, and disposal of radioactive waste. These programs also support requirements imposed by license conditions or other rules, records, and orders of the Commission. Therefore, the U.S. Department of Energy meets the requirements for record keeping and reporting of repository operations.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.72. The U.S. Department of Energy has provided an adequate description of the construction records and record keeping programs. Therefore, the U.S. Department of Energy meets the requirements to maintain records of construction of the geologic repository operations area.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.73. The U.S. Department of Energy has an adequate program to report deficiencies to the Commission that includes substantial safety hazards, deviations from the design criteria or design basis, and deviations from the conditions and technical specifications stated in the license. Therefore, the U.S. Department of Energy meets the requirements to report deficiencies found in the characteristics, design, and construction of the Yucca Mountain site.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.74. The U.S. Department of Energy will permit tests associated with radioactive waste; the geologic repository operations area and its structures, systems, and components; radiation detection and monitoring equipment; other equipment and devices used to receive, handle, and store radioactive waste; and the performance confirmation program. Therefore, the U.S. Department of Energy meets the requirements for tests by the U.S. Department of Energy or the U.S. Nuclear Regulatory Commission to satisfy Commission testing needs at the geologic repository operations area.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.75. The U.S. Department of Energy has provided an adequate description of the inspection program and associated U.S. Department of Energy-provided infrastructure. Therefore, the U.S. Department of Energy meets the requirements to facilitate Commission inspections at the geologic repository operations area.

4.5.2.5 References

None.

4.5.3 Training and Certification of Personnel

Although the U.S. Department of Energy is not expected to have prepared procedures and a program for training and certification of personnel at the time of the application for the license, the U.S. Department of Energy should commit to developing and implementing them to meet or exceed the acceptance criteria in this section.

4.5.3.1 U.S. Department of Energy Organizational Structure as it Pertains to Construction and Operation of Geologic Repository Operations Area

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.3.1.1 Areas of Review

This section reviews the organizational structure of the U.S. Department of Energy as it pertains to construction and operation of the geologic repository operations area. Reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(i).

The staff will evaluate the following parts of the organizational structure of the U.S. Department of Energy as it pertains to construction and operation of the geologic repository operations area, using the review methods and acceptance criteria in Sections 4.5.3.1.2 and 4.5.3.1.3.

- The U.S. Department of Energy delineation of responsibilities and decision-making authority to on-site and Headquarters staff, major contractors, sub-contractors, principal consultants, service organizations, and other affected organizations;
- Address of the office of record and the identity of the point of contact of each organizational entity; and
- Procedure for delegation of authority.

4.5.3.1.2 Review Methods

Review Method 1 Definition of Responsibilities

Determine that the U.S. Department of Energy provides an adequate delineation of responsibility and decision-making authority during construction and operation of the geologic repository operations area so responsibility for actions can be traced through the management and staff hierarchy (on-site and at Headquarters); contractors; subcontractors; consultants; service organizations; and other affected organizations.

Verify that the address of the office of record for each entity, a point of contact, and a telephone number, fax number, or e-mail address are provided in the license application.

Review Method 2 Procedure for Delegation of Authority

Determine that an adequate authority delegation procedure is in place for positions having responsibility to act in routine or emergency situations. Confirm that an identified party always has responsibility and sufficient authority to act, and the appropriate qualifications. The development and maintenance of procedures are reviewed using Section 4.5.6 of the Yucca Mountain Review Plan.

4.5.3.1.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.21(c)(22)(i).

Acceptance Criterion 1 Responsibilities Are Adequately Defined.

- The U.S. Department of Energy provides an adequate delineation of assignments of responsibility and decision-making authority during construction and operation of the geologic repository operations area, so that responsibility for actions can be traced through the management and staff hierarchy of the U.S. Department of Energy (onsite and at Headquarters); contractors; subcontractors; consultants; service organizations; and other affected organizations; and

- The address of the office of record for each entity, a point of contact, and a telephone number, fax number, or e-mail address are provided in the license application.

Acceptance Criterion 2 An Adequate Procedure for Delegation of Authority Situations Is In Place.

- There is an adequate authority delegation procedure in place for positions having responsibility to act in routine or emergency situations. An identified party will always have responsibility and sufficient authority to act, along with the appropriate qualifications.

4.5.3.1.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.3.1.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements at 10 CFR 63.21(c)(22)(i). The U.S. Department of Energy has provided an adequate organizational structure as it pertains to the construction and operation of the geologic repository operations area, including the delegation of authority and assignment of responsibilities.

4.5.3.1.5 References

None.

4.5.3.2 Key Positions Assigned Responsibility for Safety and Operations of Geologic Repository Operations Area

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

At the time of the application for the license, the U.S. Department of Energy is not expected to have identified specific individuals to fill key positions. Therefore, portions of the review defined in this section may be delayed at the time of application for the license. At the time of application to receive, possess, process, store, or dispose of high-level radioactive waste, the U.S. Department of Energy is required to have identified specific individuals to fill key positions.

4.5.3.2.1 Areas of Review

This section reviews key positions assigned responsibility for safety and operations of the geologic repository operations area. Reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(ii).

The staff will evaluate the following parts of key positions assigned responsibility for safety and operations of geologic repository operations area, using the review methods and acceptance criteria in Sections 4.5.3.2.2 and 4.5.3.2.3.

- Descriptions of the key positions assigned responsibility for safety at the geologic repository operations area, including minimum skills and experience for each position;
- Qualifications of personnel assigned to key positions important to safety at the geologic repository operations area; and

- Identification of alternates for persons in key positions.

4.5.3.2.2 Review Methods

Review Method 1 Descriptions of Key Positions

Verify that the U.S. Department of Energy provides an adequate description of each key position at the geologic repository operations area that includes the minimum skills and experience necessary to hold each position. These positions include, but are not limited to, those with responsibilities in health physics, nuclear criticality safety, training and certification, emergency planning and response, operations, maintenance, engineering, and quality assurance.

Evaluate the qualifications of the personnel assigned to geologic repository operations area key positions important to safety, based on the minimum skills and experience necessary to hold each key position.
Confirm that qualified alternates are identified, to act in the absence of individuals assigned to geologic repository operations area key positions, based on minimum skills and experience necessary to hold each key position.

4.5.3.2.3 Acceptance Criteria

The following acceptance criterion is based on meeting the requirements of 10 CFR 63.21(c)(22)(ii).

Acceptance Criterion 1 Description of Key Positions Are Adequate for Safety at the Geologic Repository Operations Area.

- The U.S. Department of Energy provides an adequate description, of each key position at the geologic repository operations area, that includes the minimum skills and experience necessary to hold each position;

- The U.S. Department of Energy provides an acceptable description of the qualifications of the personnel assigned to geologic repository operations area key positions important to safety based on the minimum skills and experience necessary to hold each key position; and

- Qualified alternates are identified to act in the absence of individuals assigned to geologic repository operations area key positions, based on minimum skills and experience necessary to hold each key position.

4.5.3.2.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.3.2.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was

reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(22)(ii). The U.S. Department of Energy provides an adequate description of the key positions assigned responsibility for safety and operations of the geologic repository operations area and the qualifications of the persons occupying these positions.

4.5.3.2.5 References

None.

4.5.3.3 Personnel Qualifications and Training Requirements

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

At the time of application for a license, the U.S. Department of Energy is not required to have a U.S. Nuclear Regulatory Commission-approved personnel training and qualification program in place. A commitment to have such an approved program before receipt of waste is sufficient for granting the license. At the time of application to receive, possess, process, store, or dispose of high-level radioactive waste, the U.S. Department of Energy is required to have a U.S. Nuclear Regulatory Commission-approved personnel training and qualification program in place.

4.5.3.3.1 Areas of Review

This section reviews personnel qualifications and training requirements. Reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(iii).

The staff will evaluate the following parts of personnel qualifications and training requirements, using the review methods and acceptance criteria in Sections 4.5.3.3.2 and 4.5.3.3.3.

- Standards used for selection, training, and certification of personnel;
- Program for general training, proficiency testing, and certification of geologic repository operations area personnel;
- Procedures for managing and maintaining the training program;
- Preoperational and operational radioactive materials training program;
- Operator and supervisor training and certification programs and requirements for structures, systems, and components important to safety;
- Operator and supervisor requalification program;

- Physical requirements for personnel operating equipment and controls that are important to safety;
- Methods for selecting and training security guards; and
- Methods used to evaluate operator testing procedures.

4.5.3.3.2 Review Methods

Review Method 1 Standards for Selection, Training, and Certification of Personnel

Confirm that any standards used for the programs for selection, training, and certification of personnel are adequate. For example, the U.S. Department of Energy may use a systems approach to training such as described at 10 CFR 55.4.

Review Method 2 Programs for General Training, Proficiency Testing, and Certification of Geologic Repository Operations Area Personnel

Additional guidance to support a review of training programs for nuclear facility operators is in Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants" (U.S. Nuclear Regulatory Commission, 1996).

Determine that the training program establishes the bases for geologic repository operations area personnel qualification and defines the qualification requirements of operators, supervisors, and other staff. The characteristics of this program should be consistent with American National Standards Institute/American Nuclear Society 3.1, Section 5.1, "General Aspects;" Section 5.3, "Training of Personnel Not Requiring U.S. Nuclear Regulatory Commission Licenses;" Section 5.4, "General Employee Training;" and Section 5.5, "Retraining." Confirm that the training program is approved by the U.S. Nuclear Regulatory Commission before receipt of waste at the geologic repository operations area.

Verify the U.S. Department of Energy has procedures to manage and maintain the training program. These procedures should include identification of the personnel responsible for developing training programs, conducting training; retraining employees (including new employee orientations); and maintaining up-to-date records on the status of trained personnel. Development and maintenance of procedures are reviewed using Section 4.5.6 of the Yucca Mountain Review Plan.

Confirm the U.S. Department of Energy specifies training requirements for each job category.

Verify the U.S. Department of Energy will train new hires on a timely schedule.

Review Method 3 Preoperational and Operational Radioactive Materials Training Program

Additional guidance to support a review of the radioactive materials training program for nuclear facility operators is in Regulatory Guide 8.29, "Instructions Concerning Risks from Occupational Radiation Exposure" (U.S. Nuclear Regulatory Commission, 1996); NUREG–0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities"

(Raddatz and Hagemayer, 1995); American Society for Testing and Materials E 1168, "Guide for Radiation Protection Training for Nuclear Facility Workers" (American Society for Testing and Materials, 1995); and Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable," paragraph C.1.c (U.S. Nuclear Regulatory Commission, 1984).

Verify the U.S. Department of Energy will implement the radioactive materials training program before conduct of operations involving radioactive material (i.e., preoperational training). Confirm that the U.S. Department of Energy commits to substantial completion of operator training and certification before receipt of radioactive material.

Determine that operator radiation safety training includes such topics as the nature and sources of radiation, methods for controlling contamination, interactions of radiation with matter, biological effects of radiation, use of monitoring equipment, as low as is reasonably achievable concepts, facility access and visitor controls, decontamination procedures, use of personal monitoring and protective equipment, regulatory and administrative exposure and contamination limits, site-specific hazards, and principles of criticality hazards control.

Determine that individuals who, in the courses of their employment, are likely to receive yearly occupational doses in excess of 100 mrem (1 mSv), are instructed in the health protection issues associated with exposure to radioactive materials or radiation, in accordance with 10 CFR 19.12.
Determine that individuals involved are informed of estimated doses and associated risks before any special exposures occur, in accordance with 10 CFR 20.1206.

Verify the U.S. Department of Energy will provide training in radiation protection and facility exposure control procedures for all personnel whose duties require: (i) working with radioactive materials; (ii) entering radiation areas; and (iii) directing the activities of others who work with radioactive materials or enter radiation areas.

Determine that facility personnel whose duties do not require entering radiation areas or working with radioactive materials receive sufficient instructions in radiation protection and facility rules and regulations to understand why they should not enter such areas.

Review Method 4 Operation of Equipment and Controls Important to Safety

Confirm that operators of equipment and controls identified as important to safety are either trained and certified in the operations or will be under the direct visual supervision of an individual who is trained and certified.

Determine that supervisory personnel who personally direct the operation of equipment and controls that are important to safety are trained and certified in such operations.

Verify that operational training includes topics such as installation, design, and operation of structures, systems, and components; decontamination procedures; and emergency procedures.

Review Method 5 Operator and Supervisor Requalification Program for Structures, Systems, and Components Important to Safety

Determine that the U.S. Department of Energy defines an adequate program for requalification of operators, supervisors, and other staff.

Verify that the frequency of retraining and the nature and duration of training and testing records have been specified. Confirm that retraining will be periodic and conducted at least every 2 years.

Review Method 6 Physical Condition and General Health of Personnel

Additional guidance to support this review is in Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants" (U.S. Nuclear Regulatory Commission, 1998).

Confirm that any condition that might impair judgment or motor coordination, resulting in the inability of an operator to perform activities that are important to safety, has been considered, in selecting personnel to operate such equipment and controls. Such impaired judgment or motor coordination conditions need not categorically disqualify a person from operating equipment and controls important to safety provided appropriate provisions are made to accommodate any such condition.

Review Method 7 Methods for Selecting, Training, and Qualifying Security Guards

Verify that the process by which security guards (including watchmen, armed response persons, etc.) will be selected and qualified is described as required by 10 CFR 73.55(b)(4)(ii). This information will be submitted as part of the physical security plan and reviewed using Section 3.3 of the Yucca Mountain Review Plan. Confirm that selection and training criteria will conform to the general criteria for security personnel contained in 10 CFR Part 73, Appendix B. Regulatory Guide 5.20, "Training, Equipping, and Qualifying of Guards and Watchmen" (U.S. Nuclear Regulatory Commission, 1974) provides additional guidance.

Review Method 8 Methods for Evaluating Operator Testing Procedures

Verify that the methods for evaluating the effectiveness of the training program are described and that program effectiveness is determined by comparison to established objectives and criteria.

4.5.3.3.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.151, 63.152, and 63.153.

Acceptance Criterion 1 Adequate Standards Are Used for Selection, Training, and Certification of Personnel.

- Any standards used for the programs for selection, training, and certification of personnel are adequate.

Acceptance Criterion 2 Programs for General Training, Proficiency Testing, and Certification of Geologic Repository Operations Area Personnel Are Acceptable.

- The training program adequately establishes the bases for geologic repository operations area personnel qualification and defines the qualification requirements of operators, supervisors, and other staff. The characteristics of this program are consistent with American National Standards Institute/American Nuclear Society 3.1, Section 5.1 "General Aspects;" Section 5.3, "Training of Personnel Not Requiring U.S. Nuclear Regulatory Commission Licenses;" Section 5.4, "General Employee Training;" and Section 5.5, "Retraining." The training program will be approved by the U.S. Nuclear Regulatory Commission before receipt of waste at the geologic repository operations area.

- The U.S. Department of Energy establishes adequate procedures for managing and maintaining the training program. These procedures include identification of the personnel responsible for developing training programs; conducting training; retraining employees (including new employee orientations); and maintaining up-to-date records on the status of trained personnel.

- The U.S. Department of Energy specifies training requirements for each job category.

- The U.S. Department of Energy will train new hires on a timely schedule.

Acceptance Criterion 3 an Acceptable Preoperational and Operational Radioactive Materials Training Program Is Provided.

- The U.S. Department of Energy will implement the radioactive materials training program before conduct of operations involving radioactive material (i.e., preoperational training). The U.S. Department of Energy commits to substantial completion of such operator training and certification before receipt of the radioactive material;

- The operator radiation safety training includes such topics as the nature and sources of radiation, methods for controlling contamination, interactions of radiation with matter, biological effects of radiation, use of monitoring equipment, as low as is reasonably achievable concepts, facility access and visitor controls, decontamination procedures, use of personal monitoring and protective equipment, regulatory and administrative exposure and contamination limits, site-specific hazards, and principles of criticality hazards control;

- The U.S. Department of Energy will instruct all individuals who, in the course of their employment, are likely to receive yearly occupational doses in excess of 100 mrem (1 mSv), in the health protection issues associated with exposure to radioactive materials or radiation per 10 CFR 19.12;

- Before any special exposures occur, the U.S. Department of Energy will inform the individuals involved of estimated doses and associated risks, in accordance with 10 CFR 20.1206;

- The U.S. Department of Energy will provide adequate training in radiation protection and facility exposure control procedures for personnel whose duties require: (i) working with radioactive materials, (ii) entering radiation areas, and (iii) directing the activities of others who work with radioactive materials or enter radiation areas; and

- The facility personnel whose duties do not require entering radiation areas or working with radioactive materials will receive sufficient instructions in radiation protection and facility rules and regulations to understand why they should not enter such areas.

Acceptance Criterion 4 Operation of Equipment and Controls Identified as Important to Safety Is Limited to Trained and Certified Personnel or Is under the Direct Visual Supervision of an Individual with Training and Certification in Their Operation.

- Operators of all equipment and controls identified as important to safety are either trained and certified in the operations or will be under the direct visual supervision of an individual who is trained and certified in the operations;

- Supervisory personnel who personally direct the operation of equipment and controls important to safety are trained and certified in such operations; and

- Operational training includes topics such as installation, design, and operation of structures, systems, and components; decontamination procedures; and emergency procedures.

Acceptance Criterion 5 an Acceptable Operator and Supervisor Requalification Program for Structures, Systems, and Components Important to Safety Is provided.

- The U.S. Department of Energy defines an adequate program for requalification of operators, supervisors, and other staff; and

- Frequency of retraining and the nature and duration of training and testing records are specified. Retraining will be periodic and conducted at least every 2 years.

Acceptance Criterion 6 The Physical Condition and the General Health of Personnel Certified for the Operation of Equipment and Controls Important to Safety Are Such That Operational Errors That Could Endanger Other In-plant Personnel or the Public Health and Safety Will Not Occur.

- Conditions that might impair judgment or motor coordination resulting in the inability of an operator to perform activities that are important to safety are adequately considered in the selection of personnel to operate such equipment and controls.

Acceptance Criterion 7 Methods for Selecting, Training, and Qualifying Security Guards Are acceptable.

- The process by which security guards (including watchmen, armed response persons, etc.) will be selected and qualified is adequate as required by 10 CFR 73.55(b)(4)(ii). Selection and training criteria conform to the general criteria for security personnel contained in 10 CFR Part 73, Appendix B.

Acceptance Criterion 8 Methods Used to Evaluate Operator Testing Procedures Are acceptable.

- Methods for evaluating the effectiveness of the training program are described and program effectiveness is determined by comparison to established objectives and criteria.

4.5.3.3.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.3.3.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.151. Operation of systems and components important to safety will be performed only by trained and certified personnel or by personnel under the direct supervision of an individual with training and certification in such operation. Supervisory personnel will also be certified in the operations they supervise.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.152. The U.S. Department of Energy has established an adequate program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.153. The U.S. Department of Energy has established an adequate program for evaluating the physical condition and general health of personnel certified for operations that are important to safety. Conditions that might cause impaired judgment or motor coordination are adequately considered in the selection of personnel for activities important to safety.

4.5.3.3.5 References

American National Standards Institute/American Nuclear Society. "Selection, Qualification and Training of Personnel for Nuclear Power Plants." American National Standards Institute/American Nuclear Society 3.1. November 1981.

American Society of Testing and Materials. "Guide for Radiation Protection Training for Nuclear Facility Workers." E 1168. 1995

U.S. Nuclear Regulatory Commission. Regulatory Guide 1.134, "Medical Evaluation of Licensed Personnel for Nuclear Power Plants." Revision 3. Washington, DC: U.S. Nuclear Regulatory Commission. March 1998.

———. Regulatory Guide 8.29, "Instructions Concerning Risks from Occupational Radiation Exposure." Revision 1. Washington, DC: U.S. Nuclear Regulatory Commission. February 1996.

———. Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants." Revision 3. Washington, DC: U.S. Nuclear Regulatory Commission. November 1996.

———. Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable (ALARA)." Draft OP–618–4. Second Proposed Revision 4. Washington, DC: U.S. Nuclear Regulatory Commission. May 1984.

———. Regulatory Guide 5.20, "Training, Equipping, and Qualifying of Guards and Watchmen." Washington, DC: U.S. Nuclear Regulatory Commission. January 1974.
Raddatz, C.T. and D. Hagemayer. NUREG–0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities." Vol. 15. Washington, DC: U.S. Nuclear Regulatory Commission. January 1995.

4.5.4 Expert Elicitation

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.4.1 Areas of Review

This section reviews expert elicitation. Reviewers will evaluate the information required by 10 CFR 63.21(c)(19).

The U.S. Department of Energy can use expert elicitation when data are hard to obtain through normal means or within the time frame required. Generally, the U.S. Department of Energy should not use expert elicitation in place of normal data collection unless sufficient justification exists.

The staff will evaluate the following parts of expert elicitation using the review methods and acceptance criteria in Sections 4.5.4.2 and 4.5.4.3.

- Techniques to conduct expert elicitations;
- Extent to which guidance in NUREG–1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program" (Kotra, et al., 1996) was used to perform expert elicitations; and
- Rationales for any discrepancies between staff guidance in NUREG–1563 (Kotra, et al., 1996) and the U.S. Department of Energy conduct of expert elicitations.

4.5.4.2 Review Methods

Review Method 1 Use of NUREG–1563 (Kotra, et al., 1996) or Equivalent Procedures

Verify that expert elicitations either followed the nine-step procedure suggested in NUREG–1563 (Kotra, et al., 1996) or used equivalent procedures. Specifically:

- Objectives were defined;
- Criteria used to select normative experts and generalists included experts who:
  - Possessed the required knowledge and expertise;
  - Showed ability to apply their knowledge and expertise;
  - In aggregate, represented a broad diversity of independent opinion and approaches to address the topic(s);
  - Were willing to be identified publicly with their judgments; and
  - Were willing to publicly disclose potential conflicts of interest.
- Participants refined the issues and decomposed the problem to clearly and precisely specify more focused and simpler subissues;
- Basic information was adequately assembled and was circulated uniformly to the experts;
- The experts received preelicitation training that included:
  - Familiarization with the subject matter;
  - Familiarization with the elicitation process;
  - Education in uncertainty and probability encoding and the expression of expert judgment, using subjective probability;
  - Practice in formally stating judgments and clearly identifying their associated assumptions and rationales, and

- — Identification of biases that could unduly influence judgments.

- The conduct of expert elicitations included the following:
  - — An appropriate setting;
  - — The presence of generalists and normative experts;
  - — A summary of issues, definitions, and assumptions;
  - — Uniform questioning of subject-matter experts; and
  - — Documentation of responses.
- Each subject-matter expert got timely feedback from the elicitation team. The rationale for any revisions to elicited judgments was thoroughly documented;
- If expert judgments were combined, differing views were treated appropriately as suggested in staff guidance (Kotra, et al., 1996). For combined judgments, the reviewer should confirm that:
  - — The U.S. Department of Energy provided a rationale for the technique used to combine differing views;
  - — The U.S. Department of Energy provided enough documentation to trace the impact of an individual expert's judgment on the consolidated judgment; and
  - — The U.S. Department of Energy discussed effects that the disparate views have had on geologic repository operations area design or repository performance. The U.S. Department of Energy should present significantly different views as individual outputs of the elicitations so that such views may be directly used in the technical assessments or used to condition the extremes in sensitivity analyses.
- The U.S. Department of Energy properly documented the expert elicitation, including what was done, why it was done, and who did it.

Verify that the U.S. Department of Energy provided an adequate explanation for any variance from NUREG–1563 (Kotra, et al., 1996) guidance.

4.5.4.3 Acceptance Criteria

The following acceptance criterion is based on meeting the requirements of 10 CFR 63.21(c)(19).

Acceptance Criterion 1 The U.S. Department of Energy used NUREG–1563 (Kotra, et al., 1996) or Equivalent Procedures.

- Expert elicitations follow the nine-step procedure in NUREG–1563 (Kotra, et al., 1996). Specifically:
  - Objectives are defined;
  - Criteria used to select normative experts and generalists include:
    - Experts possess the required knowledge and expertise;
    - Experts demonstrate ability to apply their knowledge and expertise;
    - Experts, as a group, represent a broad diversity of independent opinion and approaches to address the topic(s);
    - Experts are willing to be identified publicly with their judgments; and
    - Experts are willing to publicly disclose potential conflicts of interest.
  - Participants refined the issues and broke down the problem to clearly specify more focused and simpler subissues;
  - The U.S. Department of Energy adequately assembled and uniformly distributed the basic information to the experts;
  - The experts received preelicitation training that included:
    - Familiarization with the subject matter;
    - Familiarization with the elicitation process;
    - Education in uncertainty and probability encoding and how to express expert judgment, using subjective probability;
    - Practice in formally articulating judgments and explicitly identifying their associated assumptions and rationales, and
    - Identification of biases that could unduly affect judgments.
  - The conduct of expert elicitations includes the following:
    - An appropriate setting;
    - The presence of generalists and normative experts;
    - A summary of issues, definitions, and assumptions;

  - Uniform questioning of subject-matter experts; and
  - Documentation of responses.
- Each subject-matter expert received timely feedback from the elicitation team. The rationale for revising elicited judgments is thoroughly documented;
- If expert judgments are combined, differing views are treated as suggested in staff guidance (Kotra, et al., 1996). Specifically:
  - The U.S. Department of Energy provided a rationale for the technique used to combine differing views: the U.S. Department of Energy included enough documentation to trace the impact of an individual expert's judgment on the combined judgment; and
  - The U.S. Department of Energy discussed the effects of differing views on facility design or repository performance. The U.S. Department of Energy presented significantly different views as individual outputs of the elicitations so that such views are directly used in the technical assessments or used to condition the extremes in sensitivity analyses.
- The U.S. Department of Energy properly documented the expert elicitation including what is done, why it is done, and who did it.

• The U.S. Department of Energy adequately explained any variance from the guidance and techniques in NUREG–1563 (Kotra, et al., 1996).

4.5.4.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.4.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(19). The U.S. Department of Energy met the requirements for the contents of the license application. In particular, the Safety Analysis Report explains how and the extent to which expert elicitation was used to characterize: (i) features, events, and processes; (ii) response of geomechanical, hydrogeological, and geochemical systems to thermal loadings; (iii) performance of the geologic repository after permanent closure; (iv) ability of the repository to limit radiological exposures in the event of limited human intrusion into the engineered barrier system; and (v) any other use of expert elicitation to evaluate performance.

4.5.4.5 References

Kotra, J.B., et al. NUREG–1563, "Branch Technical Position on the Use Of Expert Elicitation in the High-Level Radioactive Waste Program." Washington, DC: U.S. Nuclear Regulatory Commission. 1996.

4.5.5 Plans for Startup Activities and Testing

Although the U.S. Department of Energy is not expected to have prepared plans for startup activities and testing at the time of the application for the license, the U.S. Department of Energy should commit to developing and implementing these plans to meet or exceed the acceptance criteria in this section.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.5.1 Areas of Review

This section reviews plans for startup activities and testing. The reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(iv).

The staff will evaluate the following parts of plans for startup activities and testing, using the review methods and acceptance criteria in Sections 4.5.5.2 and 4.5.5.3.

A review of plans for pre-startup testing and startup activities to be used to evaluate the readiness to receive, possess, process, store, and dispose of high-level radioactive waste should include assessment of planned tests and operations for the structures, systems, and components of the geologic repository operations area. The U.S. Department of Energy is not required to have conducted testing and startup activities or to have detailed procedures in place at the time of application for the license. A commitment to have an approved testing and startup activities program for structures, systems, and components important to safety in place before receipt of waste is sufficient for granting the license. The U.S. Department of Energy is required to have either conducted testing and startup activities or to have detailed procedures in place for such testing and startup activities at the time of application to receive, possess, process, store, or dispose of high-level radioactive waste.

- Systems used to develop, review, approve, and execute individual test procedures to evaluate, document, and approve test results;
- Pre-startup test program and objectives;
- Type and source of design performance information;
- Format and content of test procedures and individual test descriptions;
- Pre-startup test program compatibility with regulatory guides (if any);
- Use of prior experience in developing pre-startup tests;

- Assessment of whether initial operating procedures will endanger worker and public health and safety;
- Planned user testing for operating, emergency, and surveillance procedures;
- Schedules for the testing program relative to the first fuel receipt, repackaging, storage, and disposal, including any overlaps in component and system testing;
- Plans for initial startup; and
- Evaluation of safety of aggregate of facility functions and associated activities.

4.5.5.2 Review Methods

Review Method 1 Systems Used to Develop, Review, and Approve Pre-startup Test Procedures

Determine, based on a summary description, that systems used to develop, review, and approve individual test procedures for each geologic repository operations area component important to safety are acceptable. The summary description should include:

- Responsibilities and functions of organizational units for development, review, and approval of test procedures;
- Qualification requirements for people assigned responsibilities for test procedure development; and
- A description of the general steps for developing, reviewing, approving, and executing tests and for documenting test results.

Review Method 2 Summaries of Pre-startup Test Programs and Objectives

Verify, based on a summary, that test programs and objectives for each geologic repository operations area structure, system, and component important to safety are acceptable. Evaluate the adequacy of the: (i) type of tests to be performed; (ii) expected response to the tests; (iii) acceptable margin of difference from the expected response; (iv) method of test validation; and (v) appropriateness of proposed corrective action for unexpected or unacceptable test results.

Review Method 3 Incorporation of Design Performance Information in Pre-startup Testing Plans

Confirm that design information and data from preconstruction performance assessments have been adequately considered in developing pre-startup testing plans. Specifically, functions or parameters of structures, systems, and components important to safety should be tested to the extent feasible.

Review Method 4 Format and Content of Test Procedures

Evaluate the format and content of test procedures for geologic repository operations area structures, systems, and components important to safety and determine if they are acceptable.

Review Method 5 Test Descriptions

Verify test descriptions are provided for structures, systems, and components that: (i) will be used to establish conformance with safety limits or limiting conditions for operation in the geologic repository operations area technical specifications (review technical specifications using Section 4.5.10 of the Yucca Mountain Review Plan); (ii) are classified as engineered safety features or will be used to support or ensure the operations of engineered safety features within design limits; (iii) are assumed to function or for which credit is taken in event sequence analyses in the preclosure safety analysis; or (iv) will be used to process, store, control, measure, or limit the release of radioactive materials. Review the conduct of the preclosure safety analysis using Section 4.1.1 of the Yucca Mountain Review Plan.

Determine that test descriptions contain objectives for each test and a summary of prerequisites, test method(s), and acceptance criteria that will ensure the functional adequacy of structures, systems, and components important to safety and that design features will be demonstrated by the tests.

Verify that test descriptions are consistent with the design requirements. Coordinate with the reviewer of Section 4.1.1.7 ("Design of Structures, Systems, and Components Important to Safety and Safety Controls") of the Yucca Mountain Review Plan to confirm the design requirements.

Confirm that test descriptions contain sufficient information to justify the test method used, particularly if the test method for a structure, system, or component important to safety will not subject the item or system to the range of design operating conditions.

Review Method 6 Compatibility of Test Programs with Applicable Regulatory Guidance

Verify that pre-startup test programs for geologic repository operations area structures, systems, and components are consistent with applicable guidance in Regulatory Guide 3.48 (U.S. Nuclear Regulatory Commission, 1989). Determine that, if the U.S. Department of Energy takes positions inconsistent with guidance, it provides suitable justification for the inconsistencies. For specific components, check for regulatory guidance that may be pertinent.

Review Method 7 Use of Experience from Similar Facilities

Confirm the license application provides an assessment of testing results and operational lessons learned from similar facilities. This assessment should be used to develop testing procedures of adequate scope.

Review Method 8 Protection of Worker and Public

Verify that procedures which will guide initial operation of geologic repository operations area structures, systems, and components important to safety, and any prerequisites and precautionary measures associated with these procedures, are acceptable. Make this determination based on evaluations of procedures using system diagrams and reviewer experience. Initial operating procedures should include the following:

- Purpose and role of test in evaluating performance of structure, system, or component function;
- Prerequisites for normal readiness testing, such as:
  - Calibrations should be performed or checked;
  - Instrumentation should be on hand for necessary performance evaluations;
  - Tools and special equipment should be on hand to facilitate evaluations;
  - Notifications with lead times necessary to eliminate unnecessary downtime during performance evaluations;
  - Checking/setting equipment controls (e.g., physical travel limits for overhead crane);
  - Checks of radiation, environmental, or other monitors for acceptable range;
  - Identification of subject(s) of tests (e.g., fuel rods to be loaded, cask to be retrieved); and
  - Logs and forms to be completed.
- Description of preceding function and relationship to function;
- Description of series of operations, including expected results, projected times, projected instrument and gauge readings, controls to be used in performance (e.g., torque, time at pressure), and threshold limits requiring contingency actions (such as hold, initiating a contingency sequence, notification);
- Requirements for records, including forms to be completed during operation (if any);
- Disposition of records and identification of parties to be notified on successful or unsuccessful completion (may be different parties) of function evaluation; and
- Identification of following function and relation to function being evaluated.

Review Method 9 Schedules

Verify that the U.S. Department of Energy provides schedules for conducting each phase of the testing program and that these schedules are compatible with schedules for high-level radioactive waste receipt, repackaging, storage, and disposal, including any schedule overlaps. Pay particular attention to start-up-sequence timing and the time available between approval of test procedures and their intended use.

Review Method 10 Testing and Evaluating Functional Adequacy of Structures, Systems, and Components

Verify that new structures, systems, and components important to safety, or untested configurations of such components, will be tested and evaluated before receipt of radioactive waste and that their performance is acceptable. Review schedules and programs for unresolved safety issues, using Section 4.3.2 of the Yucca Mountain Review Plan.

Review Method 11 Plans for Initial Startup of Geologic Repository Operations Area Structures, Systems, and Components and Integrated Operation of the Geologic Repository Operations Area

Verify that the U.S. Department of Energy has acceptable plans for a dry run (cold test) of each operation involving radioactive material to be received, handled, stored, or disposed. Confirm that the U.S. Department of Energy will use the results of these to make necessary changes to equipment and procedures to ensure public and worker health and safety.

Determine that the U.S. Department of Energy has acceptable plans to conduct routine full-load tests of equipment that is to carry high-level radioactive waste containers, to ensure public and worker health and safety.

For as low as is reasonably achievable considerations, verify that as many operating startup actions as feasible will be performed during preoperational testing before sources of radiation exposure are present.

Confirm that plans for operating start-up of the geologic repository operations area structures, systems, and components and subsequent integrated operation of the entire facility are acceptable. The operating start-up plan should include, but not be limited to, the following elements:

- Tests and confirmations of procedures and exposure times involving actual radioactive sources (e.g., radiation monitoring, repackaging operations);
- Direct radiation monitoring of casks and shielding for radiation dose rates, streaming, and surface hot-spots;
- Verification of effectiveness of heat removal procedures;

- Tests of structures, systems, and components important to safety as identified by the preclosure safety analysis (review identification of structures, systems, and components important to safety using Section 4.1.1.6 of the Yucca Mountain Review Plan); and

- Documentation of results and test evaluations.

Review Method 12 Overall Geologic Repository Operations Area Safety Supported by Startup and Testing Plans

Confirm that the overall evaluation of geologic repository operations area safety for workers and the public is supported by the aggregate effects of planned start-up activities and associated testing.

4.5.5.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.21(c)(22)(iv).

Acceptance Criterion 1 Systems Used to Develop, Review, and Approve Individual Pre-Startup Test Procedures Are Acceptable.

- Based on a summary description, the systems used to develop, review, and approve individual test procedures for each geologic repository operations area component important to safety are acceptable. The summary adequately defines:

  — Responsibilities and functions of organizational units for development, review, and approval of test procedures;

  — Qualification requirements for people assigned responsibilities for test procedure development; and

  — General steps to be followed when developing, reviewing, approving, and executing tests and for documenting test results.

Acceptance Criterion 2 Summaries of Pre-Startup Test Programs and Objectives Are adequate.

- Based on a summary description, the test programs and objectives for each geologic repository operations area structure, system, or component important to safety are acceptable. The summary adequately presents: (i) type of tests to be performed; (ii) expected response to the tests; (iii) acceptable margin of difference from the expected response; (iv) method of test validation; and (v) appropriateness of proposed corrective action for unexpected or unacceptable test results.

Acceptance Criterion 3 Design Performance Information Is Adequately Incorporated in Pre-Startup Testing Plans.

- The design information and data from preconstruction performance assessments are adequately considered in the development of pre-startup testing plans. Specifically, functions or parameters of structures, systems, and components that are important to safety are tested to the extent feasible; and

Acceptance Criterion 4 The Format and Content of Test Procedures Are Acceptable.

- The format and content of the test procedures for geologic repository operations area structures, systems, and components important to safety are acceptable.

Acceptance Criterion 5 Test Descriptions Are Acceptable.

- Adequate test descriptions are provided for those structures, systems, and components that: (i) will be used to establish conformance with safety limits or limiting conditions for operation in the geologic repository operations area technical specifications; (ii) are classified as engineered safety features or will be used to support or ensure the operations of engineered safety features within design limits; (iii) are assumed to function or for which credit is taken in event sequence analyses in the preclosure safety analysis; or (iv) will be used to process, store, control, measure, or limit the release of radioactive materials;

- The test descriptions contain acceptable objectives for each test, and also a summary of prerequisites, test method(s), and specific acceptance criteria, for each test, that will ensure that both the functional adequacy of structures, systems, and components important to safety and design features are demonstrated by the tests;

- The test descriptions are consistent with the design requirements; and

- The test descriptions contain sufficient information to justify the test method used, particularly if the test method for a given structure, system, and component important to safety will not subject the item or system under test to the range of design operating conditions.

Acceptance Criterion 6 Test Programs Are Compatible with Applicable Regulatory Guidance.

- The pre-startup test programs for geologic repository operations area structures, systems, and components are consistent with applicable regulatory guidance in Regulatory Guide 3.48 (U.S. Nuclear Regulatory Commission, 1989). If the U.S. Department of Energy takes positions inconsistent with guidance, a suitable justification for the inconsistencies is provided.

Acceptance Criterion 7 Adequate Use Is Made of Experience from Similar Facilities.

- The license application provides an assessment of testing results and operational lessons learned from similar facilities, and this assessment is used to develop testing procedures of adequate scope.

Acceptance Criterion 8 Initial Operating Procedures Will Protect Workers and the Public.

- Procedures that will guide initial operation of the geologic repository operations area structures, systems, and components important to safety and any prerequisites and precautionary measures associated with these procedures are acceptable.

Acceptance Criterion 9 Schedules for Each Phase of the Testing Program Are Acceptable.

- The U.S. Department of Energy provides schedules for conducting each phase of the testing program, and these schedules are compatible with schedules for high-level radioactive waste receipt, repackaging, storage, and disposal, including any schedule overlaps.

Acceptance Criterion 10 Structures, Systems, and Components Important to Safety Whose Functional Adequacy Has Not Been Demonstrated by Prior Use or Otherwise Validated Are Tested and Evaluated Before the Receipt of Radioactive Waste.

- The new structures, systems, and components important to safety, or untested configurations of such components, are tested and evaluated before receipt of radioactive waste, and their performance is acceptable.

Acceptance Criterion 11 Plans for Initial Start up of Geologic Repository Operations Area Structures, Systems, and Components Important to Safety and Integrated Operation of the Geologic Repository Operations Area Are Acceptable.

- The U.S. Department of Energy has acceptable plans to perform a dry run (cold test) of each operation involving radioactive material to be received, handled, stored, or disposed. The results of these tests will be used to make necessary changes to equipment and procedures to ensure public and worker health and safety;

- The U.S. Department of Energy has acceptable plans to conduct routine full-load tests of any equipment that is to carry high-level radioactive waste containers, to ensure public and worker health and safety;

- For as low as is reasonably achievable considerations, as many of the operating startup actions as feasible are performed during preoperational testing, before sources of radiation exposure are present; and

- Plans for operating startup of the geologic repository operations area structures, systems, and components and subsequent integrated operation of the entire facility are acceptable.

Acceptance Criterion 12 Overall Geologic Repository Operations Area Safety Is Adequately Supported by Facility Startup and Testing Plans.

- The overall evaluation of safety of the facility for workers and the public is supported by the aggregate of planned startup activities and associated testing.

4.5.5.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.5.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(22)(iv). Requirements for the content of the license application have been met. In particular, the plans for testing and startup of structures, systems, and components important to safety of the geologic repository operations area to receive, possess, store, process, and dispose of spent nuclear fuel and high-level radioactive waste are acceptable.

4.5.5.5 Reference

U.S. Nuclear Regulatory Commission. Regulatory Guide 3.48, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation or Monitored Retrievable Storage Installation (Dry Storage)." Revision 1. Washington, DC: U.S. Nuclear Regulatory Commission, Office of Standards Development. August 1989.

4.5.6 Plans for Conduct of Normal Activities Including Maintenance, Surveillance, and Periodic Testing

Although the U.S. Department of Energy is not expected to have prepared procedures and plans for conduct of normal activities including maintenance, surveillance, and periodic testing at the time of the application for the license, the U.S. Department of Energy should commit to developing and implementing these procedures and plans to meet or exceed the acceptance criteria in this section.

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.6.1 Areas of Review

This section reviews plans for conduct of normal activities, including maintenance, surveillance, and periodic testing. Reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(v).

The staff will evaluate the following parts of plans for conduct of normal activities, including maintenance, surveillance, and periodic testing, using the review methods and acceptance criteria in Sections 4.5.6.2 and 4.5.6.3.

Normal operations at the geologic repository operations area may include, among other operations: (i) acceptance of waste; (ii) storage of waste before repackaging; (iii) repackaging of waste; (iv) removal/reuse of transport containers; (v) storage of repackaged waste before disposal; and (vi) disposal of waste. Each activity important to safety should have written procedures in place for normal operations, maintenance, surveillance, and periodic testing.

- Procedures and plans;
- Descriptions of activities;
- Administrative procedures for review, change, and approval; and
- Independence of review of procedure development by persons outside the operating management function.

4.5.6.2 Review Methods

Review Method 1 Plans and Procedures for Normal Operations

Verify that the U.S. Department of Energy has provided adequate written procedures for normal operation of structures, systems, and components important to safety, as identified in the preclosure safety analysis and reviewed in Section 4.1 of the Yucca Mountain Review Plan, to include routine and contingency operations and any procedural requirements necessitated by technical specifications. Normal operating procedures should include the following:

- Purpose of the procedure;
- Responsibilities, training, and qualifications of personnel;
- Prerequisites such as:
  - Calibrations to be performed or checked;
  - Instrumentation;
  - Tools and special equipment;
  - Notifications to other operations personnel with associated lead times;
  - Checks or settings for equipment or controls (e.g., physical travel limits for overhead crane);
  - Operational checks of radiation, environmental, or other monitors; and

— Logs and records associated with the test.

- Description of the series of operations, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used (e.g., torque, time at pressure); and threshold limits requiring contingency actions (such as hold points, corrective action sequences, and notifications);

- Disposition of records and identification of parties to be notified on completion of the operation; and

- Identification of any required follow-on actions.

Verify that administrative procedures for the review, change, and approval of normal operating procedures for structures, systems, and components important to safety are adequate and that these procedures have adequate management controls.

Confirm that appropriate industry or U.S. Nuclear Regulatory Commission standards are used as the basis for the operating procedures for structures, systems, and components important to safety.

Verify that normal operations of structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews should be specified, in both number and technical disciplines, and should collectively have the experience and competence required to review problems in the following areas:

- Nuclear engineering;

- Chemistry and radiochemistry;

- Metallurgy;

- Nondestructive testing;

- Instrumentation and control;

- Radiological safety;

- Mechanical, civil, and electrical engineering;

- Administrative controls and quality assurance practices; and

- Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

An individual may possess competence in more than one speciality area.

Review Method 2 Plans and Procedures for Maintenance

Verify that written procedures are provided for maintenance of structures, systems, and components important to safety and include the following:

- Purpose of the maintenance procedure;
- Responsibilities, training, and qualifications of personnel;
- Prerequisites such as:
  - Calibrations to be performed or checked;
  - Instrumentation;
  - Tools and special equipment;
  - Notifications to other operations or maintenance personnel with associated lead times;
  - Checks or settings for equipment or controls;
  - Operational checks of radiation, environmental, or other monitors; and
  - Logs and records associated with the maintenance.
- Description of the maintenance activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used, and threshold limits requiring contingency actions; and
- Disposition of records and identification of parties to be notified on completion.

Verify that administrative procedures for the review, change, and approval of maintenance procedures for structures, systems, and components important to safety are adequate and that these procedures have adequate management controls.

Confirm that appropriate industry or U.S. Nuclear Regulatory Commission standards are used as the basis for the maintenance procedures for structures, systems, and components important to safety.

Verify that maintenance activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews should be specified, in both number and technical disciplines, and should collectively have the experience and competence required to review problems in the following areas:

- Nuclear engineering;

- Chemistry and radiochemistry;
- Metallurgy;
- Nondestructive testing;
- Instrumentation and control;
- Radiological safety;
- Mechanical, civil, and electrical engineering;
- Administrative controls and quality assurance practices; and
- Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

An individual may possess competence in more than one speciality area.

Review Method 3 Plans and Procedures for Surveillance

Verify that written procedures are provided to routinely evaluate, through surveillance, the proper functioning of structures, systems, and components important to safety and include the following:

- Purpose of the routine surveillance;
- Responsibilities, training, and qualifications of personnel;
- Prerequisites such as:
  - Calibrations to be performed or checked;
  - Instrumentation;
  - Tools and special equipment;
  - Notifications to operations personnel with associated lead times;
  - Checks or settings for equipment or controls;
  - Operational checks of radiation, environmental, or other monitors; and
  - Logs or records associated with the surveillance.
- Description of the surveillance activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be assessed; and

- Disposition of records and identification of parties to be notified on completion.

Verify that if structures, systems, and components important to safety are found operating outside the tolerance for normal operation during surveillance, adequate procedures are in place to assure they will be restored to normal conditions in a reasonably short time so worker and public health and safety are protected.

Verify that administrative procedures for the review, change, and approval of surveillance procedures for structures, systems, and components important to safety are adequate and that these procedures have adequate management controls.

Confirm that appropriate industry or U.S. Nuclear Regulatory Commission standards, if applicable, are used as the basis for the surveillance procedures for structures, systems, and components important to safety.

Verify that surveillance activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews should be specified, in both number and technical disciplines, and should collectively have the experience and competence required to review problems in the following areas:

- Nuclear engineering;
- Chemistry and radiochemistry;
- Metallurgy;
- Nondestructive testing;
- Instrumentation and control;
- Radiological safety;
- Mechanical, civil, and electrical engineering;
- Administrative controls and quality assurance practices; and
- Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

An individual may possess competence in more than one speciality area.

Review Method 4 Plans and Procedures for Routine Periodic Testing

Verify that written procedures for periodic testing designed to ensure that structures, systems, and components important to safety will perform their design function during normal operations are in place. This testing should be accomplished on a defined schedule and at a frequency

sufficient to ensure protection of worker and public safety. The reviewer should verify that procedures for periodic testing of structures, systems, and components important to safety include the following:

- Purpose of testing;
- Responsibilities, training, and qualifications of personnel;
- Prerequisites such as:
  - Calibrations to be performed or checked;
  - Instrumentation;
  - Tools and special equipment;
  - Notifications to other operations or testing personnel with associated lead times;
  - Checks or settings for equipment or controls;
  - Operational checks of radiation, environmental, or other monitors; and
  - Logs or records associated with the testing.
- Description of the testing activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used, and threshold limits requiring contingency actions; and
- Disposition of records and identification of parties to be notified on completion.

Verify that if structures, systems, and components important to safety are found operating outside the tolerance for normal operation during periodic testing, adequate procedures are in place to assure that they will be restored to normal conditions in a reasonably short time such that worker and public health and safety are protected.

Verify that administrative procedures for the review, change, and approval of periodic testing procedures for structures, systems, and components important to safety are adequate and that these procedures have adequate management controls.

Confirm that appropriate industry or U.S. Nuclear Regulatory Commission standards, if applicable, are used as the basis for the periodic testing procedures for structures, systems, and components important to safety.

Verify that periodic testing activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews should be specified, in both

number and technical disciplines, and should collectively have the experience and competence required to review problems in the following areas:

- Nuclear engineering;
- Chemistry and radiochemistry;
- Metallurgy;
- Nondestructive testing;
- Instrumentation and control;
- Radiological safety;
- Mechanical, civil, and electrical engineering;
- Administrative controls and quality assurance practices; and
- Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

An individual may possess competence in more than one speciality area.

4.5.6.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.21(c)(22)(v).

Acceptance Criterion 1 Plans for Normal Operation of Structures, Systems, and Components of the Geologic Repository Operations Area That Are Important to Safety Are Acceptable.

- Acceptable written procedures are provided for normal operation of structures, systems, and components important to safety, as identified in the preclosure safety analysis and reviewed in Section 4.1 of the Yucca Mountain Review Plan, to include routine and contingency operations as well as any procedural requirements necessitated by technical specifications. Normal operating procedures include the following:
  - Purpose of the procedure;
  - Responsibilities, training, and qualifications of personnel;
  - Prerequisites such as:
    - Calibrations to be performed or checked;
    - Instrumentation;

- Tools and special equipment;
- Notifications to other operations personnel with associated lead times;
- Checks or settings for equipment or controls (e.g., physical travel limits for overhead crane);
- Operational checks of radiation, environmental, or other monitors; and
- Logs and records associated with the test.

— Description of the series of operations to be performed, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used (e.g., torque, time at pressure), and threshold limits requiring contingency actions (such as hold points, corrective-action sequences, and notifications);

— Disposition of records and identification of parties to be notified on completion of the operation; and

— Identification of any required follow-on actions.

- Administrative procedures for the review, change, and approval of normal operating procedures for structures, systems, and components important to safety are adequate, and these procedures have adequate management controls.

- Appropriate industry or U.S. Nuclear Regulatory Commission standards are used as the basis for the operating procedures for structures, systems, and components important to safety.

- Normal operations of structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews are specified, in both number and technical disciplines, and collectively have the experience and competence required to review problems in the following areas:

  — Nuclear engineering;

  — Chemistry and radiochemistry;

  — Metallurgy;

  — Nondestructive testing;

  — Instrumentation and control;

  — Radiological safety;

— Mechanical, civil, and electrical engineering;

— Administrative controls and quality assurance practices; and

— Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

Acceptance Criterion 2 Plans and Procedures for Maintenance of Structures, Systems, and Components of the Geologic Repository Operations Area That Are Important to Safety Are Acceptable.

- Written procedures are provided for maintenance of structures, systems, and components important to safety and include the following:

  — Purpose of the maintenance procedure;

  — Responsibilities, training, and qualifications of personnel;

  — Prerequisites such as:

    – Calibrations to be performed or checked;

    – Instrumentation;

    – Tools and special equipment;

    – Notifications to other operations or maintenance personnel with associated lead times;

    – Checks or settings for equipment or controls;

    – Operational checks of radiation, environmental, or other monitors; and

    – Logs and records associated with the maintenance.

  — Description of the maintenance activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used, and threshold limits requiring contingency actions; and

  — Disposition of records and identification of parties to be notified on completion.

- Administrative procedures for the review, change, and approval of maintenance procedures for structures, systems, and components important to safety are adequate, and these procedures have adequate management controls;

- Appropriate industry or U.S. Nuclear Regulatory Commission standards are used as the basis for the maintenance procedures for structures, systems, and components important to safety;

- Maintenance activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews are specified, in both number and technical disciplines, and collectively have the experience and competence required to review problems in the following areas:

  — Nuclear engineering;

  — Chemistry and radiochemistry;

  — Metallurgy;

  — Nondestructive testing;

  — Instrumentation and control;

  — Radiological safety;

  — Mechanical, civil, and electrical engineering;

  — Administrative controls and quality assurance practices; and

  — Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

Acceptance Criterion 3 Plans and Procedures for Surveillance of Structures, Systems, and Components of the Geologic Repository Operations Area That Are Important to Safety Are Acceptable.

- Written procedures are provided to routinely evaluate, through surveillance, the proper functioning of structures, systems, and components important to safety and include the following:

  — Purpose of the routine surveillance;

  — Responsibilities, training, and qualifications of personnel;

  — Prerequisites such as:

    – Calibrations to be performed or checked;

    – Instrumentation;

- Tools and special equipment;
- Notifications to operations personnel with associated lead times;
- Checks or settings for equipment or controls;
- Operational checks of radiation, environmental, or other monitors; and
- Logs or records associated with the surveillance.

— Description of the surveillance activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be assessed; and

— Disposition of records and identification of parties to be notified on completion.

- If structures, systems, and components important to safety are found operating outside the tolerance for normal operation during surveillance, adequate procedures are in place to assure that they will be restored to normal conditions in a reasonably short time such that worker and public health and safety are protected.

- Administrative procedures for the review, change, and approval of surveillance procedures for structures, systems, and components important to safety are adequate, and these procedures have adequate management controls.

- Appropriate industry or U.S. Nuclear Regulatory Commission standards, if applicable, are used as the basis for the surveillance procedures for structures, systems, and components important to safety.

- Surveillance activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews are specified, in both number and technical disciplines, and collectively have the experience and competence required to review problems in the following areas:

  — Nuclear engineering;

  — Chemistry and radiochemistry;

  — Metallurgy;

  — Nondestructive testing;

  — Instrumentation and control;

  — Radiological safety;

- Mechanical, civil, and electrical engineering;
- Administrative controls and quality assurance practices; and
- Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

Acceptance Criterion 4 Plans and Procedures for Routine Periodic Testing of Structures, Systems, and Components of the Geologic Repository Operations Area That Are Important to Safety Are Acceptable.

- Written procedures for periodic testing designed to ensure that structures, systems, and components important to safety will perform their design function during normal operations are in place. This testing will be accomplished on a defined schedule and at a frequency sufficient to ensure protection of worker and public safety. Procedures for periodic testing of structures, systems, and components important to safety include the following:
  - Purpose of testing;
  - Responsibilities, training, and qualifications of personnel;
  - Prerequisites such as:
    - Calibrations to be performed or checked;
    - Instrumentation;
    - Tools and special equipment;
    - Notifications to other operations or testing personnel with associated lead times;
    - Checks or settings for equipment or controls;
    - Operational checks of radiation, environmental, or other monitors; and
    - Logs or records associated with the testing.
  - Description of the testing activities, including expected results, expected radiation dose, projected times for completion, expected instrument and gauge readings, controls to be used, and threshold limits requiring contingency actions; and
  - Disposition of records and identification of parties to be notified on completion.

- If structures, systems, and components important to safety are found operating outside the tolerance for normal operation during periodic testing, adequate procedures are in place to assure that they will be restored to normal conditions in a reasonably short time such that worker and public health and safety are protected.

- Administrative procedures for the review, change, and approval of periodic testing procedures for structures, systems, and components important to safety are adequate, and these procedures have adequate management controls.

- Appropriate industry or U.S. Nuclear Regulatory Commission standards, if applicable, are used as the basis for the periodic testing procedures for structures, systems, and components important to safety.

- Periodic testing activities on structures, systems, and components that are important to safety are performed according to written procedures that are reviewed by health, safety, and quality assurance personnel who are independent of the operating management function. Personnel assigned responsibility for these independent reviews are specified, in both number and technical disciplines, and collectively have the experience and competence required to review problems in the following areas:

  — Nuclear engineering;

  — Chemistry and radiochemistry;

  — Metallurgy;

  — Nondestructive testing;

  — Instrumentation and control;

  — Radiological safety;

  — Mechanical, civil, and electrical engineering;

  — Administrative controls and quality assurance practices; and

  — Other appropriate fields associated with the characteristics of a repository for high-level radioactive waste.

4.5.6.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.6.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

Review Plan for Safety Analysis Report

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they meet the requirements of 10 CFR 63.21(c)(22)(v). The U.S. Department of Energy has provided an adequate plan for conducting normal activities, including operations, maintenance, surveillance, and periodic testing of structures, systems, and components important to safety at the geologic repository operations area.

4.5.6.5 References

None.

4.5.7 Emergency Planning

Although the U.S. Department of Energy is not expected to have prepared an emergency plan at the time of the application for the license, the U.S. Department of Energy should commit to developing and implementing an emergency plan to meet or exceed the acceptance criteria in this section.

Review Responsibilities—High-Level Waste Branch, Division of Fuel Cycle Safety and Safeguards, and Environmental and Performance Assessment Branch

4.5.7.1 Areas of Review

This section reviews emergency planning. Reviewers will also evaluate the information required by 10 CFR 63.21(c)(21).

The staff will evaluate the following parts of emergency planning, using the review methods and acceptance criteria in Sections 4.5.7.2 and 4.5.7.3.

- Descriptions of the geologic repository operations area and nearby areas;
- Types and classifications of potential radioactive materials accidents;
- Means for detection of key initiating events and accident conditions;
- Actions to mitigate consequences of accidents;
- Methods and equipment to assess radioactive materials releases;
- Responsibilities of facility personnel during emergencies;
- Responsibilities for developing, maintaining, and updating the emergency plan;
- Means to notify and coordinate with off-site response organizations;
- Information to be communicated to off-site organizations;
- Training plans for emergency response;

- Means for restoring the facility to a safe condition;
- Provisions for quarterly communications checks;
- Plans for biennial emergency response exercises;
- Plans for semiannual radiological/health physics, medical, and fire drills;
- Certification that hazardous chemicals responsibilities are met under the Emergency Planning and Community Right-to-Know Act of 1986;
- Comments and their resolution on the emergency plan from off-site emergency response organizations;
- Assignments for off-site assistance; and
- Arrangements for providing information to the public.

4.5.7.2 Review Methods

Additional guidance for conducting this review is found in NUREG–1567, "Standard Review Plan for Spent Fuel Storage Facilities" (U.S. Nuclear Regulatory Commission, 2000). Criteria for an acceptable emergency plan are in 10 CFR 72.32(b).

Review Method 1 Emergency Plan

Confirm that the U.S. Department of Energy has included a description of the geologic repository operations area and the area near the site sufficient to support an evaluation of the emergency plan.

Verify that the application identifies each plausible type of radioactive materials accident. The radiological emergencies and accidents identified in the emergency plan should be the same as those identified during the review of event sequences conducted using Section 4.1.1.4 of the Yucca Mountain Review Plan.

Verify that the U.S. Department of Energy defines an adequate classification system to identify accidents as "alerts" or "site area emergencies."

Assess the adequacy of the means (instruments, equipment, procedures, etc.) to detect key initiating events and accident conditions. Assess the rationale for the locations and types of detection devices deployed.

Assess the adequacy of planned means to mitigate the consequences of each type of accident, including the means to protect site workers and the program to maintain mitigative equipment.

Verify that methods and equipment planned to be used to assess releases of radioactive materials are adequate to support effective emergency response.

Verify that the U.S. Department of Energy clearly defines the responsibilities of facility personnel during a radiological accident and identifies personnel responsible for prompt notification of off-site response organizations and the U.S. Nuclear Regulatory Commission.

Confirm the adequacy of information provided for off-site response organizations, including the point of contact; address; and phone number, fax, and e-mail addresses.

Ensure that the U.S. Department of Energy assigns responsibilities for developing, maintaining, and updating the emergency plan.

Verify that the U.S. Department of Energy provides a commitment to, and a brief description of, the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers. Confirm that:

- A control point will be established;
- The unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification of and coordination with off-site response organizations; and
- The U.S. Nuclear Regulatory Commission operations center will be notified within 1 hour after an emergency is declared.

Assess the description of the types of information to be provided on geologic repository operations area status, radioactive releases, and recommended protective actions (if necessary). Confirm that this information will be adequate and that it will be provided in a timely manner to off-site response organizations and the U.S. Nuclear Regulatory Commission.

Confirm that emergency response training provided to workers and any special instructions and orientation tours offered for fire, police, medical, and other off-site-based emergency personnel are adequate to support effective actions. Review the geologic repository operations area training program using Section 4.5.3 ("Training and Certification of Personnel") of the Yucca Mountain Review Plan.

Confirm that means to restore the geologic repository operations area to a safe condition after an accident will be adequate.

Confirm that quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies are planned and include the following:

- A check and update of all necessary phone numbers, fax numbers, and e-mail addresses;
- An invitation to off-site response organizations to participate in the biennial exercises (participation of off-site organizations in biennial exercises is recommended but not required);

- A commitment to use scenarios not known to most exercise participants;
- A plan for critiques of each exercise by individuals not having direct implementation responsibility for conducting the exercise. Verify that critiques will evaluate the appropriateness of the plan, emergency procedures, facilities and equipment, training of personnel, and the overall effectiveness of the response; and
- Provisions to correct deficiencies identified by the critiques.

Confirm that on-site exercises to test response to simulated emergencies will be conducted biennially.

Confirm that radiological/health physics, medical, and fire drills are planned semiannually.

Verify that the U.S. Department of Energy commits that geologic repository operations area operations will satisfy the Emergency Planning and Community Right-to-Know Act of 1986, with respect to hazardous materials at the facility.

Confirm that off-site response organizations were allowed 60 days to comment on the initial submittal of the emergency plan before it was transmitted to the U.S. Nuclear Regulatory Commission. Verify that subsequent plan changes will have a 60-day comment period if the changes affect the off-site response organizations. Confirm that any comments received during the 60-day comment period, and licensee responses, were submitted to the U.S. Nuclear Regulatory Commission with the emergency plan.

Verify that plans for use of off-site assistance include:

- Arrangements for requesting and effectively using off-site assistance and provisions for using other organizations that can augment the planned on-site response, as required;
- Provisions for prompt communication among principal response organizations to off-site personnel who would be responding on-site;
- Provision of adequate emergency facilities and equipment to support the emergency response onsite;
- Specification of methods, systems, and equipment for assessing and monitoring consequences of radiological emergency conditions;
- Arrangements for medical services for on-site contaminated and injured individuals; and
- Training in radiological emergency response for off-site personnel who may be called to assist in an emergency.

Confirm that adequate arrangements for providing timely information to the public exist.

4.5.7.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.161.

Acceptance Criterion 1 an Adequate Emergency Plan for Responding to Potential Radiological Materials and Other Accidents at the Geologic Repository Operations Area Is Provided.

- A description of the geologic repository operations area and the area near the site sufficient to support an evaluation of the emergency plan is included;
- The U.S. Department of Energy identifies each plausible type of radioactive materials accident. The radiological emergencies and accidents identified in the emergency plan are the same as those identified in event sequences;
- The classification system to identify accidents as "alerts" or "site area emergencies" is adequate
- The means (instruments, equipment, procedures, etc.) used to detect key initiating events and accident conditions are adequate. The rationale for the locations and types of detection devices deployed is acceptable;
- The planned means for mitigating the consequences of each type of accident, including the means provided to protect site workers and the program to maintain mitigative equipment, are adequate;
- The methods and equipment planned to be used to assess releases of radioactive materials to support effective emergency response actions are adequate;
- The responsibilities and identities of facility personnel during a radiological accident and of personnel responsible for prompt notification of off-site response organizations and the U.S. Nuclear Regulatory Commission are adequately defined;
- Information provided for off-site response organizations, including the point of contact; address; and phone number, fax, and e-mail addresses, is adequate.
- Responsibilities for developing, maintaining, and updating the emergency plan are acceptably defined.
- A commitment to, and a brief description of, the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers, are provided. The description also includes sufficient information to verify that:
  - A control point will be established;

- — The unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification of and coordination with off-site response organizations; and

- — The U.S. Nuclear Regulatory Commission operations center will be notified within one hour after an emergency is declared.

- The types of information to be provided on facility status, radioactive releases, and recommended protective actions (if necessary) are adequate and this information will be provided in a timely manner to off-site response organizations and the U.S. Nuclear Regulatory Commission.

- The emergency response training provided to workers, and any special instructions and orientation tours offered for fire, police, medical, and other off-site-based emergency personnel are adequate to support effective actions.

- The means to restore the facility to a safe condition after an accident are adequate.

- Quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies are planned and include the following:

  - — A check and update of all necessary phone numbers, fax numbers, and e-mail addresses;

  - — An invitation to off-site response organizations to participate in the biennial exercises;

  - — A commitment to use scenarios not known to most exercise participants;

  - — A plan for critiques of each exercise by individuals not having direct implementation responsibility for conducting the exercise. Critiques will evaluate the appropriateness of the plan, emergency procedures, facilities and equipment, training of personnel, and the overall effectiveness of the response; and

  - — Provisions to correct deficiencies identified by the critiques.

- On-site exercises to test response to simulated emergencies are conducted biennially;

- Radiological/health physics, medical, and fire drills are planned semiannually;

- The U.S. Department of Energy commits that geologic repository operations area operations will satisfy the Emergency Planning and Community Right-to-Know Act of 1986, with respect to hazardous materials at the facility;

- The off-site response organizations are allowed 60 days to comment on the initial submittal of the emergency plan before transmittal to the U.S. Nuclear Regulatory Commission. Subsequent plan changes will have a 60-day comment period if the

changes affect the off-site response organizations. Comments received during the 60-day comment period and licensee responses are submitted to the U.S. Nuclear Regulatory Commission with the emergency plan.

- Plans for use of off-site assistance include:
  - Arrangements for requesting and effectively using off-site assistance and provisions for using other organizations that can augment the planned on-site response, as required;
  - Provisions for prompt communication among principal response organizations to off-site personnel who would be responding on-site;
  - Provision of adequate emergency facilities and equipment to support the emergency response onsite;
  - Specification of methods, systems, and equipment for assessing and monitoring consequences of radiological emergency conditions;
  - Arrangements for medical services for on-site contaminated and injured individuals; and
  - Training in radiological emergency response for off-site personnel who may be called to assist in an emergency.
- Adequate arrangements for providing timely information to the public exist.

4.5.7.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.7.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.161. An acceptable emergency plan for coping with radiological accidents through permanent closure, including dismantlement and decontamination of the surface facilities at the geologic repository operations area, is provided in accordance with 10 CFR 72.32(b). Aspects of this plan include:

- Facility and nearby area descriptions;
- Types and classifications of radioactive materials accidents;
- Means for detection of accident conditions;

- Means for mitigation of consequences of accidents;
- Adequate assessment of radioactive materials releases;
- Definition of responsibilities for facility personnel during an emergency;
- Responsibilities for developing, maintaining, and updating the emergency plan;
- Identification of off-site response organizations;
- Notification and coordination with off-site response organizations;
- Information to be communicated to off-site response organizations;
- Training of on-site emergency response staff;
- Safe condition restoration;
- Exercises to demonstrate readiness to act in emergency situations;
- Hazardous chemicals responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986;
- Comments on the emergency plan from off-site emergency response team members;
- Off-site assistance requirements; and
- Arrangements for providing information to the public.

4.5.7.5 Reference

U.S. Nuclear Regulatory Commission. NUREG–1567, "Standard Review Plan for Spent Fuel Storage Facilities." Washington, DC: U.S. Nuclear Regulatory Commission, Spent Fuel Project Office. March 2000.

4.5.8 Controls to Restrict Access and Regulate Land Uses

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.8.1 Areas of Review

This section reviews controls to restrict access and regulate land uses. Reviewers will also evaluate the information required by 10 CFR 63.21(c)(24).

Controls to restrict access and regulate land uses are implemented to reduce the likelihood of adverse human actions that could reduce the ability of the repository to isolate waste.

The staff will evaluate the following parts of controls to restrict access and regulate land uses, using the review methods and acceptance criteria in Sections 4.5.8.2 and 4.5.8.3.

- Extent and adequacy of geologic repository operations area land acquisition or withdrawal;
- Compatibility of geologic repository operations area boundaries in the geologic repository operations area design and natural features;
- Means used to identify encumbrances or subsurface interests within the geologic repository operations area;
- Acceptability of additional controls for permanent closure;
- Acceptability of additional controls through permanent closure;
- Adequacy of water rights;
- Control over surface and subsurface estates;
- Means used to identify encumbrances outside the geologic repository operations area; and
- Acceptability of monument design.

4.5.8.2 Review Methods

Review Method 1 Ownership of Land

Verify that steps within the U.S. Department of Energy purview to establish effective jurisdiction and control and legislative or other transfer activities underway will be completed before the completion of the U.S. Nuclear Regulatory Commission review and decision on the license application.

Confirm that the land area of the geologic repository operations area is either land acquired by the U.S. Department of Energy, or is permanently withdrawn and is reserved for U.S. Department of Energy use, and is held by the U.S. Department of Energy free and clear of all significant encumbrances including: (i) rights arising under the general mining laws; (ii) easements for right-of-way; and (iii) all other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

Confirm that legal documentation of ownership for the geologic repository operations area includes sufficient indexes of ownership and/or control to satisfy a purchaser-of-record such as: a recorded title search showing any and all interests in the land, or a Bureau of Land Management Master Title Plan that indicates all recorded interests and claims.

If a statutory withdrawal of the geologic repository operations area land has been enacted, verify that the license application includes a copy of the legislation and that the legal

descriptions of the land area contained in the statute and the description in the application agree. Since the land area of the proposed repository site would be totally in Federal ownership, the statutory withdrawal would constitute complete ownership documentation, subject to subordinate interests.

Review Method 2 Additional Controls for Permanent Closure

Evaluate whether any controls established over surface and subsurface estates, at the geologic repository operations area or outside the geologic repository operations area, to prevent adverse human actions that could reduce the ability of the geologic repository to isolate the waste, are acceptable and sufficient. Such controls may take the form of: (i) possessory interests; (ii) servitudes; (iii) water rights; (iv) withdrawals from location or patent under the general mining laws; and (v) land use restrictions.

Confirm that the size and boundaries of the geologic repository operations area and the affected area outside the geologic repository operations area are consistent with the design or natural features, to assure the ability of the repository to achieve isolation and to reduce the risk of human activity that could adversely impact waste isolation. Collaborate with the reviewers of the site characteristics completed using Sections 3.1 "General Description" and 4.2 "Repository Safety after Permanent Closure" of the Yucca Mountain Review Plan.

Verify that legal documentation of ownership and/or control of the area outside the geologic repository operations area includes sufficient indexes of ownership and control to satisfy a purchaser-of-record such as: a recorded title search showing any and all interests in the land, or the Bureau of Land Management Master Title Plan, which indicates all recorded interests and claims.

Verify that if a statutory withdrawal has not been enacted for land outside the geologic repository operations area, the U.S. Department of Energy has taken or plans to take appropriate steps within its purview to establish effective jurisdiction and control. Legislative or other transfer activities underway should be completed before the completion of the U.S. Nuclear Regulatory Commission review and decision on the license application.

Confirm that any existing or proposed permissible rights or encumbrances that exist and may be continued, or that should be established outside the geologic repository operations area, are identified, and the nature of any activities that may permissibly occur under these rights are assessed adequately.

Evaluate the U.S. Department of Energy plan for administering and controlling its ownership rights or oversight of land. Verify that the means, such as title search and Bureau of Land Management records search, used to identify any existing or future encumbrances or other surface or subsurface interests of record in the land area outside the geologic repository operations area, were appropriate.

Review Method 3 Additional Controls Through Permanent Closure

Evaluate whether any controls necessary to ensure that the requirements at 10 CFR 63.111(a) and (b) are met, are acceptable and sufficient. Such controls, if necessary, should include land use restrictions and the authority to exclude members of the public.

Confirm that the size and boundaries of the geologic repository operations area, and the affected area outside the geologic repository operations area, are consistent with the design or natural features, to ensure that the requirements at 10 CFR 63.111(a) and (b) are met. Collaborate with the reviewers of Section 4.1 of the Yucca Mountain Review Plan "Repository Safety Prior to Permanent Closure" and with the reviewers of the site characteristics completed using Sections 3.1 "General Description" and 4.2 "Repository Safety after Permanent Closure," of the Yucca Mountain Review Plan.

Verify that legal documentation of ownership and/or control of the area outside the geologic repository operations area includes sufficient indexes of ownership and/or control to satisfy a purchaser-of-record such as: a recorded title search showing any and all interests in the land, or the Bureau of Land Management Master Title Plan, which indicates all recorded interests and claims.

Verify that if a statutory withdrawal has not been enacted for land outside the geologic repository operations area, the U.S. Department of Energy has taken appropriate steps within its purview to establish effective jurisdiction and control. Legislative or other transfer activities underway should be completed before the completion of the U.S. Nuclear Regulatory Commission review and decision on the license application.

Confirm that any existing or proposed permissible rights or encumbrances that exist and may be continued, or that should be established outside the geologic repository operations are, are identified, and the nature of any activities that may permissibly occur under these rights are assessed adequately.

Evaluate the U.S. Department of Energy plan for administering and controlling its ownership rights or oversight of land. Verify that the means, such as title search and Bureau of Land Management records search, used to identify any existing or future encumbrances or other surface or subsurface interests of record in the land area outside the geologic repository operations area, were appropriate.

Review Method 4 Water Rights

Confirm that the U.S. Department of Energy has obtained such water rights as may be necessary to accomplish the purpose of the geologic repository operations area. Coordinate with the reviewers of the geologic repository operations area design-conducted using Section 4.1, "Repository Safety Prior to Permanent Closure," of the Yucca Mountain Review Plan, to determine the water use requirements.

Review Method 5 Conceptual Design of Monuments

Confirm that the conceptual design of monuments planned to identify the site after permanent closure is adequate. The monuments should accurately identify the location of the repository, be designed to be as permanent as practicable, convey a warning against intrusion into the underground repository, because of risk to public health and safety from radioactive wastes, and have a design life of at least a few hundred years.

4.5.8.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.121 and 63.21(c)(24), regarding controls to restrict access and regulate land use and the conceptual design of monuments.

Acceptance Criterion 1 Ownership of Land Is Adequately Demonstrated.

- Steps within U.S. Department of Energy purview to establish effective jurisdiction and control and legislative or other transfer activities underway are complete;
- The land area of the geologic repository operations area is either land acquired by the U.S. Department of Energy, or is permanently withdrawn and is reserved for U.S. Department of Energy use, and is held by the U.S. Department of Energy free and clear of all significant encumbrances;
- Legal documentation of ownership for the geologic repository operations area includes sufficient indexes of ownership and control to satisfy a purchaser-of-record; and
- If a statutory withdrawal of the geologic repository operations area land has been enacted, the license application includes a copy of the legislation, and the legal descriptions of the land area contained in the statute and the description in the application agree.

Acceptance Criterion 2 Additional Controls for Permanent Closure Are Acceptable.

- Any additional controls established over surface and subsurface estates, at the geologic repository operations area or outside the geologic repository operations area, to prevent adverse human actions that could reduce the ability of the geologic repository to isolate the waste, are acceptable and sufficient;
- The size and boundaries of the geologic repository operations area and the affected area outside the geologic repository operations area are consistent with the design or natural features, to assure the ability of the repository to achieve isolation and to reduce the risk of human activity that could adversely impact waste isolation;
- Legal documentation of ownership and/or control of the area outside the geologic repository operations area includes sufficient indexes of ownership and control to satisfy a purchaser-of-record such as: a recorded title search showing any and all interests in the land, or the Bureau of Land Management Master Title Plan;

- If a statutory withdrawal has not been enacted for land outside the geologic repository operations area, the U.S. Department of Energy has taken appropriate steps within its purview to establish effective jurisdiction and control. Legislative or other transfer activities are complete;

- Any existing or proposed permissible rights or encumbrances that exist and may be continued, or that should be established outside the geologic repository operations area are identified, and the nature of any activities that may permissibly occur under these rights are assessed adequately; and

- The means, such as title search and Bureau of Land Management records search, used to identify any existing or future encumbrances or other surface or subsurface interests of record in the land area outside the geologic repository operations area, were appropriate.

Acceptance Criterion 3 Additional Controls Through Permanent Closure Are Adequate.

- Any additional controls necessary to ensure that the requirements, at 10 CFR 63.111(a) and (b), are met, are acceptable and sufficient;

- The size and boundaries of the geologic repository operations area, and the affected area outside the geologic repository operations area, are consistent with the design or natural features, to ensure that the requirements at 10 CFR 63.111(a) and (b) are met;

- Legal documentation of ownership and/or control of the area outside the geologic repository operations area includes sufficient indexes of ownership and control to satisfy a purchaser-of-record such as a recorded title search showing any and all interests in the land, or the Bureau of Land Management Master Title Plan;

- If a statutory withdrawal has not been enacted for land outside the geologic repository operations area, U.S. Department of Energy has taken appropriate steps, within its purview, to establish effective jurisdiction and control. Legislative or other transfer activities are complete;

- Any existing or proposed permissible rights or encumbrances that exist and may be continued, or that should be established outside the geologic repository operations area, are identified, and the nature of any activities that may permissibly occur under these rights is assessed adequately; and

- The means, such as title search and Bureau of Land Management records search, used to identify any existing or future encumbrances or other surface or subsurface interests of record in the land area outside the geologic repository operations area were appropriate.

Acceptance Criterion 4 The Description of Water Rights Is Adequate.

- The U.S. Department of Energy has obtained such water rights as may be necessary to accomplish the purpose of the geologic repository operations area.

Acceptance Criterion 5 The Conceptual Design of Monuments Is Adequate.

- The conceptual design of monuments planned to identify the site after permanent closure is adequate.

4.5.8.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.8.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.121 and 63.21(c)(24). Requirements for the ownership and control of interests in land and use of permanent monuments to identify the site after permanent closure have been met. In particular:

- The geologic repository operations area will be located in and on lands that are either acquired lands under the jurisdiction and control of the U.S. Department of Energy, or are permanently withdrawn and reserved for its use. These lands will be held free and clear of encumbrances such as rights arising under the general mining laws, easements for right-of-way, and other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise;

- Additional controls will be applied for permanent closure to include areas outside the geologic repository operations area. These controls will consist of jurisdiction and control, over surface and subsurface estates, as necessary to prevent adverse human actions that could significantly reduce the repository's ability to achieve isolation;

- Additional controls will be applied through permanent closure, including for areas outside the geologic repository operations area. The U.S. Department of Energy will exercise jurisdiction as required to ensure that the preclosure performance objectives in 10 CFR 63.111 are met. The controls include the authority to exclude members of the public;

- The U.S. Department of Energy has obtained water rights to accomplish the purposes of the geologic repository operations area; and

- The U.S. Department of Energy has provided the conceptual design of monuments to identify the location of the repository after permanent closure;

4.5.8.5 References

None.

4.5.9 Uses of Geologic Repository Operations Area for Purposes Other Than Disposal of Radioactive Wastes

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

4.5.9.1 Areas of Review

This section reviews the uses of the geologic repository operations area for purposes other than disposal of radioactive wastes. Reviewers will evaluate the information required by 10 CFR 63.21(c)(22)(vii).

The staff will evaluate the following parts of uses of the geologic repository operations area for purposes other than disposal of radioactive wastes, using the review methods and acceptance criteria in Sections 4.5.9.2 and 4.5.9.3.

- Proposed activities other than disposal of high-level radioactive waste and their impacts, and
- Procedures for conduct and continuing oversight of proposed activities.

4.5.9.2 Review Methods

Review Method 1 Proposed Activities

Determine whether any proposed activities at the geologic repository operations area, other than the disposal of high-level radioactive waste, will potentially impact structures, systems, and components important to safety and engineered and natural barriers important to waste isolation. Activities to be considered include, but are not limited to:

- Long-term interim storage of high-level radioactive waste;
- Access for approved purposes unrelated to the disposal of high-level radioactive waste, such as Native American cultural activities, protection of flora and fauna under appropriate regulations, recreation, and resource exploitation (e.g., minerals, geothermal, ground water); and
- Performance monitoring or confirmation by groups other than the U.S. Nuclear Regulatory Commission or U.S. Department of Energy.

Review Method 2 Procedures for Proposed Activities that Potentially Affect Structures, Systems, and Components

Assess the adequacy of procedures for the continuing oversight of proposed activities, other than disposal of high-level radioactive waste at the geologic repository operations area, that might affect structures, systems, and components important to safety and engineered and natural barriers important to waste isolation. These procedures should include: (i) purpose of

activity; (ii) detailed description of activity; (iii) radiation safety of workers; and (iv) disposition of records and identification of parties to be notified on completion.

4.5.9.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.21(c)(22)(vii), regarding uses of the geologic repository operations area for purposes other than disposal of radioactive wastes.

Acceptance Criterion 1 Proposed Activities Other than Disposal of Radioactive Wastes Are Acceptable.

- Proposed activities at the geologic repository operations area, other than the disposal of high-level radioactive waste, are adequately evaluated for their potential impacts on structures, systems, and components important to safety and engineered and natural barriers important to waste isolation, and the impacts of these activities are acceptable.

Acceptance Criterion 2 Procedures for Proposed Activities Other than Disposal of High-level Radioactive Waste Are Acceptable.

- Procedures for the continuing oversight of proposed activities, other than disposal of high-level radioactive waste, at the geologic repository operations area, that might affect structures, systems, and components important to safety, and engineered and natural barriers important to waste isolation, are adequate.

4.5.9.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.9.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

U.S. Nuclear Regulatory Commission staff has reviewed the Safety Analysis Report and other docketed material and finds, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(22)(vii). Requirements for the content of the license application have been met in that plans for any uses of the geologic repository operations area for purposes other than disposal of radioactive wastes have been adequately described. These plans include an analysis of the effects, if any, that such uses may have on the operation of the structures, systems, and components important to safety and the engineered and natural barriers important to waste isolation.

4.5.9.5 References

None.

4.5.10 License Specifications

Review Responsibilities—High-Level Waste Branch and Environmental and Performance Assessment Branch

This section reviews the variables, conditions, or other items determined by the U.S. Department of Energy to be probable subjects of license specification. The reviewers will evaluate the information required by 10 CFR 63.21(c)(18).

The review of variables, conditions, or other items that are probable subjects of license specifications, is to be integrated with reviews conducted using other sections of the Yucca Mountain Review Plan. The acceptability of proposed variables, conditions, and other items is assessed in conjunction with a determination that the repository performance objectives will be met, because these specifications and conditions define or constrain the operation and construction of the repository. Reviewers should give special attention to items that significantly influence the final design of the geologic repository operations area.

4.5.10.1 Areas of Review

The staff will evaluate the following parts of license specifications, using the review methods and acceptance criteria in Sections 4.5.10.2 and 4.5.10.3.

- License conditions proposed in the following areas, as appropriate:
  - Physical and chemical form and radioisotopic content of radioactive waste;
  - Shape, size, and materials and methods of construction for radioactive waste packaging;
  - Amount of waste permitted per unit volume of storage space;
  - Requirements for test, calibration, inspection, surveillance, and monitoring;
  - Characteristics of drifts, drip shields, backfill, ventilation systems, and other structures, systems, and components;
  - Controls to restrict access and avoid disturbance; and
  - Administrative controls.
- Technical basis for each proposed variable, condition, or other item, with emphasis given to those items that may significantly influence the final design.

4.5.10.2 Review Methods

Review Method 1 Identification and Technical Bases for Proposed License Conditions

Confirm that proposed license conditions and their technical bases have been identified and justified.

Review Method 2 Plans for Meeting License Conditions

Ensure that the U.S. Department of Energy has provided plans for meeting the license conditions and that these plans are consistent with the repository systems designs, based on the results of the reviews conducted using Sections 4.1 and 4.2 of the Yucca Mountain Review Plan.

4.5.10.3 Acceptance Criteria

The following acceptance criteria are based on meeting the requirements of 10 CFR 63.21(c)(18) and 63.43 for license specifications.

Acceptance Criterion 1 Variables, Conditions, and Other Items That Are the Subject of Proposed License Conditions Are Adequately Identified, and Acceptable Technical Bases Have Been Provided.

Acceptance Criterion 2 Plans for Meeting the Proposed License Conditions and Their Technical Bases Are Adequately Identified in the Following Categories, Where Appropriate.

- Physical and chemical form and radioisotopic content of radioactive waste;
- Shape, size, and materials and methods of construction for radioactive waste packaging;
- Amount of waste permitted per unit volume of storage space;
- Requirements relating to test, calibration, or inspection to ensure that the foregoing restrictions are observed;
- Controls to be applied to restrict access and avoid disturbance to areas that might affect repository performance; and
- Administrative controls necessary to assure that facility activities are conducted safely and in conformity with other license conditions.

4.5.10.4 Evaluation Findings

If the license application provides sufficient information and the regulatory acceptance criteria in Section 4.5.10.3 are appropriately satisfied, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the safety evaluation report prepared for

the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows.

The staff has reviewed the Safety Analysis Report and other docketed materials and has found, with reasonable assurance, that they satisfy the requirements of 10 CFR 63.21(c)(18) and 63.43. Requirements for the content of the license application have been met in that those variables, conditions, or other items that are probable subjects of license conditions have been identified and justified. Plans for meeting the license conditions have been specified. Special attention has been given to those items that may significantly influence the final design of the geologic repository operations area.

4.5.10.5 References

None.

5 GLOSSARY

This Glossary is provided for information and is not exhaustive.

absorption: The process of taking up by capillary, osmotic, solvent, or chemical action of molecules (e.g., absorption of gas by water) as distinguished from adsorption.

abstracted model: A model that reproduces, or bounds, the essential elements of a more detailed process model and captures uncertainty and variability in what is often, but not always, a simplified or idealized form. See *abstraction*.

abstraction: Representation of the essential components of a process model into a suitable form for use in a total system performance assessment. Model abstraction is intended to maximize the use of limited computational resources while allowing a sufficient range of sensitivity and uncertainty analyses.

adsorb: To collect a gas, liquid, or dissolved substance on a surface as a condensed layer.

adsorption: The adhesion by chemical or physical forces of molecules or ions (as of gases or liquids) to the surface of solid bodies. For example, the transfer of solute mass, such as radionuclides, in groundwater to the solid geologic surfaces with which it comes in contact. The term *sorption* is sometimes used interchangeably with this term.

advection: The process in which solutes, particles, or molecules are transported by the motion of flowing fluid. For example, advection in combination with dispersion controls flux into and out of the elemental volumes of the flow domain in groundwater transport models.

air mass fraction: The mass of air divided by the total mass of gas (typically air plus water vapor) in the gas phase. This expression gives a measure of the "dryness" of the gas phase, which is important in waste package corrosion models.

Alloy 22: A nickel-base corrosion resistant alloy containing approximately 22 weight percent chromium, 13 weight percent molybdenum, and 3 weight percent tungsten as major alloying elements and that may be used as the outer container material in a waste package design (see *outer barrier*).

alluvium: Detrital deposits made by streams on river beds, flood plains, and alluvial fans; especially a deposit of silt or silty clay laid down during time of flood. The term applies to stream deposits of recent time. It does not include subaqueous sediments of seas and lakes.

alternative: Plausible interpretations or designs based on assumptions other than those used in the base case that could also fit or be applicable, based on the available scientific information. When propagated through a quantitative tool such as performance assessment, alternative interpretations can illustrate the significance of the uncertainty in the base case interpretation chosen to represent the repository's probable behavior.

ambient: Undisturbed, natural conditions such as ambient temperature caused by climate or natural subsurface thermal gradients, and other surrounding conditions.

anisotropy: The condition that physical properties vary when measured in different directions or along different axes. For example, in layered rock the permeability is often greater within the horizontal layers than across the horizontal layers.

annual frequency: The number of occurrences of an event expected in one year.

aqueous: Pertaining to water, such as aqueous phase, aqueous species, or aqueous transport.

aquifer: A subsurface, saturated rock unit (formation, group of formations, or part of a formation) of sufficient permeability to transmit groundwater and yield water of sufficient quality and quantity for an intended beneficial use.

ash: Bits of volcanic rock that would be broken-up during an eruption to less than 2 mm [0.08 inches] in diameter.

basalt: A type of igneous rock that forms black, rubbly lavas and black-to-red tephras of the type commonly used as lava rocks for barbecues.

borosilicate glass: A predominantly noncrystalline, relatively homogenous glass formed by melting silica and boric oxide together with other constituents such as alkali oxides. A high-level radioactive waste matrix material in which boron takes the place of the lime used in ordinary glass mixtures.

boundary condition: For a model, the establishment of a set condition, often at the geometric edge of the model, for a given variable. An example is using a specified groundwater flux from net infiltration as a boundary condition for an unsaturated flow model.

bound: An analysis or selection of parameter values that yields pessimistic results, such that any actual result is certain to be no worse or could be worse only with an extremely small likelihood.

breach: A penetration in the waste package caused by failure of the outer and inner containers or barriers that allows the spent nuclear fuel or the high-level radioactive waste to be exposed to the external aqueous environment and eventually permits radionuclide release.

burnup: A measure of nuclear reactor fuel consumption expressed either as the percentage of fuel atoms that have undergone fission or as the amount of energy produced per unit weight of fuel.

calibration: (1)The process of comparing the conditions, processes, and parameter values used in a model against actual data points or interpolations (e.g., contour maps) from measurements at or close to the site to ensure that the model is compatible with reality, to the extent feasible. (2) For tools used for field or lab measurements, the process of taking instrument readings on standards known to produce a certain response, to check the accuracy and precision of the instrument.

canister: A cylindrical metal receptacle that facilitates handling, transportation, storage, and/or disposal of high-level radioactive waste. It may serve as (1) a pour mold and container for

vitrified high-level radioactive waste or (2) a container for loose or damaged fuel rods, non-fuel components and assemblies, and other debris containing radionuclides.

carbon steel: A steel made of carbon up to about 2 weight percent and only residual quantities of other elements. Carbon steel is a tough but ductile and malleable material used as baskets to maintain the spent fuel assemblies in fixed positions in the current waste package design.

Category 1 event sequences: Those event sequences that are expected to occur one or more times before permanent closure of a geologic repository.

Category 2 event sequences: Event sequences other than Category 1 event sequences that have at least one chance in 10,000 of occurring before permanent closure.

Center for Nuclear Waste Regulatory Analyses: A Federally funded research and development center in San Antonio, Texas, sponsored by the U.S. Nuclear Regulatory Commission, to provide the U.S. Nuclear Regulatory Commission with technical assistance for the repository program.

chain reaction: A continuing series of nuclear fission events that takes place within the fuel of a nuclear reactor. Neutrons produced by a split nucleus collide with and split other nuclei causing a chain of fission events.

cladding: The metal outer sheath of a fuel rod generally made of a zirconium alloy, and in the early nuclear power reactors of stainless steel, intended to protect the uranium dioxide pellets, which are the nuclear fuel, from dissolution by exposure to high temperature water under operating conditions in a reactor.

climate: Weather conditions including temperature, wind velocity, precipitation, and other factors, that prevail in a region.

climate states: Representations of climate conditions.

code (computer): The set of commands used to solve a mathematical model on a computer.

colloid: As applied to radionuclide migration, a colloidal system is a group of large molecules or small particles, having at least one dimension with the size range of 10^{-9} to 10^{-6} meters that are suspended in a solvent. Naturally occurring colloids in groundwater arise from clay minerals such as smectites and illites. Colloids that are transported in groundwater can be filtered out of the water in small pore spaces or very narrow fractures because of the large size of the colloids.

Colloid-Facilitated, Radionuclide Transport Model: A model that represents the enhanced transport of radionuclides by particles that are colloids.

commercial spent nuclear fuel: Nuclear fuel rods, forming a fuel assembly, that have been removed from a nuclear power plant after reaching the specified burnup.

common cause failure: Two or more failures that result from a single event or circumstance.

conceptual model: A set of qualitative assumptions used to describe a system or subsystem for a given purpose. Assumptions for the model are compatible with one another and fit the existing data within the context of the given purpose of the model.

consequence: A measurable outcome of an event or process that, when combined with the probability of occurrence, gives risk.

conservative: A condition of an analysis or a parameter value such that its use provides a pessimistic result, which is worse than the actual result expected.

continuum model: A model that represents fluid flow through numerous individual fractures and matrix blocks by approximating it as continuous flow fields.

corrosion: The deterioration of a material, usually a metal, as a result of a chemical or electrochemical reaction with its environment.

corrosion model: A theoretical representation of a corrosion process based on the application of a combination of fundamental electrochemical (chemical) and thermodynamic principles (or laws) with empirical parameters resulting from experiments, field measurements, or data obtained through industrial experience. Models can describe the penetration of a pit or a crack through a container wall as a function of time.

corrosion resistant alloy: An alloy that exhibits extremely high resistance to general or uniform corrosion in a given environment as a result of the formation of a protective film on its surface. Alloy 22, and other similar nickel-chromium-molybdenum alloys, are considered corrosion resistant alloys because they are extremely resistant to general corrosion in severe aqueous environments (e.g., high temperature brines containing acidic sulfur species).

coupling: The ability to assemble separate analyses or parameters in a performance assessment so that information can be passed among them to develop an overall analysis of system performance.

crevice corrosion: Localized corrosion of a metal surface at, or immediately adjacent to, an area that is shielded from full exposure to the environment because of close proximity between the metal and the surface of another material.

critical event: See *criticality*.

criticality: (1) A condition that would require the original waste form, which is part of the waste package, to be exposed to degradation, followed by conditions that would allow concentration of sufficient nuclear fuel, the presence of neutron moderators, the absence of neutron absorbers, and favorable geometry. (2) The condition in which nuclear fuel sustains a chain reaction. It occurs when the number of neutrons present in one generation cycle equals the number generated in the previous cycle. The state is considered critical when a self-sustaining nuclear chain reaction is ongoing.

criticality accident: The release of energy as a result of accidental production of a self-sustaining or divergent neutron chain reaction.

data: Facts or figures measured or derived from site characteristics or standard references from which conclusions may be drawn. Parameters that have been derived from raw data are sometimes, themselves, considered to be data.

U.S. Department of Energy: A Cabinet-level agency of the U.S. federal government charged with the responsibilities of energy security, national security, and environmental quality.

design concept: An idea of how to design and operate the above-ground and below-ground portions of a repository.

diffusion: (1) The spreading or dissemination of a substance caused by concentration gradients. (2) The gradual mixing of the molecules of two or more substances because of random thermal motion.

diffusive transport: Movement of solutes because of their concentration gradient. The process in which substances carried in groundwater move through the subsurface by means of diffusion because of a concentration gradient.

dike: A tabular body of igneous rock that cuts across the structure of adjacent rocks or cuts massive rocks.

dimensionality: Modeling in one, two, or three dimensions.

direct exposure: The manner in which an individual receives dose from being in close proximity to a source of radiation. Direct exposures present an external dose pathway.

dispersion (hydrodynamic dispersion): (1) The tendency of a solute (substance dissolved in groundwater) to spread out from the path it is expected to follow if only the bulk motion of the flowing fluid were to move it. The tortuous path the solute follows through openings (pores and fractures) causes part of the dispersion effect in the rock. (2) The macroscopic outcome of the actual movement of individual solute particles through a porous medium. Dispersion causes dilution of solutes, including radionuclides, in groundwater, and is usually an important mechanism for spreading contaminants in low flow velocities.

disposal container: A cylindrical metal receptacle designed to contain spent nuclear fuel and high-level radioactive waste that will become an integral part of the waste package when loaded with spent nuclear fuel or high-level radioactive waste. In the current waste package design, the inner container will have spacing structures or baskets to maintain fuel assemblies, shielding components, and neutron absorbing materials in position to control the possibility of criticality.

disruptive event: An unexpected event that, in the case of the potential repository, includes volcanic activity, seismic activity, and nuclear criticality. Disruptive events have two possible effects: (1) direct release of radioactivity to the surface, or (2) alteration of the nominal behavior of the system. For the purposes of screening features, events, and processes for the total system performance assessment, a disruptive event is defined as an event that has a significant effect on the expected annual dose and that has a probability of occurrence during the 10,000-year period of performance less than 1.0, but greater than a cutoff of 0.0001.

disruptive event scenario class: The scenario, or set of related scenarios, that describes the behavior of the system if perturbed by disruptive events. The disruptive scenarios contain all disruptive features, events, and processes that have been retained for analysis.

dissolution: (1) Change from a solid to a liquid state. (2) Dissolving a substance in a solvent.

distribution: The overall scatter of values for a set of observed data. A term used synonymously with frequency distribution or probability distribution function. Distributions have structures that are the probability that a given value occurs in the set.

drift: From mining terminology, a horizontal underground passage. The nearly horizontal underground passageways from the shaft(s) to the alcoves and rooms. Drifts include excavations for emplacement (emplacement drifts) and access (access mains).

drift scale: The scale of an emplacement drift, or approximately 5 meters in diameter.

Drift-Scale Heater Test: A test being conducted in the Exploratory Studies Facility to investigate thermal-hydrologic, thermal-chemical, and thermal-mechanical processes.

drip shield: A metallic structure placed along the extension of the emplacement drifts and above the waste packages to prevent seepage water from directly dripping onto the waste package outer surface.

edge effects: Conditions at the edges of the potential repository that are cooler and wetter because heat dissipates more quickly there than at the center of the repository.

effective porosity: The fraction of a porous medium volume available for fluid flow and/or solute storage, as in the saturated zone. Effective porosity is less than or equal to the total void space (porosity).

empirical: Reliance on experience or experiment rather than on an understanding of the fundamental processes as related to the laws of nature.

emplacement drift: See *drift*.

enrichment: The act of increasing the concentration of ^{235}U from its value in natural uranium. The enrichment (typically reported in atom percent) is a characteristic of nuclear fuel.

equilibrium: The state of a chemical system in which the phases do not undergo any spontaneous change in properties or proportions with time; a dynamic balance.

events: (1) Occurrences that have a specific starting time and, usually, a duration shorter than the time being simulated in a model. (2) uncertain occurrences that take place within a short time relative to the time frame of the model. For the purposes of screening features, events, and processes for the total system performance assessment, an event is defined to be a natural or human-caused phenomenon that has a potential to affect disposal system performance and that occurs during an interval that is short compared with the period of performance.

event tree: A modeling tool that illustrates the logical sequence of events that follow an initiating event.

expert elicitation: A formal process through which expert judgment is obtained.

Exploratory Studies Facility: An underground laboratory at Yucca Mountain that includes a 7.9-kilometer [4.9-mile] main loop (tunnel); a 2.8-kilometer [1.75-mile] cross-drift; and a research alcove system constructed for performing underground studies during site characterization. The data collected will contribute toward determining the suitability of the Yucca Mountain site for a repository. Some or all of the Exploratory Studies Facility may eventually be incorporated into the potential repository.

fault (geologic): A planar or gently curved fracture across which there has been displacement parallel to the fracture surface.

fault tree: A graphical logic model that depicts the combinations of events that result in the occurrence of an undesired event.

features: Physical, chemical, thermal, or temporal characteristics of the site or potential repository system. For the purposes of screening features, events, and processes for the total system performance assessment, a feature is defined to be an object, structure, or condition that has a potential to affect disposal system performance.

ferritic steel: A subclass of carbon steels characterized by a relatively low strength but good ductility as a result of the ferrite microstructure. A type of ferritic steel, mild steel, or low-carbon steel containing up to about 0.1 weight percent carbon is the metallic material most commonly used for construction purposes.

film flow: Movement of water as a film along a surface such as a fracture plane.

finite element analysis: A commonly used numerical method for solving mechanical deformation problems. A technique in which algebraic equations are used to approximate the partial differential equations that comprise mathematical models to produce a form of the problem that can be solved on a computer. For this type of approximation, the area being modeled is formed into a grid with irregularly shaped blocks. This method provides an advantage in handling irregularly shaped boundaries, internal features such as faults, and surfaces of engineered materials. Values for parameters are frequently calculated at nodes for convenience, but are defined everywhere in the blocks by means of interpolation functions.

flow: The movement of a fluid such as air, water, or magma. Flow and transport are processes that can move radionuclides from the proposed repository to the receptor group location.

flow pathway: The subsurface course that water or a solute (including radionuclides) would follow in a given groundwater velocity field, governed principally by the hydraulic gradient.

fracture: A planar discontinuity in rock along which loss of cohesion has occurred. It is often caused by the stresses that cause folding and faulting. A fracture along which there has been displacement of the sides relative to one another is called a fault. A fracture along which no

appreciable movement has occurred is called a joint. Fractures may act as fast paths for groundwater movement.

fracture aperture: The space that separates the sides of a fracture, and the measured width of the space separating the sides of a fracture.

fracture permeability: The capacity of a rock to transmit fluid that is related to fractures in the rock.

frequency: The number of occurrences of an observed or predicted event during a specific time period.

galvanic: Pertains to an electrochemical process in which two dissimilar electronic conductors are in contact with each other and with an electrolyte, or in which two similar electronic conductors are in contact with each other and with dissimilar electrolytes.

galvanic corrosion: Accelerated corrosion of a metal resulting from electrical contact with a more noble metal or non metallic conductor in a corrosive electrolyte.

geochemical: The distribution and amounts of the chemical elements in minerals, ores, rocks, soils, water, and the atmosphere; and the movement of the elements in nature on the basis of their properties.

geologic-framework model: A digital, scaled, geometrically congruent , three-dimensional model of the geologic system.

groundwater: Water contained in pores or fractures in either the unsaturated or saturated zones below ground level.

half-life: The time required for a radioactive substance to lose have its activity due to radioactive decay. At the end of one half-life, 50 percent of the original radioactive material has decayed.

heterogeneity: The condition of being composed of parts or elements of different kinds. A condition in which the value of a parameter such as porosity, which is an attribute of an entity of interest such as the tuff rock containing the potential repository, varies over the space an entity occupies, such as the area around the repository, or with the passage of time.

high-level radioactive waste glass: A waste form produced by melting a mixture of high-level radioactive waste and components of borosilicate glass at a high temperature (approximately 1,100 degrees centigrade).

hydrologic: Pertaining to the properties, distribution, and circulation of water on the surface of the land, in the soil and underlying rocks, and in the atmosphere.

igneous: (1) A type of rock that has formed from a molten, or partially molten, material. (2) A type of activity related to the formation and movement of molten rock either in the subsurface (intrusive) or on the surface (volcanic).

infiltration: The process of water entering the soil at the ground surface. Infiltration becomes percolation when water has moved below the depth at which it can be removed (to return to the atmosphere) by evaporation or transpiration. See *net infiltration*.

inner barrier: The inner container in the current design of the waste package. Type 316NG stainless steel is the DOE preferred material of construction.

invert: A constructed surface that would provide a level drift floor and enable transport and support of the waste packages.

isothermal: Having a constant temperature.

license application: An application, to the U.S. Nuclear Regulatory Commission for a license to construct and operate a repository.

localized corrosion: Corrosion at discrete sites (e.g., pitting and crevice corrosion).

magma: Molten or partially molten rock that is naturally occurring and is generated within the earth. Magma may contain crystals along with dissolved gasses.

Mathematical Model: A mathematical description of a conceptual model.

matrix: Tuff rock material and its pore space exclusive of fractures. As applied to Yucca Mountain tuff, the ground mass of an igneous rock that contains larger crystals.

matrix diffusion: As used in the Total System Performance Assessment for the Site Recommendation conceptual models, the process by which molecular or ionic solutes, such as radionuclides in groundwater, move from areas of higher concentration to areas of lower concentration. This movement is through the pore spaces of the rock material as opposed to movement through the fractures.

matrix permeability: The capability of the matrix to transmit fluid.

mean (arithmetic): For a statistical data set, the sum of the values divided by the number of items in the set. The arithmetic average.

mechanical disruption: Damage to the drip shield or waste package because of external forces.

median: A value such that one-half of the observations are less than that value and one-half are greater than the value.

meteorology: The study of climatic conditions such as precipitation, wind, temperature, and relative humidity.

microbe: An organism too small to be viewed with the unaided eye. Examples of microbes are bacteria, protozoa, and some fungi and algae.

microbial influenced corrosion: Deterioration of metals as a result of the metabolic activity of microorganisms.

migration: Radionuclide movement from one location to another within the engineered barrier system or the environment.

mineral model: A description of the kinds and relative abundances of minerals that is used to approximate the true mineralogical system.

mineralogical: Of or relating to the chemical and physical properties of minerals, their occurrence, and their classification.

model: A depiction of a system, phenomenon, or process, including any hypotheses required to describe the system or explain the phenomenon or process.

near field: The area and conditions within the potential repository including the drifts and waste packages and the rock immediately surrounding the drifts. The region around the potential repository where the natural hydrogeologic system has been significantly impacted by the excavation of the repository and the emplacement of waste.

net infiltration: The amount of infiltration that escapes the zone of evapotranspiration, which is generally the zone below the zone of plant roots. See *infiltration*.

nominal behavior: (1) Expected behavior of the system as perturbed only by the presence of the potential repository. (2) Behavior of the system in the absence of disruptive events.

nominal features, events, and processes: Those features, events, and processes expected, given the site conditions as described from current site characterization information.

nominal scenario class: The scenario, or set of related scenarios, that describes the expected or nominal behavior of the system as perturbed only by the presence of the potential repository. The nominal scenarios contain all expected features, events, and processes that have been retained for analysis.

nuclear criticality safety: Protection against the consequences of a criticality accident, preferably by prevention of the accident.

U.S. Nuclear Regulatory Commission: An independent agency, established by the U.S. Congress under the Energy Reorganization Act of 1974, to ensure adequate protection of the public health and safety, the common defense and security, and the environment, in the use of nuclear materials in the United States. The U.S. Nuclear Regulatory Commission scope of responsibility includes regulation of the transport, storage, and disposal of nuclear materials and waste.

Nuclear Waste Policy Act (42 U.S.C. 10101 et seq.): The Federal statute enacted in 1982 that established the Office of Civilian Radioactive Waste Management and defined its mission to develop a federal system for the management, and geologic disposal, of commercial spent nuclear fuel and other high-level radioactive wastes. The Act also: (1) specified other federal

responsibilities for nuclear waste management; (2) established the Nuclear Waste Fund to cover the cost of geologic disposal; (3) authorized interim storage under certain circumstances; and (4) defined interactions between federal agencies and the states, local governments, and Indian tribes. The act was substantially amended in 1987.

Nuclear Waste Policy Amendments Act of 1987: Legislation that amended the Nuclear Waste Policy Act to: (1) limit repository site characterization activities to Yucca Mountain, Nevada; (2) establish the Office of the Nuclear Waste Negotiator to seek a state or Indian tribe willing to host a repository or monitored retrievable storage facility; (3) create the Nuclear Waste Technical Review Board; and (4) increase state and local government participation in the waste management program.

numerical model: An approximate representation of a mathematical model that is constructed using a numerical description method such as finite volumes, finite differences, or finite elements. A numerical model is typically represented by a series of program statements that are executed on a computer.

Office of Civilian Radioactive Waste Management: A U.S. Department of Energy office created by the Nuclear Waste Policy Act of 1982 to implement the responsibilities assigned by the Act.

outer barrier: The outer container in the current design of the waste package. Alloy 22 is the U.S. Department of Energy preferred material of construction.

oxidation: (1) A corrosion reaction in which the corroded metal forms an oxide, usually applied to reaction with a gas containing elemental oxygen, such as air. (2) An electrochemical reaction in which there is an increase in the valence of an element resulting from the loss of electrons.

parameter: Data, or values, such as those that are input to computer codes for a total system performance assessment calculation.

patch: A circumscribed area of a surface. In the DOE modeling of waste package corrosion, it is the minimal surface area of the outer container over which uniform corrosion occurs, as opposed to localized corrosion in pits.

pathway: A potential route by which radionuclides might reach the accessible environment and pose a threat to humans. For example, direct exposure is an external pathway, and inhalation and ingestion are internal pathways.

permeability: The ability of a material to transmit fluid through its pores when subjected to a difference in head (pressure gradient). Permeability depends on the substance transmitted (oil, air, water, etc.) and on the size and shape of the pores, joints, and fractures in the medium and the manner in which they are interconnected.

phase: A physically homogeneous and distinct portion of a material system, such as the gaseous, liquid, and solid phases of a substance. In liquids and solids, single phases may coexist.

phase stability: A measure of the ability of a particular phase to remain without transformation.

pit: A small cavity formed in a solid as a result of localized dissolution.

pitting corrosion: Localized corrosion of a metal surface, confined to a small area, that takes the form of cavities named pits.

porosity: The ratio of openings, or voids, to the total volume of a soil or rock expressed as a decimal fraction or as a percentage. See also *effective porosity*.

pre-startup and startup testing: Activities to evaluate the readiness to receive, possess, process, store, and dispose of high-level radioactive waste.

probabilistic: (1) Based on or subject to probability. (2) Involving a variate, such as temperature or porosity. At each instance of time, the variate may take on any of the values of a specified set with a certain probability. Data from a probabilistic process are an ordered set of observations, each of which is one item from a probability distribution.

probabilistic risk assessment: (1) A systematic process of identifying and quantifying the consequences of scenarios that could cause a release of radioactive materials to the environment. (2) Using predictable behavior to define the performance of natural, geologic, human, and engineered systems for thousands of years into the future including probability distributions to account for uncertainty and variability.

probability: The chance that an outcome will occur from the set of possible outcomes. Statistical probability examines actual events and can be verified by observation or sampling. Knowing the exact probability of an event is usually limited by the inability to know, or compile, the complete set of possible outcomes over time or space.

probability distribution: The set of outcomes (values) and their corresponding probabilities for a random variable.

processes: Phenomena and activities that have gradual, continuous interactions with the system being modeled. For the purposes of screening features, events, and processes for the total system performance assessment, a process is defined as a natural or human-caused phenomenon that has a potential to affect disposal system performance and that operates during all or a significant part of the period of performance.

process model: A depiction or representation of a process, along with any hypotheses required to describe or to explain the process.

radioactive decay: The process in which one radionuclide spontaneously transforms into one or more different radionuclides, which are called daughter radionuclides.

radioactivity: The property possessed by some elements (i.e., uranium) of spontaneously emitting radiation (e.g., alpha particles, beta particles, or gamma rays) by the disintegration of atomic nuclei.

radiolysis: Chemical decomposition by the action of radiation.

radionuclide: Radioactive type of atom with an unstable nucleus that spontaneously decays, usually emitting ionizing radiation in the process. Radioactive elements are characterized by their atomic mass and atomic number.

range (statistics): The numerical difference between the highest and lowest value in any set.

receptor: An individual for whom radiological doses are calculated or measured.

relative permeability: The ability of a material to transmit fluid through its pores when subjected to a pressure gradient under unsaturated conditions. Relative permeability is a function of permeability (has a value between 0 and 1).

repository footprint: The areal extent of the underground repository facility.

retardation: Slowing or stopping radionuclide movement in groundwater by mechanisms that include sorption of radionuclides, diffusion into rock matrix pores and microfractures, and trapping of large colloidal molecules in small pore spaces or dead ends of microfractures.

risk: The probability that an undesirable event will occur, multiplied by the consequences of the undesirable event.

risk assessment: An evaluation of potential consequences or hazards that might be the outcome of an action. This assessment focuses on potential negative impacts on human health or the environment.

rock matrix: See *matrix*.

runoff: Lateral movement of water at the ground surface, such as down steep hillslopes or along channels, that is not able to infiltrate at a specified location. See *runon*.

runon: Lateral movement of water along the ground surface from some upstream location that becomes available for infiltration. See *runoff*.

safety question: A question regarding the adequacy of structures, systems, and components important to safety and engineered or natural barriers important to waste isolation.

scenario: A well-defined, connected sequence of features, events, and processes that can be thought of as an outline of a possible future condition of the potential repository system. Scenarios can be undisturbed, in which case the performance would be the expected, or nominal, behavior for the system. Scenarios can also be disturbed, if altered by disruptive events such as human intrusion or natural phenomena such as volcanism or nuclear criticality.

scenario class: A set of related scenarios sharing sufficient similarities that they can usefully be aggregated for the purposes of screening or analysis. The number and breadth of scenario classes depend on the resolution at which scenarios have been defined. Coarsely defined scenarios result in fewer, broad scenario classes, whereas narrowly defined scenarios result in

many narrow scenario classes. Scenario classes (and scenarios) should be aggregated at the coarsest level at which a technically sound argument can be made while still retaining adequate detail for the purposes of the analysis.

seepage: The inflow of groundwater moving in fractures or pore spaces of permeable rock to an open space in the rock such as a drift. Seepage rate is the percolation flux that enters the drift. Seepage is an important factor in waste package degradation and mobilization and migration of radionuclides out of the potential repository.

seismic: Pertaining to, characteristic of, or produced by earthquakes or earth vibrations.

shallow infiltration: The amount of infiltration that escapes the root zone and percolates downward into the unsaturated zone. See *net infiltration*.

site recommendation: A recommendation by the Secretary of Energy to the President that the Yucca Mountain site is suitable for development as the Nation's first high-level radioactive waste repository.

sorb: To undergo a process of sorption.

sorption: The binding, on a microscopic scale, of one substance to another. A term that includes both adsorption and absorption. The sorption of dissolved radionuclides onto aquifer solids or waste package materials by means of close-range chemical or physical forces is potentially an important process in a repository. Sorption is a function of the chemistry of the radioisotopes, the fluid in which they are carried, and the mineral material they encounter along the flow path.

sorption coefficient (K_d): Coefficient for a term for the various processes by which one substance binds to another.

source term: Types and amounts of radionuclides that are the source of a potential release.

spatial variability: A measure of how a property, such as rock permeability, varies at different locations in an object such as a rock formation.

speciation: The existence of the elements, such as radionuclides, in different molecular forms in the aqueous phase.

spent nuclear fuel: Fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing. Spent fuel that has been burned (irradiated) in a reactor to the extent that it no longer makes an efficient contribution to a nuclear chain reaction. This fuel is more radioactive than it was before irradiation, and releases significant amounts of heat from the decay of its fission product radionuclides. See *burnup*.

stratigraphy: The science of rock strata. It is concerned with all characters and attributes of rocks as *strata* and their interpretation in terms of mode of origin and geologic history.

stress corrosion cracking: A cracking process that requires the simultaneous action of a corrodent and sustained (residual or applied) tensile stress. Stress corrosion cracking excludes both the fracture of already corroded sections and the localized corrosion processes that can disintegrate an alloy without the action of residual or applied stress.

structure: In geology, the arrangement of the parts of the geologic feature or area of interest such as folds or faults. This includes features such as fractures created by faulting and joints caused by the heating of rock.

tectonic: Pertaining to geologic forms or effects created by deformation of the earth's crust.

tephra: A collective term for all clastic materials ejected from a volcano and transported through the air. It includes volcanic dust, ash, cinders, lapilli, scoria, pumice, bombs, and blocks.

thermal-chemical: Of or pertaining to the effect of heat on chemical conditions and reactions.

thermal-hydrologic: Of or pertaining to changes in groundwater movement due to the effects of changes in temperature.

thermal-hydrologic processes: Processes that are driven by a combination of thermal and hydrologic factors. These processes include evaporation of water near the potential repository when it is hot and subsequent redistribution of fluids by convection, condensation, and drainage.

thermal hydrology: The study of a system that has both thermal and hydrologic processes. A thermal-hydrologic condition, or system, is expected to occur if heat-generating waste packages are placed in the potential repository at Yucca Mountain.

thermal-mechanical: Of or pertaining to changes in mechanical properties of rocks from effects of changes in temperature.

thermodynamics: A branch of physics that deals with the relationship and transformations between work as a mechanical action and heat.

total system performance assessment: A risk assessment that quantitatively estimates how the potential Yucca Mountain repository system will perform in the future under the influence of specific features, events, and processes, incorporating uncertainty in the models and uncertainty and variability of the data.

transparency: The ease of understanding the process by which a study was carried out, which assumptions are driving the results, how they were arrived at, and the rigor of the analyses leading to the results. A logical structure ensures completeness and facilitates in-depth review of the relevant issues. Transparency is achieved when a reader or reviewer has a clear picture of what was done in the analysis, what the outcome was, and why.

transpiration: The removal of water from the ground by vegetation (roots).

transport: A process that allows substances to be carried in a fluid through (1) the physical mechanisms of convection, diffusion, and dispersion; and (2) the chemical mechanisms of sorption, leaching, precipitation, dissolution, and complexation. Types of transport include advective, diffusive, and colloidal.

tuff: A general term for all consolidated pyroclastic rocks. The most abundant type of rock at the Yucca Mountain site.

uncertainty: How much a calculated or measured value varies from the unknown true value.

uniform corrosion: A type of corrosion attack (deterioration) more or less uniformly distributed over a metal surface. Corrosion that proceeds at approximately the same rate over a metal surface. Also called general corrosion.

unsaturated zone flow: The movement of water in the unsaturated zone driven by capillary, viscous, gravitational, inertial, and evaporative forces.

variable: A non-unique property or attribute.

variability (statistical): A measure of how a quantity varies over time or space.

volcanism: Pertaining to volcanic activity.

watershed: The area drained by a river system including the adjacent ridges and hillslopes.