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Nuclear Regulatory Commission

Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report; Notice

NUCLEAR REGULATORY COMMISSION

Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and public comments and responses.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the availability of ''Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report,'' public comments on that document and NRC response to comments. The ''Yucca Mountain Review Plan'' provides guidance to NRC staff for evaluating a potential license application to receive and possess high-level radioactive waste at a geologic repository constructed or operated at Yucca Mountain, Nevada.

ADDRESSES: Copies of any documents related to this action may be examined at the NRC Public Document Room, One White Flint North, Public File Area O1–F21, 11555 Rockville Pike, Rockville, Maryland. Documents are also available electronically at NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm.html*. From this site, the public can gain entry into NRC's Agencywide Documents Access and Management System, which provides text and image files of NRC's public documents. For more information, contact NRC's Public Document Room Reference staff by telephone at (800) 397–4209: (301) 415–4737: or e-mail: *pdr@nrc.gov*.

The document is also available at NRC's Web site at: *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1804/*. A hard copy may also be purchased from one of these two sources: (1) The Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328, Internet: *http://bookstore.gpo.gov*. Telephone: 202–512–1800, Fax: 202–512–2250; or (2) The National Technical Information Service, Springfield, VA 22161–0002, Internet: *http://www.ntis.gov*. Telephone: 1–800–553–6847 or 703–605–6000. A copy of the ''Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report'' is also available for inspection, and copying for a fee, in NRC's Public Document Room, One White Flint North, Public File Area O1–F21, 11555 Rockville Pike, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Jeffrey A. Ciocco, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T–7F3, Washington, DC 20555–0001, telephone (301) 415–6391, e-mail: *jac3@nrc.gov*.

SUPPLEMENTARY INFORMATION: In preparing ''Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report,'' the U.S. Nuclear Regulatory Commission (NRC) staff carefully reviewed and considered more than 900 discrete comments received during the public comment period in about 35 individual letters and extracted from the transcripts of three public meetings. To facilitate the analysis, NRC staff grouped all written and oral comments on the Yucca Mountain Review Plan into the following 11 major topic areas:

(1) Introduction;
(2) Acceptance Review;
(3) General Information;
(4) Preclosure Period;
(5) Postclosure Period;
(6) Research and Development Program to Resolve Safety Issues;
(7) Performance Confirmation;
(8) Administrative and Programmatic Areas;
(9) Structure of the Yucca Mountain Review Plan;
(10) Selected Topics; and
(11) Other Comments.

Throughout this response to public comments, references to Yucca Mountain Review Plan sections use the section numbering that was in Revision 2, ''Draft Report for Comment,'' published in March 2002. As a result of changes to address public comments, Chapter 1 of the draft Yucca Mountain Review Plan is now Appendix A in Revision 2, ''Final Report,'' and Chapter 2 is now Appendix B. Consequently, Chapter 1 is the ''Review Plan for General Information,'' and the ''Review Plan for Safety Analysis Report'' is now Chapter 2. The numbering of sections throughout the plan has been modified accordingly. For example, Section 3.2.1 in the ''Draft Report for Comment'' is now Section 1.2.1 in the ''Final Report,'' and Section 4.2.1.3.7 in the ''Draft Report for Comment'' is Section 2.2.1.3.7 in the ''Final Report.''

1 Introduction

1.1 The U.S. Nuclear Regulatory Commission Staff Licensing Review

Issue 1: Will NRC staff conduct a thorough licensing review?

Comment. A number of commenters expressed concern about the statement in the Yucca Mountain Review Plan ''Introduction'' that NRC staff would conduct limited in-depth, detailed analyses and would not seek scientific precision. Commenters disagreed with the statement, in the Yucca Mountain Review Plan ''Introduction,'' that a licensing review is not intended to be a detailed evaluation of all aspects of facility operations.

Another commenter stated the Yucca Mountain Review Plan appeared to be a menu of options rather than a plan for a thorough regulatory review using a risk-informed, performance-based decision process to review the Yucca Mountain license application.

Commenters stated that the Yucca Mountain Review Plan is subjective in nature and appears to be the same, or more lenient than, the process used for power reactors. Other commenters noted the lack of a performance history to support establishing defense-in-depth measures and safety margins, and suggested that any assumptions must be adequately supported and justified.

A commenter stated the risk-informed basis of the review plan and the lack of definitive criteria allows the U.S. Department of Energy (DOE) to determine the level of importance of almost all aspects of the repository program and allows DOE to determine the level of NRC review effort. A commenter also stated that the licensing review process must not only identify discrepancies but must also document them.

Response. NRC implements a licensing process in which a license applicant has the responsibility to demonstrate that nuclear material can be safely received and possessed, and a nuclear facility can be safely operated, in accordance with regulations. NRC staff licensing review determines whether this demonstration of compliance with regulations is adequate. The regulatory standard for a high-level waste repository at Yucca Mountain is ''reasonable assurance'' for preclosure matters, and ''reasonable expectation'' for postclosure matters. NRC regulations require a license applicant to provide information that is supported by a sound scientific and technical basis.

While NRC staff reviews the entire license application, the amount of information required to demonstrate that regulatory requirements are met may vary depending on the importance of the information. Specifically, for a risk-informed, performance-based regulatory program, NRC staff focuses on those areas that have been shown to have the greatest importance to public health and safety. Areas requiring detailed, NRC staff independent analyses are determined by NRC staff and reviewed to the level necessary to confirm analyses in order to make a reasonable assurance or reasonable expectation determination.

The Yucca Mountain Review Plan facilitates a risk-informed, performance-based review and allows for flexibility in the level of detail required for this review. The Commission addressed the use of a risk-informed, performance-based review for a potential Yucca Mountain repository licensing proceeding in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55732, 55736–55737, November 2, 2001) as follows.

In developing these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation [''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities—Final Policy Statement'' (60 FR 42622; August 16, 1995)]. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (*e.g.*, defense in depth), and performance history are used to: (1) Focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making.

Relevant defense-in-depth, safety margin, and performance history information from other facilities can be applied to a high-level waste repository. Many aspects of design and performance for nuclear facilities are analogous to those that would be used for a high-level waste repository. For example, there is extensive regulatory guidance on design and implementation of radiation health physics programs at nuclear facilities. Because this information would be used in review of a license application for a proposed repository at Yucca Mountain, the Yucca Mountain Review Plan references such regulatory guidance.

To clarify the risk-informed, performance-based review, the ''Introduction'' section of the draft Yucca Mountain Review Plan (now Appendix A) and the ''Acceptance Review'' section (now Appendix B) have been modified, as appropriate, to clarify the scope of NRC staff's licensing review.

Issue 2: Does the Yucca Mountain Review Plan assume that all licensing issues will be resolved and a license for a high-level waste repository at Yucca Mountain will be approved?

Comment. A commenter was concerned that the statement in the draft Yucca Mountain Review Plan ''Introduction'' that NRC staff will resolve issues using its technical understanding implied that all issues will be resolved in favor of licensing.

Response. The language in the draft Yucca Mountain Review Plan ''Introduction'' was not intended to suggest that NRC staff had prejudged the acceptability of a license application for Yucca Mountain. A conclusion as to whether all licensing issues are resolved is premature. NRC staff must first conduct a detailed technical review of the license application and consider whether information in DOE's application satisfies regulatory requirements and demonstrates that public health and safety, and environment can be protected.

NRC staff revised the language in the Yucca Mountain Review Plan to clarify this point.

Issue 3: Does NRC have adequate authority to impose license conditions?

Comment. Two commenters expressed concern that NRC lacked authority to impose and enforce license conditions because the ''Introduction'' of the draft Yucca Mountain Review Plan states that an applicant must agree to any license conditions. The commenters are concerned that applicants can reject or negotiate license conditions with the party having the greater political power having the advantage. The commenters also expressed concern with the statement in the Yucca Mountain Review Plan ''Introduction'' that the Commission has no authority to compel an applicant to come forward with or prepare a different proposal.

Response. The language in the ''Introduction'' was intended to state that license conditions should be discussed with the licensee and imposed only as necessary to meet the reasonable assurance or reasonable expectation standard. It was not intended to suggest that the Commission lacks the authority to impose license conditions. In fact, 10 CFR 63.42 provides that the ''Commission shall include any license conditions, including license specifications, it considers necessary to protect the health and safety of the public, the common defense and security, and environmental values'' in any license issued under 10 CFR part 63.

The Commission has authority to require regulatory compliance and protection of public health and safety and the environment. The Commission, however, cannot mandate that an applicant submit an application or adopt a specific design or analysis. The Commission has the authority to deny an application, grant an application, or grant an application with conditions. Unless the Commission concludes that regulations will be complied with and a facility will be safely operated and material safely received and possessed, a license will not be granted.

The ''Introduction'' section of the Yucca Mountain Review Plan has been modified to clarify NRC's authority.

Issue 4: When will the Yucca Mountain Review Plan be finalized?

Comment. One commenter stated that NRC should consider and incorporate the comments received as soon as practicable after the close of the comment period on the Yucca Mountain Review Plan.

Response. Consistent with the comment and NRC's responsibility to provide guidance on a timely basis, this **Federal Register** notice indicates the availability of the Yucca Mountain Review Plan, NUREG–1804, Revision 2, Final Report, well in advance of the projected December 2004 DOE license application.

2 Acceptance Review

2.1 Acceptance Review Process

Issue 1: Will an acceptance review of a license application for a high-level waste repository at Yucca Mountain be adequate?

Comment. Commenters expressed concern about the statement in the ''Acceptance Review'' section of the draft Yucca Mountain Review Plan that NRC staff does not determine the technical adequacy of information during the acceptance review and the potential for NRC staff to accept biased and erroneous information and the need for NRC to determine the accuracy and adequacy of information.

Response. The purpose of the acceptance review is to determine whether the application can be docketed, that is, whether the application is complete and contains sufficient information to enable NRC staff to conduct its detailed licensing review. The acceptance review does not presuppose what that licensing decision will be and, therefore, does not evaluate the technical adequacy of the information. If the license application passes the acceptance review, the application would be docketed, and the detailed technical review would begin. During the detailed technical review, NRC staff would determine whether the submitted information is accurate and demonstrates that regulatory requirements are met. If the license application fails the acceptance review (for example, it is incomplete and lacks sufficient information to support the

detailed licensing review), the license application would be rejected and returned to DOE, or NRC would identify the deficiencies and request additional information from DOE.

To allow NRC staff sufficient time to conduct a thorough acceptance review, NRC anticipates that the review can reasonably be completed within 90 days after the submission of the license application. During that time, the NRC staff will determine whether the application is complete and contains sufficient information for the NRC staff to conduct a detailed technical review. If the application is found acceptable for docketing, a notice would published in the **Federal Register** offering an opportunity for a formal adjudicatory hearing and public participation in the licensing process.

The ''Acceptance Review'' section of the Yucca Mountain Review Plan has been modified to clarify the purpose of the acceptance review.

Issue 2: What does completeness of information mean with respect to the acceptance review?

Comment. One commenter questioned the validity of the option ''Accept, request additional information'' that is contained within the checklist in the draft Yucca Mountain Review Plan section on Acceptance Review. The commenter expressed concerned that this option could lead to the incorrect impression that specific issues had been resolved, when in fact, more information is required for the detailed technical review.

Another commenter stated that use of the term ''complete,'' in the Acceptance Review section of the draft Yucca Mountain Review Plan is confusing and recommended that this section be clarified to state that the degree of information available and appropriate for specific subject areas in the review plan may vary with the stage of repository development.

Response. The use of the option ''accept, request additional information'' is consistent with other NRC regulatory programs and the purpose of an acceptance review.

An acceptance review is conducted to determine whether the application is acceptable for docketing, that is, whether the application is complete and contains sufficient information to support a detailed licensing review. An application could be found deficient in an acceptance review due to the failure to submit required documents, or because there are omitted sections, illegible figures, or missing analyses.

If deficiencies are limited, NRC staff can proceed with a detailed licensing review while awaiting additional specific information from the applicant, provided the applicant provides omitted information in a timely manner.

The NRC staff decision, at the acceptance review stage, to accept or reject an application would be based on consideration of the submitted information and the importance of the missing information for beginning the detailed technical review.

The ''Acceptance Review'' section of the Yucca Mountain Review Plan has been modified to clarify the purpose of the acceptance review.

3 General Information

3.1 Content of the General Information Section of the Yucca Mountain Review Plan

Issue: What is the nature of the inspection and testing, of waste forms and waste packages listed in the ''General Information'' section of the draft Yucca Mountain Review Plan?

Comment. One commenter asked the purpose of the inspection and testing of waste forms and waste packages included in the ''General Information'' section of the Yucca Mountain Review Plan. Another commenter asked whether Naval reactor fuel would be inspected.

Response. Section 3.1, ''General Information,'' of the draft Yucca Mountain Review Plan provides procedures and acceptance criteria for review of general information that is required to be in a license application for a high-level waste repository at Yucca Mountain in accordance with 10 CFR 63.21(b)(1). Review Method 2, ''General Nature of the Geologic Repository Operations Area Activities,'' of this section provides guidance to NRC staff to confirm that DOE has provided a summary description of the proposed geologic repository operations area operations, including information on plans for the inspection and testing of waste forms and waste packages as they are received. The associated Acceptance Criterion 2 specifies that these plans should have been provided. The ''Review Method'' indicates that a detailed technical review of this information would be conducted using Section 4.5.6, ''Plans for Conduct of Normal Activities, Including Maintenance, Surveillance, and Periodic Testing,'' of the draft Yucca Mountain Review Plan.

The purpose of the inspection and testing plans is to ensure that waste forms and waste packages arriving at a repository are intact and are functioning properly. Should waste forms or waste packages not be intact or not functioning properly, DOE would be required to take actions to place them in a safe condition.

DOE has the authority and the responsibility to characterize, inspect, and monitor Naval reactor fuel. Additionally, the characteristics of Naval fuel and its associated materials and compounds must be considered in DOE's demonstration of compliance with preclosure and postclosure performance objectives.

No changes to the Yucca Mountain Review Plan were made as a result of this comment.

3.2 Adequacy of Site Characterization

Issue 1: Would there be a need for additional site characterization work once a license application for a potential high-level waste repository at Yucca Mountain is submitted?

Comment. Commenters expressed concern about Acceptance Criterion 3 in Section 3.5, ''Description of Site Characterization Work,'' of the draft Yucca Mountain Review Plan. This acceptance criterion addresses limitations that would qualify the descriptions of site characterization work and notes that the license application would have to identify any ''additional site characterization work necessary to increase basic scientific understanding of any significant feature, event, and process.'' The commenters asked why a license application would be accepted if the applicant had not finished site characterization work or did not have a scientific understanding of any feature, event, or process. Other commenters noted that other licenses issued for shorter period are not granted until the applicants have completed their evaluations and that incomplete site characterization should not be relegated to the ''Performance Confirmation Program'' or to the ''Research and Development Program to Resolve Safety Questions.''

Response. A license for a potential high-level waste repository at Yucca Mountain can not be granted unless the applicant has demonstrated, and NRC has determined, regulatory requirements are met. Under 10 CFR 63.15, DOE is required to conduct a program of site characterization, with respect to the Yucca Mountain site, before DOE submits a license application. The statement in the review plan acknowledges that knowledge about the site and repository will evolve over the life-cycle of a repository as the required performance confirmation program continues in accordance with 10 CFR 63, subpart F. The objectives of the performance confirmation program is to confirm the assumptions, data and analyses that led to the findings that

permitted construction of the repository and subsequent emplacement of waste. Per the requirements of 10 CFR 63.131, the program must provide data that indicate, where practicable, whether ''[a]ctual subsurface conditions encountered and changes to those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review.'' Also, the performance confirmation program must be started during site characterization and continue until permanent closure.

This section of the Yucca Mountain Review Plan has been modified to clarify the site characterization description.

Issue 2: Should the definition of the location and characteristics of the reasonably maximally exposed individual be clarified?

Comment. One commenter stated that Review Method 2 of draft Yucca Mountain Review Plan, Section 3.5, ''Description of Site Characterization Work,'' incorrectly stated that the location and characteristics of the reasonably maximally exposed individual had already been specified by regulation. The commenter argued that it is the responsibility of DOE to propose these details in its license application.

Response. The Yucca Mountain Review Plan text has been revised consistent with 10 CFR 63.312 to reflect the required location and characteristics of the reasonably maximally exposed individual.

3.3 Material Control and Accounting Program

Issue 1: What level of detail is appropriate for the material control and accounting program for a construction authorization?

Comment. One commenter noted that the information on material control and accounting activities may be in rudimentary form and not as detailed as other areas at the construction authorization stage. Commenters concluded that the related information would not need to be complete at the time of construction authorization application. Commenters further suggested that the license application should describe the material control and accounting program and contain a commitment to meet the requirements at 10 CFR 63.78.

Response. Pursuant to 10 CFR part 63, there are specific requirements for the material control and accounting program that go beyond a simple commitment at the time of application for a construction authorization. Pursuant to 10 CFR 63.21(b), a license application must contain a description of the material control and accounting program to meet the requirements of 10 CFR 63.78, including design basis information, an assessment of potential impact of the material control and accounting program on design features, and a description of physical aspects of the material control and accounting program.

The introductory paragraph to Section 3.4, ''Material Control and Accounting Program,'' of the draft Yucca Mountain Review Plan has been modified to clarify these requirements.

Issue 2: How will spent nuclear fuel and high-level radioactive waste in storage be inventoried?

Comment. One commenter noted that there are no specific guidelines in the Yucca Mountain Review Plan for a detailed inventory process of spent nuclear fuel and high-level radioactive waste after the waste is placed within sealed disposal canisters. Another commenter stated that inventory of emplaced waste would be ensured by controlling access to the subsurface.

Response. The Yucca Mountain Review Plan states, in accordance with 10 CFR 63.21, that the applicant must provide a description of how physical inventories of the repository will be planned, conducted, assessed, and reported. Consistent with the performance-based regulations in 10 CFR part 63, the Yucca Mountain Review Plan does not prescribe the methods for a demonstration of compliance. Accordingly, the applicant has the flexibility to design and implement a material control and accounting program that meets regulatory requirements.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 3: Under what conditions would spent nuclear fuel or high-level waste be transferred out of the geologic repository operations area?

Comment. One commenter asked for a definition of conditions that would require movement of waste from a repository.

Response. The geologic repository operations area is defined by 10 CFR part 63 as a high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted. As the Commission has previously indicated (66 FR 55732, 55743, November 2, 2001) ''[w]aste retrieval is intended to be an unusual event only to be undertaken to protect public health and safety.''

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 4: Should the Yucca Mountain Review Plan define the quantity of material that would initiate reporting the loss of nuclear materials?

Comment. One commenter suggested that the review methods and acceptance criteria of draft Yucca Mountain Review Plan Section 3.4, ''Material Control and Accounting Program,'' that address reporting requirements for lost nuclear material should apply not only to a significant quantity, but to any quantity of material that may be missing. Another commenter asked who would be responsible for preventing theft of special nuclear material.

Response. NRC must be notified of any loss of special nuclear material.

As is the case for other NRC-licensed facilities, the licensee, in this case DOE, is responsible for the safe and secure operation of the facility and for safe receipt and possession, including prevention of theft of nuclear material. NRC staff will review the license application to determine whether DOE has adequate physical protection and material control and accountability programs. Additionally, if a license is issued, NRC staff would conduct inspections to verify whether physical protection, and material control and accountability programs, are being properly implemented.

The term ''significant quantity'' was deleted from this section of the Yucca Mountain Review Plan.

Issue 5: Should the Yucca Mountain Review Plan address storage of emplaced waste?

Comment. One commenter expressed concern that the statement ''the reviewer should consider that emplaced waste is stored until the repository is closed'' in the Yucca Mountain Review Plan implies (because of requirements in 10 CFR 72.72) that physical inventory would be required at least yearly for waste packages in the subsurface. The commenter suggested deleting this statement, arguing that 10 CFR 63.2 defines disposal as ''the emplacement of radioactive waste in a geologic repository with the intent of leaving it there permanently,'' which distinguishes disposal from storage operations. The commenter believes that the inventory aspect of the material control and accounting program could be met by controlling access to the subsurface, in conjunction with the use of Material Status Reports and the requirements in 10 CFR 63.71(b) for a record of movement of wastes within the geologic repository operations area.

Response. DOE has the flexibility to demonstrate appropriate techniques for meeting material control and accounting requirements. The statement addressing storage of emplaced waste has been removed.

3.4 Physical Protection

Issue 1: How would sensitive physical security plan information be protected?

Comment. Numerous commenters expressed concern about the level of protection from public access that would be provided for Yucca Mountain physical protection plans, programs, and procedures.

Response. Yucca Mountain physical protection plan information submitted to NRC staff for review and approval would be handled as Safeguards Information. Safeguards Information is protected from unauthorized disclosure in accordance with NRC regulations at 10 CFR 73.21. Access would be limited to those persons with an established ''need to know.''

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 2: Will NRC staff require a physical protection plan to be submitted with the license application?

Comment. Numerous comments were received regarding whether a physical protection plan must be submitted with a license application. The commenters were concerned that there would not be adequate information in the plan and that the plan should be a complete and comprehensive document at the time of application submission.

Response. Pursuant to 10 CFR 63.21(b)(3), DOE must submit ''A description of the detailed security measures for physical protection of high-level radioactive waste in accordance with section 73.51 of this chapter. This plan must include the design for physical protection, the licensee's safeguards contingency plan, and security organization personnel training and qualification plan. The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with such requirements.'' The applicant must be knowledgeable as to the requirements in 10 CFR 73.51 and must design the requirements into the facility during the engineering and design phase of the project. After the issuance of a construction authorization, the applicant would submit a baseline physical protection plan for technical review to enable the NRC staff to determine whether the requirements of 10 CFR 73.51 are met. Revisions to the physical protection plan will be submitted for technical review as needed should requirements or design specifications warrant a change in security methods and procedures.

Modifications were made to the Yucca Mountain Review Plan to clarify the requirements for physical protection information.

Issue 3: Are physical protection requirements appropriately reflected in the Yucca Mountain Review Plan?

Comment. One commenter stated that the draft Yucca Mountain Review Plan sets forth physical protection requirements beyond those required by regulations. For example, 10 CFR 73.51(d)(4) requires daily random patrols for the protected area, but the draft Yucca Mountain Review Plan adds that a minimum of two patrols per security duty work shift should be conducted, unless the facility is in a remote area where more patrols may be necessary. Also, 10 CFR 73.51(d)(8) requires redundant communications capability, but the draft Yucca Mountain Review Plan adds a requirement that diverse systems should be used to ensure communications. In addition, the commenter recommends that the Yucca Mountain Review Plan simply state that DOE should commit to implementing the requirements of 10 CFR 73.51.

Response. The Yucca Mountain Review Plan is a guidance document and cannot impose regulatory requirements. The Yucca Mountain Review Plan has been revised consistent with the requirements in 10 CFR 73.51.

Issue 4: Should the Yucca Mountain Review Plan indicate that a designated response force could be used for security response?

Comment. One commenter suggested that for consistency with regulations, the Yucca Mountain Review Plan should indicate that DOE may use a designated response force rather than a local law enforcement authority in response to physical security threat.

Response. The Yucca Mountain Review Plan was modified to allow use of a designated response force, consistent with 10 CFR part 73.

Issue 5: Does the Yucca Mountain Review Plan include realistic measures for verifying the effectiveness of the physical protection system?

Comment. One commenter noted that the draft Yucca Mountain Review Plan statement in Section 3.5, ''Physical Protection Plan,'' that verification of the physical protection system should be conducted on-site by the reviewer before plan approval should be deleted. The commenter noted that on-site verifications cannot be performed at the construction authorization stage and that this statement was inconsistent with other Yucca Mountain Review Plan statements that address only how the system will be designed, tested, and maintained.

Response. The Yucca Mountain Review Plan was modified to remove the statement that on-site verification of the physical protection system was required before plan approval at the construction authorization stage.

4 Preclosure Period

4.1 Preclosure Operations

Issue 1: What procedures will be used to control processes and event sequences during the operational phase of a repository?

Comment. One commenter questioned control of processes and events that might occur during operations at a repository. The commenter asked for details of procedures that would be implemented in specific cases.

Response. As is the case for other facilities regulated by NRC, operations related to safety or waste isolation must be performed using formal procedures. These procedures must address routine operations as well as emergencies. At a high-level waste repository, the procedures would also reflect the results of the preclosure safety analysis, to the extent applicable, which includes hazards identification, consequence evaluation, and risk assessment.

Operating procedures would be evaluated before approval for receipt and possession of waste and would continue to be evaluated under the NRC inspection program that would be in place during the entire operational period of a repository.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 2: What are specific operating limits, parameters, or design criteria for the repository preclosure period?

Comment. Commenters asked questions relating to specific operating limits, parameters, or design criteria for the operating period of a repository. Commenters also asked how NRC could evaluate the adequacy of a preclosure safety analysis if the design contained in the license application was not final.

Response. Specific operating limits, parameters, and design criteria are not included in the Yucca Mountain Review Plan. DOE must define these parameters. The review methods and acceptance criteria in the Yucca Mountain Review Plan are flexible rather than prescriptive because the regulations at 10 CFR part 63 are risk-informed and performance-based.

Pursuant to 10 CFR 63.21, the application must be as complete as possible in the light of information that

is reasonably available at the time of docketing. The regulations also require that DOE update the application to permit a timely review before the issuance of a license. These requirements also apply to the repository design.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 3: What is the meaning of the term ''operational period''?

Comment. One commenter asked for a definition of the term ''operational period'' as used in Section 4.1.1.1, ''Site Description as It Pertains to Preclosure Safety Analysis,'' of the draft Yucca Mountain Review Plan. The commenter asked whether the term includes emplacement only or also post-emplacement performance monitoring.

Response. A definition of the term ''operational period'' is found in 10 CFR 63.102(c), which states:

> * * * A period of operations follows the Commission's issuance of a license. The period of operations includes the time during which emplacement of waste occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing openings to the repository. Permanent closure represents the end of the performance confirmation program; final backfilling of the underground facility, if appropriate; and the sealing of shafts, ramps, and boreholes.

Since this definition is included in 10 CFR part 63, no changes were made to the Yucca Mountain Review Plan.

4.2 Waste Retrieval Operations

Issue 1: Does the Yucca Mountain Review Plan adequately address waste retrieval operations?

Comment. Commenters raised questions regarding waste retrieval. One commenter asked for: (i) Any assumptions associated with waste retrieval; (ii) the time frame after closure for retrieval; and (iii) the number of years after closure during which it would be possible to retrieve waste. The same commenter stated that once waste retrieval criteria are established, they must not be watered down. A commenter stated that a ''high-speed, fast and dirty'' retrieval procedure should be established to respond to sudden, catastrophic events. Other commenters stated that the Yucca Mountain Review Plan should require DOE to physically show it can remotely emplace and retrieve disposal canisters.

Response. The Commission has previously addressed issues related to retrievability of waste from a high-level waste repository at Yucca Mountain (66 FR 55743, November 2, 2001) and indicated that a physical demonstration of retrievability would not be necessary for a construction authorization.

> Some commenters were concerned that NRC's proposed regulations required DOE to submit plans for retrievability, but did not require an actual demonstration that the plans were feasible. Some commenters suggested that the NRC should require DOE to demonstrate the feasibility of its retrieval plans. * * * If necessary to protect public health and safety, waste package retrieval in a deep geologic repository would be a first-of-a-kind endeavor with unique engineering and geotechnical challenges. The Commission recognizes that the retrieval operation would be an unusual event, and may be an involved and expensive operation (U.S. Nuclear Regulatory Commission, ''Staff Analysis of Public Comments on Proposed Rule10 CFR part 60, 'Disposal of High-Level Radioactive Wastes in Geologic Repositories,' '' Office of Nuclear Regulatory Research, NUREG–0804, December 1983; p. 11). As such, DOE can expect that its plans and procedures in this area will receive extensive, detailed review by the NRC staff as part of any construction authorization review. The feasibility and reasonableness of DOE's retrieval plans will be reviewed by the NRC staff at the time of the license application submittal. * * * However, the Commission does not envision that DOE will need to build full-scale prototypes of its retrieval systems to demonstrate that its retrieval plans are practicable at the time of construction authorization. Rather, DOE needs to design (and build) the repository in such a way that the retrieval option is not rendered impractical or impossible.

With regard to the time frame for waste retrieval, the Commission stated (66 FR 55743, November 2, 2001):

> Some commenters expressed a belief that the period of waste package retrieval could be accomplished beyond 50 years, and there should be flexibility for extending the period of retrievability to longer time periods. One commenter suggested that the repository should be monitored to determine if there will be problems (*e.g.*, too high a temperature, too much water inflow) that would require the waste to be retrieved. The same commenter suggested that stewardship of the waste be maintained (indefinitely) so that waste could be made available for future energy needs. * * * The 50-year limit on waste retrieval operations was adopted from the generic requirements found at Part 60. At the time Part 60 was first promulgated, the Commission solicited comment on what was then a proposed 100-year retrieval period (46 FR 35282; July 8, 1981). However, after an analysis of public comments, it was determined that the Commission's earlier proposal was excessive, and the shorter 50-year period was decided [up]on (U.S. Nuclear Regulatory Commission, ''Staff Analysis of Public Comments on Proposed Rule 10 CFR part 60, 'Disposal of High-Level Radioactive Wastes in Geologic Repositories,' '' Office of Nuclear Regulatory Research, NUREG–0804, December 1983). In specifying this time period, the Commission noted that the 50-year period was ''provisional'' and subject to possible modification (*i.e.*, longer periods) in light of both the planned waste emplacement schedule and completion of the performance confirmation program and a review of those results. After 50 years of waste emplacement operations and performance confirmation, the Commission previously reasoned, it is likely that significant technical uncertainties will be resolved, thereby providing greater assurance that the performance objectives will be met. It should be noted that DOE is free to design the repository for retrieval periods greater than 50 years. In fact, the Commission understands that DOE is contemplating working designs that may provide for a retrieval period of up to 300 years. * * * Thus, as recommended in this comment, allowance for longer waste retrieval periods greater than 50 years is permitted under the regulation. As for longer retrieval periods that would permit the recovery of the high-level waste as a potential resource, the Commission has previously noted that its retrieval provision is not intended to facilitate recovery. Waste retrieval is intended to be an unusual event only to be undertaken to protect public health and safety.

The Commission also generally addressed assumptions about waste retrieval (66 FR 55743, November 2, 2001):

> One commenter inquired as to the disposition of the waste if it is determined that retrieval is necessary. * * * Part 63 does not specifically address any required actions for the handling of retrieved waste from an operating geologic repository, but * * * Section 63.21(c)(7) [in the final rule] does require that DOE's Safety Analysis Report include a description of its plans for the alternate storage of the radioactive wastes, should retrieval be necessary. Retrieved waste would need to be controlled in compliance with applicable regulations at the time of retrieval.

DOE must justify in a license application any assumptions used in its plans for waste retrieval. DOE must demonstrate that the repository is designed to allow retrieval in a manner that would protect health and safety as well as keeping radiation exposures as low as is reasonably achievable. Neither the Nuclear Waste Policy Act nor 10 CFR part 63 include a requirement for an expedited retrieval in case of sudden catastrophic events, however, NRC would require actions necessary to protect health and safety.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 2: Does the Yucca Mountain Review Plan adequately address plans for alternate storage of waste?

Comment. One commenter stated that DOE did not address alternate storage of waste in the Yucca Mountain Final Environmental Impact Statement. The commenter asked whether, by including

alternative storage in the Yucca Mountain Review Plan, NRC is inferring its expectation that a license application for a high-level waste repository at Yucca Mountain would cover alternate storage. The commenter noted the Yucca Mountain Review Plan is specific about assumed elements of the repository system, but does not describe such elements earlier in the review plan. The commenter suggested that the Yucca Mountain Review Plan be revised to include NRC expectations of the specific elements of the repository system that would be the subject of a license application.

Response. A review of DOE plans for alternate storage of waste is included within the Yucca Mountain Review Plan because these plans are specifically required by 10 CFR 63.21(c)(7), which requires that DOE's Safety Analysis Report include a description of plans for the alternate storage of the radioactive wastes should retrieval be necessary. Retrieved waste would need to be controlled in compliance with applicable regulations at the time of retrieval. Beyond requiring such plans, the regulations have no specific requirements on this subject. Accordingly, the three components of the related Review Method and Acceptance Criterion for reviewing plans for alternative storage of waste (*i.e.*, the physical location and boundary of the proposed alternate storage area are adequately defined; the proposed alternate storage area is sufficient to hold the waste; and the area is adequate to protect workers and the public during the transport of the waste to alternate storage) are sufficient.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

4.3 Criticality

Issue: What equipment would be available for addressing criticality accidents?

Comment. One commenter asked what equipment would be available in a repository for high-level waste at Yucca Mountain to deal with criticality accidents.

Response. Pursuant to 10 CFR 63.112(e)(6), DOE must address the potential for criticality accidents during the preclosure period of operations. After any criticality risks have been established, NRC will evaluate whether equipment should be provided to deal with such accidents.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

4.4 Preclosure Safety Analysis

Issue 1: Is the definition of probability associated with Category 2 event sequences adequate?

Comment. One commenter stated that the use of one chance in 10,000 over 300 years is illogical and non-conservative considering the trillions of curies that would be present in a high-level waste repository at Yucca Mountain. The commenter stated that if the criteria for excluding events from Category 2 are based on opinion and speculation, the information could be biased, erroneous, or misleading. The commenter stated that the criteria for Category 2 must be broadened to overcome these inadequacies and that NRC staff needs to be careful when excluding catastrophic events from Category 2.

Response. A licensing review for a high-level waste repository at Yucca Mountain will be conducted in an objective manner to determine whether information is accurate and regulatory standards are met. Error in analyses will be addressed in NRC staff's review of analysis, design, and operations.

The Commission addressed the Category 2 criteria in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55741–55742, November 2, 2001) as follows.

> The Commission agrees that the basis for determining the probability for design basis events and what initiating events should be considered in the safety analysis should be clarified. * * * the Commission has revised the rule for clarity as follows: (1) A new term ''initiating event'' is defined; (2) the present term ''design basis event'' is replaced with a new term ''event sequence''; and (3) Section 63.102(f) is revised to clarify the scope of the preclosure safety analysis and the requirements for the inclusion or exclusion of specific, naturally-occurring, and human-induced hazards in the safety analysis.
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> Initiating events are to be considered for inclusion in the preclosure safety analysis for determining event sequences only if they are reasonable (*i.e.*, based on the characteristics of the geologic setting and the human environment, and are consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public).
>
> * * * * *
>
> Within the context of the ISA (PSA), DOE is expected to identify the relevant initiating events and event sequences and estimate potential radiologic exposures. Part 63 provides flexibility to DOE in selecting an appropriate approach for estimating doses, including selection of pertinent exposure pathways and the degree of conservatism or realism to include in the analysis. DOE will need to defend and support whatever approach it selects for identifying initiating events and analyzing event sequences. In the selection of a particular approach, DOE will need to consider the uncertainties and limitations associated with a particular method of analysis and data.

Regulation of nuclear facilities requires realistic or reasonably conservative approaches that take into account importance to safety, technical complexity, and the degree and nature of any associated uncertainty. These concepts underlie the ''reasonable assurance'' and ''reasonable expectation'' determinations that would be applied in reviewing the DOE license application. However, the Yucca Mountain Review Plan recognizes that, consistent with a risk-informed, performance-based approach, DOE has the flexibility to select an approach that could include reasonably conservative analyses.

The Commission addressed the issue of conservatism in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55739–55740, November 2, 2001).

> Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process * * *. The Commission does not believe that NRC's use of ''reasonable assurance,'' as a basis for judging compliance, causes focus on extreme values (*i.e.*, tails of distributions) for representing the performance of a Yucca Mountain repository. Further * * * if the Commission is called on to make a decision * * * the Commission will consider the full record before it. That record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) * * *. The Commission could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public.
>
> The Commission is satisfied that a standard of ''reasonable expectation'' allows it the necessary flexibility to account for inherently greater uncertainties in making long-term projections of a repository's performance. The Commission agrees with EPA and others that it is important to not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence * * *. The Commission expects that the required analyses of postclosure performance will focus on the full range of defensible and reasonable parameter distributions, and that they should not be constrained only to extreme physical situations and parameter values. For other determinations regarding compliance of the repository with preclosure objectives, the Commission will retain a standard of ''reasonable assurance'' consistent with its practice for other licensed operating facilities subject to active licensee oversight and control.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 2: Has an evaluation of the characteristics of the controlled area been included in the Yucca Mountain Review Plan?

Comment. One commenter stated that no mention could be found in the Yucca Mountain Review Plan of the size and location of the controlled area. The commenter argued that specification of the controlled area is a key factor in the licensing process and must be addressed in a license application and in the NRC review.

Response. The controlled area is defined by 10 CFR part 63.302. This is addressed in Section 4.1.1.1, ''Site Description as It Pertains to Preclosure Safety Analysis'', of the draft Yucca Mountain Review Plan.

The Yucca Mountain Review Plan was modified to include reference to the controlled area, where appropriate.

Issue 3: Does the Yucca Mountain Review Plan adequately evaluate radiation exposures during the preclosure operations at a potential high-level waste repository at Yucca Mountain?

Comment. One commenter noted that the Yucca Mountain Final Environmental Impact Statement indicated that the predominant radiological impacts during the preclosure period would be from radon releases. The commenter stated that the Yucca Mountain Review Plan does not address radiological safety associated with potential radon releases and associated worker exposures. The commenter suggests that these potential safety issues be added to the review.

Response. Safety issues related to radiation exposure, including radon, during the preclosure period are covered in the Yucca Mountain Review Plan. DOE is required by 10 CFR 63.111 to use a preclosure safety analysis to evaluate compliance with performance objectives for the preclosure period. A preclosure safety analysis proceeds from an identification of hazards, events, and event sequences to assessments of consequence and risk. This process includes an evaluation of radiation hazards and risks. The Yucca Mountain Review Plan reflects a thorough review of DOE's preclosure safety analysis as set forth in Section 4.1.1, ''Preclosure Safety Analysis,'' of the draft Yucca Mountain Review Plan.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

4.5 Structures, Systems, and Components of the Subsurface Facility

Issue: Will the design, construction, control, and quality assurance of the waste canisters be adequate?

Comment. Commenters expressed a number of concerns about the standards to be used for waste canisters. One commenter raised a number of concerns regarding how the quality assurance requirements would be met for structures, systems, and components important to safety, safety controls, and measures to ensure availability of safety systems.

Response. If the waste canisters are important both to safety and to waste isolation, their design, manufacture, and performance would be subject to NRC's quality assurance requirements. These requirements are defined in 10 CFR part 63, subpart G, and are consistent with NRC's quality assurance standards for other nuclear facilities. DOE must satisfy these quality assurance requirements by performing planned and systematic actions necessary to provide confidence that the geologic repository and its structures, systems, and components will perform satisfactorily.

The regulations require that quality assurance requirement for systems, structures, and components be evaluated during a licensing review for a high-level waste repository at Yucca Mountain. NRC staff would use the quality assurance requirements in 10 CFR part 63, subpart G to determine whether the program was adequate.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

4.6 Alternative Designs

Issue: Should alternative designs be examined in a license application for a high-level waste repository at Yucca Mountain?

Comment. One commenter was concerned that nowhere in the Yucca Mountain Review Plan is there clear direction to NRC staff reviewers to ensure that DOE, in its application and supporting documents, has adequately considered alternative repository designs. The commenter noted that the subject is touched on in draft Yucca Mountain Review Plan Section 4.3, ''Research and Development Program to Resolve Safety Questions,'' however, this section does not specifically address alternative designs, outside of the scope of the research and development program, to resolve safety questions.

The commenter noted that because DOE's design could be contested during licensing, and Nye County, Nevada, the Nuclear Waste Technical Review Board, and others believe that a cooler repository would reduce uncertainties in long-term performance, NRC staff reviewers should take steps to ensure that the DOE license application is complete and of high quality on that issue. The commenter concluded that a thorough and comprehensive test of DOE's design, specifically with respect to reducing thermal effects and the potential for water to contact the waste packages, should be a minimum test of the adequacy and completeness of a DOE license application for a high-level waste repository at Yucca Mountain.

Response. The question as to whether DOE must consider alternative repository designs was previously addressed by the Commission in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55748–55749, November 2, 2001) as follows:

> The Commission agrees with the comments and has removed [this requirement to evaluate alternative designs] from the regulations. The NRC review should focus on the safety aspects of DOE's proposed approach. DOE should only be required to propose alternatives from its proposed approach in areas where the NRC review determines DOE's approach is deficient. When developing proposed part 63, the NRC staff adopted this requirement from 10 CFR part 60, the existing generic NRC high-level waste disposal regulation, which contains a similar requirement in 10 CFR 60.21(c)(1)(ii)(D). At the time of the issuance of part 60, DOE objected to this specific requirement with basically the same argument presented for Part 63. In the ''Statement of Considerations'' for part 60 (published in [the] **Federal Register** [notice] on June 21, 1983; 48 FR 28194), the Commission justified the requirement by stating ''If the Commission finds, on the basis of its review, that the adoption of some alternative design feature would significantly increase its confidence that the performance objectives would be satisfied, and that the costs of such an approach are commensurate with the benefits, it should not hesitate to insist that the alternative be adopted.''
>
> The decision to require DOE to submit alternatives for certain site design features was a discretionary action on the part of the Commission as nothing (in either the Atomic Energy Act of 1954, as amended, or the Nuclear Waste Policy Act of 1982, as amended) required the Commission to obtain information on alternative designs at the site level. At the time part 60 was initially published (1983), the Commission implemented an appropriate regulatory framework for a generic program facing many uncertainties. Multiple sites with very different geological settings were under consideration. The NRC's generic HLW regulations had to address the resolution of a large number of technical issues in the relative short licensing review period established by the Nuclear Waste Policy Act of 1982. With all the uncertainties in the program, the Commission believed it was important to require design alternatives be submitted with the application to increase the probability of NRC approval of the license application within the three-year schedule mandated by Congress.

The Commission has revisited the decision to require submission of alternative designs. Specifically, the Commission no longer believes this information should be submitted with a license application and, accordingly, has removed this requirement. To protect public health and safety and the common defense and security, which is the NRC's mandate under the Atomic Energy Act of 1954 as amended, the Commission will closely scrutinize the design proposed by DOE. Consistent with this mandate, the new part 63 is designed to be a risk-informed, performance-based regulation which establishes overall repository performance objectives. DOE must demonstrate that the repository meets the performance objectives. The NRC review is an audit of DOE's demonstration to determine if we agree that the performance objectives have been met. If the NRC believes that the site does not meet the performance objectives within uncertainties addressed in the analysis, then it is DOE's responsibility to either defend its current design or propose an alternative design that can meet the NRC acceptance criteria.

Because thermal effects and the potential for water to contact the waste packages may be important considerations in the design of a potential high-level waste repository at Yucca Mountain, DOE would need to provide an assessment of the thermal operating range for a design in its license application. The NRC staff will determine, before docketing, whether the information provided is sufficient for NRC to conduct its review.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

5 Postclosure Period

5.1 Consistency With Postclosure Requirements in 10 CFR Part 63

Issue 1: Should the text in the postclosure sections of the Yucca Mountain Review Plan be modified to more closely reflect the language of 10 CFR part 63?

Comment. Several commenters identified places where the text of the Yucca Mountain Review Plan could be revised to better reflect the language of postclosure requirements in 10 CFR part 63, subpart L. One commenter noted several places where text should be modified to refer to the dose to the reasonably maximally exposed individual rather than more general terms such as average annual dose. Another commenter noted incorrect citations in Section 4.2.1.3.14.4 of the draft Yucca Mountain Review Plan. Additional comments indicated several locations where the draft Yucca Mountain Review Plan text on postclosure public health and environmental protection (Section 4.2.1.4) could be modified to be more consistent with the requirements of 10 CFR part 63, subpart L.

Response. The text in the Yucca Mountain Review Plan should accurately reflect the language and intent of 10 CFR part 63.

The Yucca Mountain Review Plan has been modified, as appropriate, to provide correct references to the postclosure requirements in 10 CFR part 63. Text citations for the required characteristics of the reference biosphere [10 CFR 63.305(a–d)] have been corrected as needed. Also, text in Section 4.2.1.4 of the draft Yucca Mountain Review Plan has been modified to improve consistency between the review methods and acceptance criteria and the postclosure public health and environmental standards specified in 10 CFR part 63, subpart L.

Issue 2: Is the description of the representative volume consistent with NRC regulations in 10 CFR 63.312?

Comment. Several commenters stated that the use of a representative volumes of groundwater in Sections 4.2.1.3.12, ''Representative Volume,'' and 4.2.1.4.3, ''Analysis of Repository Performance that Demonstrates Compliance with Separate Ground-Water Protection Standards,'' of the draft Yucca Mountain Review Plan is not consistent with U.S. Environmental Protection Agency and NRC implementation regulations at 10 CFR part 63.

Response. Section 4.2.1.3.12 of the draft Yucca Mountain Review Plan confuses the concept of water demand for the postclosure individual protection standard with the concept of the representative volume of water for the postclosure ground-water protection standard.

The postclosure individual protection standard at 10 CFR 63.111 requires that DOE demonstrate the reasonably maximally exposed individual would receive an annual cumulative effective dose equivalent of no more than 150 microsieverts. Under 10 CFR 63.312(c), the reasonably maximally exposed individual will use ''well water with concentrations of radionuclides based on an annual water demand of 3,000 acre-feet.'' 10 CFR part 63 also mandates use of the representative volume of water concept in demonstrating compliance with the separate ground-water protection standards. The definition of the representative volume of water also specifies a volume of 3,000 acre-feet per year; however, the applicant must also define the dimensions of this volume using one of two specified methods.

The Yucca Mountain Review Plan has been modified to clarify these requirements.

Issue 3: Are the review methods and acceptance criteria for evaluating the demonstration of compliance with the human-intrusion standard adequate?

Comment. One commenter stated that the review methods and acceptance criteria for evaluating the demonstration of compliance with the human-intrusion standard are not complete or consistent with NRC regulations at 10 CFR part 63. For example, the commenter expressed concern that the review methods in Section 4.2.1.4.2.1, ''Demonstration of Compliance with the Human Intrusion Standard,'' of the draft Yucca Mountain Review Plan indicate that the review need only confirm that performance assessment for human intrusion is performed during the 10,000-year regulatory time period. The commenter also noted that, if the projected doses from an intrusion reach the reasonably maximally exposed individual after the 10,000-year regulatory time period, 10 CFR 63.321 requires DOE to include the results of the analysis and its basis in the Yucca Mountain environmental impact statement. The commenter also stated that the draft Yucca Mountain Review Plan does not call for DOE to identify the specific mechanism for radionuclide transport from a breached waste package to the saturated zone.

Response. The review methods in Section 4.2.1.4.2.2 of the draft Yucca Mountain Review Plan have been modified to clarify that the human-intrusion performance assessment should be conducted regardless of the estimated time of the intrusion. The review methods have also been modified to note that 10 CFR 63.321 requires that exposures to the reasonably maximally exposed individual that might result from human intrusion and occur after the 10,000-year regulatory time period are to be included in the Yucca Mountain environmental impact statement. In addition, the regulations at 10 CFR 63.322 require that DOE consider the transport of radionuclides in ground water through the borehole to the saturated zone. The Yucca Mountain Review Plan, however, is guidance for NRC staff safety review and will not be used to review DOE's environmental impact statement. Environmental reviews would be performed according to the requirements of 10 CFR 51.109, and applicable guidance.

The review methods in Section 4.2.1.4.2.2 of the draft Yucca Mountain Review Plan have been modified for clarification.

5.2 Multiple Barriers

Issue 1: Will the Yucca Mountain Review Plan consider limitations of each barrier's capability?

Comments. Commenters argued that numerous unresolved questions remain with respect to the engineered and natural barriers (*e.g.*, durability of the waste package, amount of water flowing into repository drifts) that raise concerns regarding how the Yucca Mountain Review Plan considers the limitations in barrier capabilities. Commenters asked a number of questions regarding how specific systems, subsystems, and components of the repository would perform.

Response. In accordance with 10 CFR 63.115, NRC staff's review of the capability of each barrier relied upon by DOE will include consideration of uncertainty in the behavior of the barriers. Additionally, the barrier capability is to be described in terms of the approaches used in the performance assessment, which include potential limitations in barrier capabilities, through consideration of uncertainty in parameters; alternative conceptual models; and degradation, deterioration, and alteration processes of the engineered barriers. Each of the model abstractions (*i.e.*, degradation of engineered barriers, flow paths in the saturated zone) in the Yucca Mountain Review Plan includes consideration of potential limitations in the representation of the repository barriers. The Yucca Mountain Review Plan supports a detailed review of repository barriers and provides understanding of the intended function of each of the barriers and of the potential limitations regarding individual barrier performance. The concerns noted in the comment must be adequately addressed in a DOE license application for a high-level waste repository at Yucca Mountain.

Section 4.2.1.1, ''System Description and Demonstration of Multiple Barriers,'' of the draft Yucca Mountain Review Plan indicates that: (i) There are no quantitative limits placed on individual barriers or categories of barriers; and (ii) the intent of the review is to understand the capability of each barrier to perform its intended function and the relationship of that barrier's role to limiting radiological exposure in the context of the overall performance assessment.

Issue 2: Does the Yucca Mountain Review Plan appropriately describe potential barrier functions?

Comment. The commenter recommended that the exact wording from the definition of barrier in 10 CFR part 63 (that is, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste) be used to describe the potential functions of the barriers in Sections 4.2.1.1.1, ''System Description and Demonstration of Multiple Barriers,'' of the draft Yucca Mountain Review Plan.

Response. Use of the exact wording from the definition of barrier in 10 CFR 63.2 to describe the potential functions of the barriers in the Yucca Mountain Review Plan is appropriate and the Yucca Mountain Review Plan has been modified accordingly.

Issue 3: Should the Yucca Mountain Review Plan specify that a specific natural or engineered barrier be the primary barrier for the repository?

Comment. Some commenters were concerned that current expectations for the waste package to be corrosion-resistant for more than 10,000 years reduce the requirement that the repository include natural or geologic barriers. One commenter requested that the repository be required to be substantially geologic. Another commenter asked that Section 4.2.1.1, ''System Description and Demonstration of Multiple Barriers,'' of the draft Yucca Mountain Review Plan clarify that neither natural nor engineered barriers need be the primary barriers for containing radionuclides, reflecting that overall performance of the repository is important, rather than subsystem requirements.

Response. The regulations at 10 CFR 63.115 require DOE to identify the barriers of the repository system, describe the capabilities of the barriers, and provide the technical basis for each barrier's capability. The Yucca Mountain Review Plan addresses this requirement.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

5.3 Screening Features, Events, and Processes

Issue 1: How will NRC determine whether the appropriate features, events, and processes have been included in a postclosure performance assessment?

Comment. Several commenters expressed concern whether DOE would provide a complete evaluation of features, events, and processes, in developing its postclosure performance assessment (similar in concept to the Category 1 and 2 initiating events in the preclosure section of the Yucca Mountain Review Plan). One commenter proposed establishing a Category 3 that would encompass natural and man-made events and stated that the total system performance assessment should include an analysis of climate changes over 10,000 years. Additional comments on specific potential disruptive scenarios included were provided.

Several commenters cited the current DOE design plans calling for titanium drip shields as evidence that the Yucca Mountain environment contains significant amounts of water, and expressed concern that this water and the geochemically oxidizing environment for the proposed repository would lead to corrosion of the waste packages. Commenters also expressed concern about the performance of Alloy C–22 and cladding, and requested specific technical information on engineered materials performance.

Another commenter expressed concern that if the consequence of an event were high, it must be considered in the performance assessment, regardless of the probability of its occurrence. The same commenter took exception to the use of the term ''credible natural events,'' arguing that this was an artificial means of removing disruptive events from further consideration for mitigation. One commenter asked whether microbial influenced events were being evaluated.

Response. Consideration of features, events, and processes, especially those with potentially adverse effects, is a key part of the performance assessment process. A number of features, events, and processes have been or are being considered relevant to the performance of the proposed repository at Yucca Mountain. DOE has the responsibility to prepare the postclosure performance assessment and demonstrate compliance with the postclosure performance objectives of 10 CFR 63.113. In meeting the performance objectives, the regulations in 10 CFR 63.114 require DOE to consider pertinent features, events, and processes. As described in Section 4.2.1.2, ''Scenario Analysis and Event Probability,'' of the draft Yucca Mountain Review Plan, it is anticipated that DOE would screen an initial list of features, events, and processes that include the issues raised by the commenters. The purpose of the screening is for DOE to develop a final list that will be considered in detail in its postclosure performance assessment. DOE must provide a technical basis for the inclusion or exclusion of features, events, and processes from the performance assessment. As defined in 10 CFR 63.114(d), one of the screening

criteria is to establish as credible only those events with a probability of occurrence of one chance in 10,000 per year over 10,000 years. As discussed in Section 4.2.1.2 of the draft Yucca Mountain Review Plan, DOE must provide the technical basis for screening events based on probability.

Based on prelicensing exchanges and on earlier iterative performance assessments provided by DOE, NRC anticipates that DOE would include many of the features, events, and processes identified by the commenters (*e.g.*, climate change, volcanic disruption, seismic activity, glaciation, groundwater transport) in its performance assessment. If other features, events, and processes identified by the commenter are excluded from the postclosure performance assessment, DOE must include the technical bases for the exclusions as expressed by 10 CFR 63.114(e). Part of this technical basis must include site characterization information such as groundwater chemistry, location of faults and igneous features, and geomorphology.

To support the postclosure performance assessment, DOE is required to submit data on the hydrology, geochemistry, and geology of the Yucca Mountain site by 10 CFR 63.114(a). Specific information of the type identified in several comments (groundwater temperature, fluoride concentration, C–22 alloy performance) is the responsibility of DOE. NRC staff will evaluate the adequacy of this information as part of a licensing review, using the review methods and acceptance criteria presented in the Yucca Mountain Review Plan.

No changes were made to the Yucca Mountain Review Plan in response to these comments.

Issue 2: Why do the review methods in the Yucca Mountain Review Plan specify time and extent of past patterns of natural events?

Comment. A comment stated that review methods for probability models refer to site-specific information that NRC staff should consider during a review of a license application. The commenter argued that this information is too prescriptive and based on NRC judgements of what is important for probability models. The commenter asks for a more generalized discussion in Review Methods 2 and 3 of Section 4.2.1.2.2, ''Identification of Events with Probabilities Greater Than 10^{-8} Per Year,'' of the draft Yucca Mountain Review Plan. The same commenter also expressed concern that the past patterns of natural events in the Yucca Mountain region provide overly prescriptive information for NRC staff review of probability models.

Response. In using Acceptance Criterion 2 of Section 4.2.1.2.2, NRC staff would consider the past patterns of natural events in the Yucca Mountain region. This acceptance criterion is used considering the range of information that NRC staff may consider with respect to the timing and general extent of past events. Thus, Review Method 2 provides general guidance regarding the timing (*e.g.*, ''past igneous activity since about 12 million years'') and extent (*e.g.*, ''within about 50 kilometers of the proposed repository site'') of past natural events to provide a basis for use of Acceptance Criterion 2. DOE is not restricted to these general definitions for past patterns of natural events and may provide any technical basis that it believes demonstrates compliance with the requirements of 10 CFR 63.114(a)(4).

As noted in Acceptance Criterion 2, an appropriate technical basis for probability estimates would be based on past patterns of natural events in the Yucca Mountain region. Acceptable probability models would be based on past events in the Yucca Mountain region; however, these models may incorporate additional considerations, as deemed appropriate by DOE. These additional considerations would be reviewed by NRC staff in a licensing review.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 3: Why do the review methods call for use of independently developed probability models?

Comment. A commenter stated that Section 4.2.1.2.2, ''Identification of Events with Probabilities Greater Than 10^{-8} Per Year,'' of the draft Yucca Mountain Review Plan, refers to the use of independently developed probability models. The commenter noted that more specific guidance to reviewers is needed for the use of independent probability models, and that use of independent models would bias NRC staff reviews.

Response. In its licensing review, NRC staff considers information submitted by the license applicant and results of independent NRC staff analyses. The use of independent probability models enables NRC staff to focus on those areas that are most important to risk consistent with a risk-informed, performance-based approach.

Guidance on the use of independent models in Review Method 3 of Section 4.2.1.2.2 has been modified.

Issue 4: Is it appropriate to relate igneous activity to other geologic processes?

Comment. One commenter asserted that igneous activity is incorrectly related to other geologic processes. The commenter also stated that the use of tectonic models in Acceptance Criterion 3 and Review Method 3 of Section 4.2.1.2.2, ''Identification of Events with Probabilities Greater Than 10^{-8} Per Year,'' of the draft Yucca Mountain Review Plan is overly prescriptive and that the consideration of information from comparable volcanic systems outside the Yucca Mountain region in Review Method 4 of Section 4.2.1.2.2 also appears overly prescriptive.

Response. Review Method 3 in Section 4.2.1.2.2 states ''Assess whether igneous-activity probability models are consistent with the range of tectonic models used to assess other geological processes, such as seismic source characterization, site geological models, and patterns of ground-water flow.'' This statement does not relate igneous activity to other geologic processes through tectonic processes. Rather, it instructs reviewers to evaluate the consistency between tectonic models used in igneous activity probability models with tectonic models used to evaluate other geologic processes. Consistent use of tectonic models for different, relevant geologic processes may provide support for probability models.

Not all parameters used in a probabilistic volcanic hazard assessment for Yucca Mountain would necessarily need to consider information from comparable volcanic systems. Paragraph 2 of Review Method 4 of Section 4.2.1.2.2 has been rewritten to clarify this point.

Issue 5: Does the Yucca Mountain Review Plan contain excessively prescriptive requirements with regard to the use of analog information to assess the effects of igneous activity on repository performance?

Comment. The commenter argued that use of analog information ''to the extent possible'' as discussed in Acceptance Criterion 3 of Section 4.2.1.2.2 is overly prescriptive and suggested use of analog information only ''to the extent appropriate.'' The same commenter also suggested changing requirements for the accuracy of probability models to avoid excess prescriptiveness.

Response. DOE may submit any information it believes will satisfy the requirements of 10 CFR 63.114(a)(4). The use of information from analog volcanic fields, to the extent appropriate, could be used as a basis for model justification.

The text of the Yucca Mountain Review Plan has been modified to

clarify that analog information should be used to the extent appropriate.

5.4 Model Abstraction

Issue 1: What site characterization information would be included in the postclosure performance assessment?

Comment. A number of commenters provided examples of features, events, and processes that they contended should be included in the postclosure performance assessment. These included general lists of information on characteristics of the geologic and hydrologic setting, an inventory of potential corrosives from waste canisters, and climatologic information. One commenter stated that the performance assessment should include types of indirect information that may indicate the occurrence of past natural disruptive events. The same commenter noted that the general description should include trends in seismic and volcanic activity, as well as a study of volcanically active regions in the Cascade Mountains, and should evaluate the possibilities of similar activity at Yucca Mountain.

Response. DOE has the responsibility to prepare the postclosure performance assessment and demonstrate compliance with the performance objectives of 10 CFR 63.113. 10 CFR 63.114 requires DOE to provide a technical basis for the inclusion or exclusion of features, events, and processes in the performance assessment. This technical basis would include site characterization information.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 2: How would uncertainty be addressed in the model abstractions used in the postclosure performance assessment?

Comment. A number of comments were provided on uncertainties related to the engineered barriers and natural system, and how these uncertainties would be addressed in the review of a postclosure performance assessment. One commenter expressed concern that there were inconsistencies in how the alternative conceptual models are to be used in evaluating uncertainty in the postclosure performance assessment. Another commenter asked how NRC would consider uncertainties in reviewing DOE's performance assessment and requested more detail on the role uncertainty would play in establishing priorities for the licensing decision. Another commenter noted concerns about the basis for performance assessment model abstractions expressed in letters from the Advisory Committee on Nuclear Waste to NRC Chairman Richard Meserve (September 28, 2001; and January 17, 2002).

Response. Accounting for uncertainty in estimating repository performance is an important factor in the evaluation of DOE's license application. The regulations at 10 CFR 63.114 and 63.304 require the performance assessment to provide for the full range of defensible and reasonable parameters and models, and account for uncertainty. NRC staff review will evaluate the nature and magnitude of the uncertainties and the impact of uncertainty on repository performance. Consideration of alternative models is one means of evaluating the conceptual model uncertainty in performance assessment. The postclosure performance assessment requirements in 10 CFR 63.114(c) require DOE to consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding and to evaluate the effects that alternative conceptual models have on the performance of the geologic repository. The Yucca Mountain Review Plan provides guidance regarding review of these requirements and that DOE has the flexibility to demonstrate compliance, consistent with a risk-informed, performance-based licensing approach.

As discussed in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR pp. 55747–55748, November 2, 2001), the Commission recognizes ''* * * the uncertainties inherent in evaluating a first-of-a-kind facility like the repository and in estimating system performance over very long time periods (*i.e.*, 10,000 years).'' In response to these uncertainties, NRC modified 10 CFR part 63 to require that DOE include uncertainty in its postclosure performance assessment and provides sufficient information to allow NRC to evaluate DOE's uncertainty analysis. For example, 10 CFR 63.114(b) requires DOE to account for uncertainties and parameter variability, and to provide the technical bases for its treatment of uncertainty in the postclosure performance assessment. In addition, DOE is required by 10 CFR 63.114(c) to provide additional assurances that uncertainty in the information (*e.g.*, evaluation of site characterization data) used to develop the performance assessment has been evaluated by consideration of alternative conceptual models of features and processes that are consistent with available data and current scientific understanding. The regulation at 10 CFR 63.113(g) provides that DOE conduct corroborative testing of its performance assessment to the extent feasible, and for DOE to use additional bases beyond performance assessment to compensate for uncertainty and to provide confidence that the postclosure performance objectives of 10 CFR 63.113 are met. For example, 10 CFR part 63, subpart F, requires that a performance confirmation program confirm that the behavior of the barriers of the repository system is consistent with assumptions in the performance assessment. Further, 10 CFR 63.113 and 10 CFR part 63, subpart G, require use of multiple barriers and a quality assurance program.

As described in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55747–55748, November 2, 2001):

> The Commission will consider all these requirements in determining whether it has sufficient confidence (*i.e.*, reasonable expectation) that DOE has demonstrated or has not demonstrated the safety of the repository. Specification of an acceptable level of uncertainty is neither practical nor appropriate due to the limited knowledge currently available to support any such specification and the range of uncertainties that would need to be addressed. The Commission believes the approach to performance assessment in the proposed rule, which includes the treatment of uncertainty, is appropriate and has retained this approach in the final rule.
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> * * * * *
>
> If NRC were to specify an acceptable level of uncertainty, the specified value would be somewhat arbitrary because: (1) Understanding of the site is evolving as site studies continue; (2) repository design options are still being evaluated; and (3) differences in the types of uncertainties (*e.g.*, variability in measured parameters, modeling assumptions, expert judgment, *etc.*) complicate the specification.
>
> * * * * *
>
> Although the Commission does not require an ''accurate'' prediction of the future, uncertainty in performance estimates cannot be so large that the Commission cannot find a reasonable expectation that the postclosure performance objectives will be met (*see* discussion under ''Reasonable Expectation'') [Section 1.4, 66 FR 55739–55740]. At this time, the Commission is not aware of any information that suggests the uncertainties are so large that NRC will be unable to make a regulatory decision regarding the safety of a potential repository at Yucca Mountain.

Each of the performance assessment model abstractions, provided in Section 4.2.1.3, ''Model Abstraction,'' of the draft Yucca Mountain Review Plan, provides specific review methods and acceptance criteria that address both data uncertainty (parameter variability) and model uncertainty (whether the model is adequate and appropriate). Therefore, the review methods and

acceptance criteria in the Yucca Mountain Review Plan provide sufficient guidance to evaluate DOE's treatment of uncertainty against the requirements of 10 CFR part 63.

Suggested editorial changes were made to the Yucca Mountain Review Plan in response to these comments.

5.5 Compliance With Postclosure Public Health and Environmental Standards

Issue: What is the expected groundwater contamination from the repository?

Comment. One commenter expressed concern that the proposed repository at Yucca Mountain could have long-term impacts on groundwater quality.

Response. The groundwater pathway is a potential exposure pathway as identified in previous DOE and NRC performance assessments for a proposed high-level waste repository at Yucca Mountain. Groundwater will be protected provided DOE can demonstrate that the groundwater protection standard in 10 CFR part 63.331 and 63.332 are met.

Several Sections 4.2.1.3.6, ''Flow Paths in the Unsaturated Zone,'' 4.2.1.3.7, ''Radionuclide Transport in the Unsaturated Zone,'' 4.2.1.3.8, ''Flow Paths in the Saturated Zone,'' and 4.2.1.3.9, ''Radionuclide Transport in the Saturated Zone,'' of the draft Yucca Mountain Review Plan provide specific review methods and acceptance criteria to evaluate whether DOE's abstraction of groundwater flow and radionuclide transport satisfies the postclosure performance objectives at 10 CFR 63.113. In addition, as discussed in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55758, November 2, 2001):

> The Commission has commented previously that an individual, all-pathway dose limit of either 0.15–mSv (15–mrem) or 0.25–mSv (25–mrem) TEDE ensures that the risks from all radionuclides and all exposure pathways, including the ground-water pathway, are acceptable and protective. The EPA itself acknowledged, in publishing final standards for Yucca Mountain, that an ''* * * Individual Protection Standard is adequate in itself to protect public health and safety.'' However, ultimately, the EPA had to make the decision whether to include separate requirements for groundwater protection and the final EPA standards for Yucca Mountain include such requirements for the purpose of protecting groundwater. Therefore, as required by law, final Part 63 requirements incorporate final U.S. Environmental Protection Agency standards for Yucca Mountain at 40 CFR part 197, including separate ground-water protection requirements. These requirements, sections 197.30 and 197.31, appear in the final 10 CFR part 63 regulations as sections 63.331 and 63.332, respectively.

The Yucca Mountain Review Plan has been revised to ensure consistency with the groundwater protection standards in 10 CFR 63.331 and 10 CFR 63.332. These changes, combined with the review methods and acceptance criteria in Section 4.2.1.3, ''Model Abstraction,'' of the draft Yucca Mountain Review Plan, will ensure that the NRC review of DOE's license application takes into account DOE's demonstration of compliance with the applicable postclosure performance objective and groundwater protection standards.

5.6 Postclosure Monitoring

Issue: Would there be control over the Yucca Mountain site after permanent closure and license termination?

Comment. Several commenters expressed concern about the extent of NRC oversight activities after permanent closure of a high-level waste repository at Yucca Mountain. One commenter asked about plans for monitoring ambient radiation in the drifts and tunnels after permanent closure. Another commenter requested information on security and physical protection plans for the repository after permanent closure. Other commenters asked NRC to provide a postclosure plan for waste retrieval and whether the Yucca Mountain Review Plan addressed possible postclosure terrorist problems and the postclosure performance assessment.

Response. If DOE is granted a license, it may seek an amendment under 10 CFR 63.51 for permanent closure of a high-level waste repository at Yucca Mountain. As part of its amendment request, DOE must submit its program for continued oversight, including a description of a program for postclosure monitoring of the repository, and a detailed description of measures to regulate or prevent activities that could impair the long-term performance of the repository. NRC will review the adequacy of DOE's programs for continued oversight following permanent closure and decontamination of surface facilities.

DOE may also apply for license amendment to terminate the license pursuant to 10 CFR 63.52. NRC will terminate the license if it finds that final waste disposition conforms to DOE's plan, as amended and approved as part of the license, and the geologic repository operations area conforms to plans for permanent closure and decontamination or decontamination and dismantlement of surface facilities.

Section 122 of the Nuclear Waste Policy Act provides for retrieval of any spent fuel for any reason pertaining to public health and safety, or the environment, or for the purpose of permitting the recovery of the economically valuable contents of spent fuel. The implementing regulations at 10 CFR part 63 provide for retrieval of waste before permanent closure of the repository. During a period of waste disposal that may extend over several decades, DOE is required by license to maintain performance confirmation, monitoring, and security programs to ensure that the natural and engineered components assumed to operate as barriers during permanent closure of the repository are functioning as intended and anticipated at the time of license application. Thus, it is DOE that must legally provide security for the Yucca Mountain site. NRC staff will evaluate whether the security measures would be adequate to protect the site.

NRC will conduct an inspection program to ensure that DOE complies with its license. DOE is not required to have plans in place for retrieval or security after permanent closure of the repository.

The draft Yucca Mountain Review Plan Section 4.5.8, ''Controls to Restrict Access and Regulate Land Uses,'' examines compliance with the requirements for ownership and control of interests in land. The scope of these regulatory requirements includes, among others, land acquisition and withdrawal, acceptability of controls through and for permanent closure, control over surface and subsurface estates, and design of monuments to identify the site. Draft Yucca Mountain Review Plan Section 4.5.9, ''Uses of the Geologic Repository Operations Area for Purposes Other Than Disposal of Radioactive Wastes,'' examines procedures for conduct and continuing oversight of proposed activities. These two sections of the Yucca Mountain Review Plan enable NRC staff to determine whether adequate security would be provided for the site after permanent closure.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

6 Research and Development Program To Resolve Safety Issues

6.1 Scope of the Research and Development Program To Resolve Safety Questions

Issue: What is the appropriate scope of the research and development program to resolve safety issues?

Comment. One commenter expressed concern about the text in the ''Areas of Review'' for Section 4.3, ''Research and

Development Program to Resolve Safety Questions,'' of the draft Yucca Mountain Review Plan. The commenter stated that the research and development program was not intended to address the adequacy of site characterization or natural barriers, as the review plan currently states. The commenter argued that the adequacy of information on these two topics should be demonstrated in the license application as submitted and that it is not acceptable to use the research and development program to resolve safety questions to complete work that should have been done before the submittal of the license application.

Response. The applicable regulation, 10 CFR 63.21(c)(16), states that the license application shall contain ''an identification of those structures, systems, and components of the geologic repository, both surface and subsurface, that require research and development to confirm the adequacy of design. For structures, systems, and components important to safety and for the engineered and natural barriers important to waste isolation, DOE shall provide a detailed description of the programs designed to resolve safety questions, including a schedule indicating when these questions would be resolved.''

The research and development program to resolve safety questions should be used appropriately to address questions as appropriate. The regulation recognizes that some research and development programs are confirmatory in nature while others resolve safety questions. The license application should contain sufficient information on site characterization and natural barriers to enable NRC staff to conduct a detailed review of the application.

The text of Section 4.3 of the draft Yucca Mountain Review Plan has been revised to narrow the scope of the research and development program to resolve safety questions.

7 Performance Confirmation

7.1 Performance Confirmation Program

Issue 1: Are the acceptance criteria for performance confirmation monitoring and testing too prescriptive?

Comment. Commenters stated that Section 4.4, ''Performance Confirmation Program,'' of the draft Yucca Mountain Review Plan is more prescriptive than 10 CFR part 63 regarding specific performance confirmation testing and monitoring citing specific examples including cases where the language used in Section 4.4 was not identical to language used in subpart F of 10 CFR part 63. One commenter stated that Section 4.4, like 10 CFR part 60, is prescriptive with regard to requirements for particular barriers, and inconsistent with the risk-informed, performance-based approach in 10 CFR part 63. Commenters stated that DOE would determine the parameters, measurements, and observations that are appropriate for inclusion in the performance confirmation program based on their importance to confirming repository performance and to the uncertainties in that performance.

Response. DOE has the responsibility to determine the parameters, measurements, and observations to be included in a performance confirmation program. As stated in ''Statement of Considerations'' for final 10 CFR part 63 (66 FR 55745, November 2, 2001) ''The Commission believes that it is DOE's responsibility to specify the important geotechnical and design parameters to be evaluated through observation and measurement during construction and operation, subject to NRC approval through review and evaluation of the license application. DOE will provide this information in their performance confirmation plan included in the license application. If necessary, NRC staff will provide guidance to DOE in this area through pre-licensing interactions and/or the Yucca Mountain Review Plan.''

With respect to the examples of inconsistency with language in subpart F of 10 CFR part 63, the recommended changes were accepted, and Section 4.4 has been modified accordingly. However, the fact that a specific parameter or process is not mentioned in the regulation, does not necessarily mean that parameter or process should not be considered for inclusion in the performance confirmation program. Such decisions should be made using risk-informed, performance-based approach. In developing 10 CFR part 63, the Commission chose not to adopt an approach that would prescribe in detail the specifics and limits of a performance confirmation program to allow DOE the flexibility to develop a focused and effective performance confirmation program (66 FR 55745, November 2, 2001).

Section 4.4 of the draft Yucca Mountain Review Plan has been modified for consistency with 10 CFR part 63.

Issue 2: Are the acceptance criteria for procedures supporting the performance confirmation program too prescriptive?

Comment. Commenters stated that the draft Yucca Mountain Review Plan is more prescriptive than 10 CFR part 63 regarding procedures supporting the performance confirmation program. A commenter stated that DOE should have the flexibility to determine the context in which procedures need to be developed and that such procedures may be developed after a license application for construction authorization is submitted. There were also a number of detailed comments specifically related to procedures supporting a performance confirmation plan.

Response. The Yucca Mountain Review Plan recognizes that DOE has the flexibility to devise the performance confirmation program consistent with regulations, including how to document its methods or procedures (whether directly in a performance confirmation plan or indirectly by reference to another document). Any procedures referenced would be subject to either NRC staff review or inspections.

Accordingly, Section 4.4 of the draft Yucca Mountain Review Plan has been revised to delete the word procedures and to be less prescriptive regarding this subject.

8 Administrative and Programmatic Areas

8.1 Record-Keeping Requirements

Issue: What are the requirements for keeping records of the repository and its operations?

Comment. A commenter asked about the plan for keeping records over the 10,000-year life span of a repository at Yucca Mountain and requested that records on private shippers of waste to a repository should include ''* * * liability information, accident records, breached or leaking cask records, judgments, accusations, and penalty records.''

Response. There are a number of record keeping requirements which relate to the repository which address many of the items identified by the commenter. NRC regulations at 10 CFR part 63, subpart D, specify the requirements for maintaining records at a Yucca Mountain high-level waste repository, including those required by the conditions of the license or by rules, regulations, and orders of the Commission, pursuant to 10 CFR 63.71(b). Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area must contain sufficient information to provide a history of the movement of the waste from the shipper through all phases of storage and disposal. The records must be placed in the archives and land-record systems of local, State, and Federal government agencies, and archives elsewhere in the world. The

records are to identify the location of the geologic repository operations area, including the underground facility, boreholes, shafts ramps, and the boundaries of the site, and the nature and hazards of the waste.

DOE must also meet the 10 CFR 63.72 requirement to maintain records of construction in a manner that ensures their usability for future generations. These construction records must include surveys; a description of materials encountered; geologic maps and cross sections; locations and amount of seepage; details of equipment, methods, progress, and sequence of work; construction problems; anomalous conditions encountered; instrument locations, readings, and analyses; location and description of structural support systems; location and description of dewatering systems; details, methods of emplacement, and locations of seals used; and facility design records.

DOE must also maintain the records required by 10 CFR part 72, ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste,'' Subpart D, Sections 72.72, 72.74, 72.76, and 72.78. These additional records include material balance, inventory, and records requirements for stored material; reports of accidental criticality or loss of special nuclear material; material status reports; and nuclear material transfer reports.

DOE would also have to comply with U.S. Department of Transportation requirements for shipment of high-level radioactive waste and with NRC regulations at 10 CFR part 71, ''Packaging and Transportation of Radioactive Material.''

No changes were made to the Yucca Mountain Review Plan in response to this comment.

8.2 Land Ownership and Use

Issue 1: Does the land that might be used for a high-level waste repository at Yucca Mountain belong to Native American Tribes?

Comment. A commenter asked whether, for the purpose of controlling access to a repository at Yucca Mountain, the government was sure that the land does not belong to Native American Tribes. Another commenter asked where the Yucca Mountain Review Plan addressed the requirements for DOE to prove ownership and title to the land. A third commenter contended that the Ruby Valley Treaty of 1863 is being violated because land around the Yucca Mountain site belongs to the Western Shoshone Nation.

Response. NRC regulations at 10 CFR 63.121 require that the geologic repository operations area must be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use. The land must also be free from significant encumbrances such as mining rights, right-of-ways, or rights of entry. DOE must satisfy these regulations in order to be granted a license for a high-level waste repository at Yucca Mountain. In its review of the license application, NRC staff would determine whether DOE has provided information that demonstrates compliance with these requirements. This review is addressed in Section 4.5.8, ''Controls to Restrict Access and Regulate Land Uses,'' of the draft Yucca Mountain Review Plan (Review Method 1 and Acceptance Criterion 1). In addition, the Commission addressed tribal claims regarding Yucca Mountain in the Statement of Considerations for 10 CFR part 63 (66 FR 55766, November 2, 2001):

> The NRC is aware that the Western Shoshone National Council disputes the claim of the United States to have legal title to land that includes the Yucca Mountain site. However, there are Federal court decisions which have addressed these land claim issues and which are binding on both DOE and NRC. Section 63.121 requires that, before NRC licensing of a waste repository at the Yucca Mountain site, DOE must establish that the geologic repository operations area and the site are located in and on land that is either acquired land under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for DOE's use.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

Issue 2: What uses may be made of a geologic repository operations area other than disposal of radioactive waste?

Comment. One commenter was concerned that there might be plans to use a geologic repository operations area for purposes other than disposal of radioactive wastes and stated that building a monitored retrievable storage facility at Yucca Mountain is specifically prohibited by the Nuclear Waste Policy Act.

Response. Section 4.5.9, ''Uses of Geologic Repository Operations Area for Purposes Other than Disposal of Radioactive Wastes,'' of the draft Yucca Mountain Review Plan would be used to evaluate compliance with the 10 CFR 63.21(c)(22)(vii) requirement that a license application must contain ''Plans for uses of the geologic repository operations area at the Yucca Mountain site for purposes other than disposal of radioactive wastes, with 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.''

The regulations require DOE to identify uses that are unrelated to waste disposal. Section 141 of the Nuclear Waste Policy Act prohibits the construction of a monitored retrievable storage facility at Yucca Mountain.

NRC staff will evaluate any such proposed uses if included in a license application for a high-level waste repository at Yucca Mountain, and determine whether such uses are contrary to the Nuclear Waste Policy Act.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

8.3 Expert Elicitation

Issue: What is the appropriate scope for the use of expert elicitation?

Comment. A commenter expressed concerns about the use of expert elicitation in a license application for a high-level radioactive waste repository at Yucca Mountain. The commenter stated that because DOE has had 20 years to obtain data to evaluate the suitability of the Yucca Mountain site, DOE use of expert elicitation should be limited and should not be a substitute for information obtainable during site characterization. The commenter also stated that NRC staff should not allow DOE to substitute expert opinion for data that it was afraid to collect.

Response. It is not acceptable to use expert elicitation as a substitute for information that could have been reasonably obtained during site characterization or to avoid collection of relevant data. The regulations at 10 CFR 63.21(c)(19) requires ''an explanation of how expert elicitation was used.''

Section 4.5.4, ''Expert Elicitation,'' of the draft Yucca Mountain Review Plan uses NUREG–1563, ''Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program'' (NRC, 1996). The NUREG–1563 states, in part:

> In matters important to the demonstration of compliance, the use of formal expert elicitation should be considered whenever one or more of the following conditions exist:
>
> (a) Empirical data are not reasonably obtainable, or the analyses are not practical to perform;
>
> (b) Uncertainties are large and significant to a demonstration of compliance;
>
> (c) More than one conceptual model can explain, and be consistent with, the available data; or

(d) Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative.

NRC staff will apply this guidance in evaluating an application for the construction of a high-level waste repository at Yucca Mountain.

The Yucca Mountain Review Plan text has been modified to specifically state the cited items from NUREG–1563.

8.4 U.S. Department of Energy Organizational Structure

Issue: Should the Yucca Mountain Review Plan discussion of DOE responsibilities for project management be expanded?

Comment. One commenter noted that the license application should contain an evaluation of DOE's procedures for assuring that delegated activities are carried out in accordance with the license and with the Commission's regulations. The commenter noted that DOE would be responsible for safe repository operations, even if certain activities are delegated to a contractor. The commenter stated it is unclear regarding the procedures that DOE must use to manage the overall project, including the delegated activities.

Response. Draft Yucca Mountain Review Plan Section 4.5.3.1, ''DOE Organizational Structure as it Pertains to Construction and Operation of Geologic Repository Operations Area,'' provides guidance to NRC staff to determine whether DOE's procedures governing its project management responsibilities are adequate.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

8.5 Water Rights

Issue: Does the Yucca Mountain Review Plan adequately evaluate whether DOE has obtained the necessary water rights for operation of a high-level waste repository at Yucca Mountain?

Comment. One commenter questioned whether DOE would need to have obtained water rights to accomplish the purposes of the geologic repository operations area. The commenter noted that the phrase ''water rights'' has specific meaning in Nevada and suggests that the Yucca Mountain Review Plan clarify whether DOE is required to have water rights as granted by the State of Nevada or to simply demonstrate that an adequate supply of water is available for the site.

Response. The provisions in Section 4.5.8 of the draft Yucca Mountain Review Plan are based on the requirements regarding water rights specified in 10 CFR 63.121. DOE must obtain ''such water rights as may be needed to accomplish the purpose of the geologic repository operations area.'' In addition, for permanent closure, DOE ''* * * shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.''

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

8.6 License Conditions

Issue: Should the list of proposed license conditions for a high-level waste repository at Yucca Mountain include mitigating actions from the environmental impact statement?

Comment. One commenter expressed concern that the list of areas for which NRC believes DOE should propose license conditions is unnecessarily limited and is not consistent with conditions contained in licenses for other nuclear facilities. The commenter cites, for example, the absence of a provision for adequate off-site emergency response and medical capabilities. The commenter suggested that the revised plan provide a much more comprehensive listing, for consideration of possible license conditions, which would include all measures to mitigate repository system impacts identified within the Yucca Mountain Final Environmental Impact Statement and impact reports prepared by others.

Response. Mitigating actions that might be required as a result of potential environmental impacts of a repository at Yucca Mountain must be addressed by DOE in the Yucca Mountain Final Environmental Impact Statement. The content of the Yucca Mountain Final Environmental Impact Statement is outside the scope of the safety review encompassed by the Yucca Mountain Review Plan. NRC staff will evaluate the Yucca Mountain Final Environmental Impact Statement in accordance with Commission regulations at 10 CFR part 51 and applicable regulations. If appropriate, mitigating actions may be identified as license conditions.

The list of areas for potential license conditions presented in the Yucca Mountain Review Plan guidance is not all-inclusive. Under 10 CFR 63.42, the Commission will impose any conditions, including license specifications, it considers necessary to protect public health and safety, the common defense and security and the environment. NRC staff has modified the section in the Yucca Mountain Review Plan to make reviewers aware that the listing is not intended to be complete. License conditions will be imposed on a high-level waste repository at Yucca Mountain determined based on a review of information presented in the license application, as well as the environmental impact statement, as needed to reach the reasonable assurance or reasonable expectation standard for the repository.

8.7 Quality Assurance

Issue 1: Are Yucca Mountain Review Plan quality assurance acceptance criteria consistent with 10 CFR part 63 requirements and relevant regulatory guidance?

Comment 1. A commenter stated that the draft Yucca Mountain Review Plan applies quality assurance acceptance criteria that seem to exceed or expand on 10 CFR part 63 requirements and relevant regulatory guidance, such as NRC-endorsed consensus standards, American Society of Mechanical Engineers Standard NQA–1, other nuclear facility review plans, and standard industry practice as implemented under 10 CFR parts 21, 50, 70, and 72. The commenter stated that the draft Yucca Mountain Review Plan, therefore, unnecessarily constrains the license applicant's ability to establish quality assurance program implementation methods by setting expectations for specific compliance or implementation methods that are rigid and differ significantly from those applicable to other nuclear facilities regulated by NRC.

Another commenter stated that the draft Yucca Mountain Review Plan quality assurance acceptance criteria are too restrictive, are inconsistent with other NRC criteria for quality assurance program descriptions, and would require continual application of the quality assurance program description change process.

The commenters specified a number of places in the Yucca Mountain Review Plan related to their concerns.

Response 1. The Yucca Mountain Review Plan quality assurance acceptance criteria are consistent with 10 CFR part 63, subpart G, requirements and relevant regulatory guidance. In preparing the Yucca Mountain Review Plan, NRC staff considered many sources of information including consensus standards, American Society of Mechanical Engineers Standard NQA–1, other nuclear facility standard review plans, and standard industry

practice. NRC staff tailored information from those sources to the unique requirements specifically applicable to a Yucca Mountain repository.

As stated in Section 4.5.1, ''Quality Assurance Program,'' of the draft Yucca Mountain Review Plan, DOE has flexibility in defining methods and controls while still satisfying pertinent regulations, and DOE may adopt exceptions and alternatives to the 18 acceptance criteria in the Yucca Mountain Review Plan, provided DOE can otherwise show it satisfies the requirements in 10 CFR part 63.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

Comment 2. Two commenters questioned whether quality assurance acceptance Criteria 19–22, that address software, sample control, scientific investigation, and field surveys, respectively, are necessary and whether these areas are already adequately covered by quality assurance acceptance criteria 1–18.

Response 2. The Yucca Mountain Review Plan quality assurance acceptance criteria are consistent with the quality assurance criteria of 10 CFR part 50, appendix B, which apply to nuclear power plants and fuel reprocessing plants. Criteria 19–22 clarify certain quality assurance requirements in 10 CFR part 50, appendix B, for application to the Yucca Mountain repository. However, these four acceptance criteria did not expand the scope of applicability for quality assurance.

To maintain consistency between the structure in the Yucca Mountain Review Plan and quality assurance requirements in 10 CFR part 63, subpart G, NRC staff has consolidated specific acceptance criteria 19–22 into specific acceptance criteria 3, 8, and 10 as follows: Acceptance Criterion 19, ''Software,'' and Acceptance Criterion 21, ''Scientific Investigation,'' have been consolidated into Acceptance Criterion 3, ''Design Control''; Acceptance Criterion 20, ''Sample Control,'' has been consolidated into Acceptance Criterion 8, ''Identification and Control of Materials, Parts, and Components''; and Acceptance Criterion 22, ''Field Surveys,'' has been consolidated into Acceptance Criterion 10, ''Inspection.''

Issue 2: Are Yucca Mountain Review Plan quality assurance acceptance criteria and review methods more prescriptive than appropriate for a risk-informed, performance-based regulatory approach?

Comment. A commenter argued that many of the quality assurance acceptance criteria and review methods prescribe quality assurance program features more narrowly than is consistent with risk-informed, performance-based principles. The commenter stated that this approach limits the license applicant to a program that is not based on common nuclear industry practice and would place an unnecessary burden on the applicant to justify deviation from the specified approach. The commenter further stated that this approach would result in a description of implementation details in the quality assurance program description that may be more appropriate for inclusion in detailed implementing procedures.

The commenter identified a number of specific locations in the Yucca Mountain Review Plan that are related to these comments.

Response. The Yucca Mountain Review Plan quality assurance acceptance criteria are appropriate for a risk-informed, performed-based quality assurance program. The Yucca Mountain Review Plan quality assurance acceptance criteria provide guidance on issues associated with the uniqueness of the geologic repository. Exceptions from Yucca Mountain Review Plan approaches are acceptable, so long as the quality assurance requirements in 10 CFR part 63 are satisfied. Exceptions and alternatives to the acceptance criteria contained in the Yucca Mountain Review Plan may be adopted by DOE, provided DOE demonstrates that it can otherwise satisfy the requirements of part 63.

A quality assurance program description written in compliance with 10 CFR part 63, subpart G, is specifically tailored to the proposed high-level waste repository at Yucca Mountain and the Yucca Mountain Review Plan incorporates appropriate NRC quality assurance guidance. The Yucca Mountain Review Plan states that, where appropriate, the quality assurance program description may reference a commitment to comply with certain provisions of documents identified in Section 4.5.1.5 of the draft Yucca Mountain Review Plan and need not repeat the text of the document in the quality assurance program description.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

Issue 3: Should certain text from quality assurance standards that is included in the Yucca Mountain Review Plan be replaced by references to the corresponding text in those standards?

Comment. A commenter stated that many of the more prescriptive acceptance criteria appear to be direct or modified excerpts from references that could be more simply identified as NRC-endorsed sources, allowing the license applicant to maintain flexibility in developing implementation methods, consistent with risk-informed, performance-based principles. The commenter argued that the Yucca Mountain Review Plan should only reference these sources as acceptable means to implement NRC's quality assurance regulations.

A number of specific locations in the Yucca Mountain Review Plan where these comments apply were identified.

Response. Several quality assurance standards referenced in the Yucca Mountain Review Plan were written for a 10 CFR part 50, appendix B-type quality assurance program. Although 10 CFR part 50, appendix B requirements are similar to 10 CFR part 63 quality assurance requirements, unique considerations associated with a geologic high-level waste repository that relies on both natural and engineered barriers pose major differences. Therefore, the Yucca Mountain Review Plan includes text from these quality assurance standards, modified as necessary, in order to provide clear guidance during a license application review. This approach provides guidance on, and background for, the quality assurance elements unique to the geologic repository in one document. Section 4.5.1, ''Quality Assurance Program'' of the draft Yucca Mountain Review Plan states, ''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 draft Yucca Mountain Review Plan and not repeat the text of the document in the quality assurance program.''

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 4: Should the Yucca Mountain Review Plan reference more recent quality assurance standards?

Comment. Three commenters recommended using a more recent edition of standard NQA–1 rather than NQA–1–1983 and revising the text of the Yucca Mountain Review Plan accordingly. Another commenter suggested incorporating Nuclear Safety Standards from July 2002.

Response. NRC endorses standards through the use of regulatory guides. These regulatory guides provide sufficient detail to ensure that programs and activities governed by such standards comply with the applicable regulations.

Licensees with 10 CFR part 50, appendix B, quality assurance programs have committed to using quality assurance standard NQA–1–1983, the latest edition endorsed by NRC in Regulatory Guide 1.28 or committed to the ANSI 45.2 series standards. More recent editions of NQA–1 do not contain sufficient detail to describe how the applicable NRC quality assurance requirements would be satisfied. For example, in NQA–1–1997, many detailed provisions have either been removed from the standard or relocated to a non-mandatory appendix.

However, Section 4.5.1, ''Quality Assurance Program,'' of the draft Yucca Mountain Review Plan provides that ''Exceptions and alternatives to these acceptance criteria and the documents and positions contained in Section 4.5.1.5 of the draft Yucca Mountain Review Plan may be adopted by DOE, provided the applicant can otherwise demonstrate compliance with quality assurance program requirements in 10 CFR part 63.'' Therefore, DOE may propose alternatives to the Yucca Mountain Review Plan quality assurance acceptance criteria, provided adequate justification is submitted to demonstrate that the proposed alternatives adequately describe how the quality assurance requirements of 10 CFR Part 63 will be satisfied.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 5: Which nonmandatory requirements of NQA–1–1983 must be followed?

Comment. A commenter stated that the Yucca Mountain Review Plan is not clear on the use of the ''non-mandatory guidance'' in NQA–1–1983.

Response. Guidance on the use of nonmandatory requirements in NQA–1–1983 is sufficiently clear in the Yucca Mountain Review Plan. Commitment to NQA–1–1983 requirements is subject to exceptions, clarifications, or modifications provided in the Yucca Mountain Review Plan quality assurance acceptance criteria or Paragraph C of ''Regulatory Position,'' of Regulatory Guide 1.28. Any nonmandatory requirements identified in NQA–1–1983 that are not addressed in either the Yucca Mountain Review Plan quality assurance acceptance criteria or Paragraph C of Regulatory Guide 1.28 need not be followed.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 6: Which elements of the quality assurance program should be in place at the time of license application submittal?

Comment. A commenter recommended that the Yucca Mountain Review Plan clearly state which elements of DOE's quality assurance program should be in place at the time of license application submittal. The commenter stated an expectation that, as for nuclear power reactor licensing activities, the quality assurance program description would be submitted to NRC separately from the Safety Analysis Report, well before the quality assurance program is fully implemented. Field procedures would be in place, with follow-on commitments to ensure that planned programmatic activities are implemented.

Response. The time frame for implementation of the quality assurance program is sufficiently clear in the Yucca Mountain Review Plan. Section 4.5.1.3, ''Acceptance Criteria,'' states that ''The DOE quality assurance program and associated quality assurance program controls and implementing procedures regarding activities performed must be in place before activities begin.'' These activities include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; and performance confirmation.

Section 4.5.1.3 of the draft Yucca Mountain Review Plan has been modified to identify these activities.

Issue 7: Should the step-wise licensing approach be applied to the review of the quality assurance program description?

Comment. A commenter recommended that the step-wise licensing approach be applied to the content and level of detail of the quality assurance program description required for the different phases of repository licensing. Another commenter stated that, typically, a quality assurance program description that encompasses all phases of repository construction, operation, and closure, as required by the Yucca Mountain Review Plan quality assurance acceptance criteria, is prepared in stages (*i.e.*, there are specific elements of the quality assurance program description required to be submitted and reviewed for the design and construction phase/activities, whereas others are required to be submitted and reviewed for the operations phase). This commenter also stated that, although some of the elements of the quality assurance program descriptions are similar among licensing steps, there are different policies, organizations, programs, and procedures that will be implemented for each step.

Response. A step-wise licensing approach should be applied to the review of the quality assurance program description. Section 4.5.1.3 of the Yucca Mountain Review Plan has been modified to state the following:

> The U.S. Department of Energy shall establish a quality assurance program to include all activities up to the time of receipt of high-level radioactive waste for disposal in the geologic repository. These activities include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; and performance confirmation. The Yucca Mountain Review Plan will be modified, at the appropriate time, to include facility operation, permanent closure, and decontamination and dismantling of surface facilities. The U.S. Nuclear Regulatory Commission staff should assure that the scope of the Yucca Mountain Review Plan includes those activities described in the U.S. Department of Energy quality assurance program under review. Appropriate conditions should be imposed on quality assurance program and Yucca Mountain Project approvals that reflect the scope of activities described in the quality assurance programs and applications submitted for U.S. Nuclear Regulatory Commission review and approval by the U.S. Department of Energy.

Issue 8: Why are quality assurance program references (Section 4.5.1.5) divided into two groups?

Comment. A commenter stated that the rationale is not clear for division of quality assurance references'' between ''commitments'' and ''noncommitments.''

Response. Identifying the scope of potentially applicable information will facilitate a licensing review and preparation of a more complete license application. The ''commitments'' listing of references is mandatory. Commitments are required to be addressed by DOE. The ''noncommitments'' are not mandatory, but guidance documents that may be used by both DOE and NRC staff reviewers as a source of additional guidance. If noncommitment documents are identified in the license application, NRC staff can refer to these same documents during the review process.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 9: Is it necessary to have both general and specific acceptance criteria for the review of the quality assurance program description?

Comment. A commenter argued that because there are no ''general'' quality assurance requirements identified in the applicable NRC regulations, it is inappropriate to have ''general'' quality

assurance acceptance criteria, in addition to ''specific'' quality assurance acceptance criteria, in the Yucca Mountain Review Plan. The commenter requested clarification as to the difference between the general and specific acceptance criteria and provided specific recommendations for revisions.

Response. The general acceptance criteria in Section 4.5.1.3 of the draft Yucca Mountain Review Plan provide NRC staff with a broad view of the overall quality assurance requirements and the specific criteria provide the details of the individualized quality assurance requirements. Reiteration of the requirements is useful to promote consistency in NRC staff review.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 10: Is the Yucca Mountain Review Plan guidance for review of the quality assurance program description appropriate for performance assessment?

Comment. A commenter recommended revisions to reflect a quality assurance program geared to performance assessment, rather than only experimental activities and calculations.

Response. A preclosure safety analysis and a postclosure performance assessment regulatory requirements are important components in evaluating the Yucca Mountain project. The quality assurance terminology is appropriate and adequate for performance assessment because it has been proven effective in a wide range of applications.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 11: How much overlap is appropriate between acceptance criteria in Section 4.5.1, ''Quality Assurance Program,'' and Section 4.2.1.3, ''Model Abstraction''?

Comment. A commenter stated that the data and model criteria in Acceptance Criterion 21 of Section 4.5.1.3, ''Acceptance Criteria'' appear to be redundant or inconsistent with the technical requirements in Section 4.2.1.3, ''Model Abstraction.''

Response. In response to other comments, Acceptance Criterion 21, ''Scientific Investigation,'' has been consolidated into Acceptance Criterion 3, ''Design Control.'' This change has not changed the scope of the quality assurance requirements.

Issue 12: How should quality assurance software requirements be applied?

Comment. Two commenters requested clarification as to which types of software were subject to quality assurance software requirements. One commenter argued that quality assurance software requirements should apply only to software developed to support a safety or waste isolation function.

Response. Section 4.5.1, ''Quality Assurance Program,'' of the Yucca Mountain Review Plan has been modified to specify that it applies to software developed to support functions important to safety or to waste isolation.

Issue 13: Should the discussion of the corrective action program be clarified?

Comment. Two commenters recommended that the discussion of the corrective action program be clarified with respect to terminology, procedures, and the role of quality assurance staff in the program.

Response. The discussion of the corrective action program in Section 2.5.13 of the draft Yucca Mountain Review Plan is appropriate as written because it is consistent with widely accepted and proven approaches to corrective action in quality assurance programs.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 14: Is the review of quality control and certification for nuclear waste transportation canisters and casks and their fabrication included in the review of the quality assurance program description?

Comment. A commenter asked whether NRC will review the quality control for the manufacturing processes used to produce nuclear waste transportation canisters and casks. The commenter also asked whether NRC will specify conditions or criteria for certification of canisters and whether manufacturing processes, construction, and quality control issues are periodically reviewed by NRC to ensure adherence to approved certification criteria and that canisters are constructed to required specifications.

Response. Under 10 CFR part 71, NRC is responsible for certifying the designs of shipping casks that may be used to move commercial nuclear waste by truck or rail to Yucca Mountain. NRC will also review the manufacturing processes used to produce transportation canisters and will periodically inspect the manufacturing processes and construction to ensure that design criteria are adhered to and that transportation canisters are constructed to applicable specifications.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 15: What is the scope of license applicant qualification information that should be covered in the review of the quality assurance program description?

Comment. A commenter recommended that NRC provide for a thorough review of the background, experience, management capability, and track record of the license applicant in the Yucca Mountain Review Plan.

Response. DOE, in accordance with 10 CFR 63.21(c)(22), is required to include information about its organizational structure as it pertains to construction and operation of the repository, and the personnel qualifications and training requirements. NRC has a program in place to observe detailed technical and programmatic audits of DOE's Yucca Mountain project and its contractors. Various aspects of DOE's quality assurance program, specifically with regard to the Yucca Mountain project, are routinely evaluated by NRC. However, only the license applicant activities specifically related to a Yucca Mountain repository fall under the scope of the regulatory requirements in 10 CFR part 63.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 16: Should the text be revised to address various consistency, clarification, editorial, and format issues?

Comment. A commenter provided several comments on various consistency, clarification, editorial, format, and other miscellaneous issues.

Response. Section 4.5.1, ''Quality Assurance Program'' of the draft Yucca Mountain Review Plan has been modified, as appropriate, to incorporate various editorial changes for consistency, clarification, and format issues related to this comment.

9 Structure of the Yucca Mountain Review Plan

9.1 Level of Detail

Issue: Is the level of detail in the Yucca Mountain Review Plan appropriate to guide the review of a license application?

Comment. Commenters noted that the degree of specification in review methods varies substantially throughout the Yucca Mountain Review Plan. In some sections, presumptions are made as to what is important to safety or waste isolation by including discussion of specific design solutions (*e.g.*, backfill). The commenters consider these assumptions to be inconsistent with the risk-informed, performance-based regulations at 10 CFR part 63. The

commenters suggested that the Yucca Mountain Review Plan be revised to clarify that the applicant will specify structures, systems, and components important to safety and natural and engineered barriers important to waste isolation, compatible with the risk-informed, performance-based regulations. The commenters noted that since these presumptions occur throughout the document, a general discussion in the Yucca Mountain Review Plan ''Introduction'' could address the issue.

One commenter stated that the general description of the geologic repository must include detailed descriptions of surface and interim storage facilities. The commenter also stated that the general information review should focus on natural threats to repository integrity and identified a number of such specific potential threats. Another commenter requested more detailed information on the status of activities to meet requirements for ownership and control of interests in land and on the schedule for meeting these requirements.

Another commenter stated that the general information section of the Yucca Mountain Review Plan indicates that information be presented at the level of an ''executive summary,'' but the actual level of detail requested is more appropriate for discussion in the safety analysis report rather than in an executive summary.

Response. DOE has the responsibility to specify structures, systems, and components that are important to safety and multiple barriers both natural and engineered important to waste isolation. This responsibility is noted in several places in the Yucca Mountain Review Plan. The Yucca Mountain Review Plan makes no presumptions regarding these structures, systems, components, or barriers, and mentions specific design features only as examples or to restate language in NRC's regulations.

The general information submitted with a license application, as required by 10 CFR 63.21(b)(1) and (2), need not contain detailed descriptions of surface and interim storage facilities and other features, events, and processes that might exist or occur at a repository for high-level radioactive waste at Yucca Mountain, or of the status of compliance with specific regulatory requirements. The general information portion of a license application includes a description of the proposed repository at Yucca Mountain, including an identification of the location of the repository operations area, the general character of proposed activities, proposed schedules for construction, receipt and emplacement of waste. This information should be at a level of detail to provide the reviewer enough background information to provide a context for detailed reviews of information using, for example, Chapter 4, ''Review Plan for Safety Analysis Report,'' of the draft Yucca Mountain Review Plan. Reviews conducted using Chapter 4 of the plan will require detailed descriptions of surface and interim storage facilities proposed in the facility design as well as evaluations of the features, events, and processes that might occur at a repository. It is not necessary that such information be duplicated in the ''General Information'' section of the Yucca Mountain Review Plan.

In the general information section of the Yucca Mountain Review Plan, material should be addressed at the level of a summary and should not duplicate the detailed information required to be stated in the safety analysis report.

The Yucca Mountain Review Plan has been modified to clarify the purpose of the general information section is to request descriptive information (except with respect to the detailed security plan measures that are required by 10 CFR part 63), and to reflect in the Introduction section (now Appendix A) that NRC staff has made no presumptions regarding which items contribute to performance.

9.2 Information and Level of Detail Required for Each Licensing Step

Issue: Should the Yucca Mountain Review Plan more clearly acknowledge the step-wise licensing process and define the level of detail that would be applicable for each licensing step for a repository at Yucca Mountain.

Comment. Commenters stated that regulations in 10 CFR part 63 confirm that repository licensing will occur in steps and that the level of detail required to proceed with each licensing step will increase as more information is obtained. According to one commenter, in developing this step-wise approach to repository licensing, NRC drew on decades of experience in licensing nuclear reactors in discrete steps under regulations at 10 CFR part 50.

The commenters argued that the Yucca Mountain Review Plan should clearly acknowledge that a step-wise licensing approach is applicable to a repository and that the license application should include not only a description of the robustness of the system and an assessment of performance, but also an acknowledgment that additional information will continue to be developed.

The commenters stated that the draft Yucca Mountain Review Plan does not clearly and consistently differentiate the information needed for the different steps of licensing. Accordingly, the plan does not differentiate how the areas of review, review methods, and acceptance criteria should vary for each of the licensing steps.

One commenter stated that, although DOE is expected to develop a sufficiently robust and well-documented license application that would permit NRC to independently determine the safety of a repository, DOE is not expected to have resolved all design and long-term repository performance issues at the construction authorization step. However, one commenter expressed a concern that the draft Yucca Mountain Review Plan inappropriately allows the DOE to simply commit to complying with certain regulatory requirements rather than to demonstrate actual compliance.

The commenter identified locations in the draft Yucca Mountain Review Plan that are related to these comments.

Response. The regulations at 10 CFR 63.21(a) require that ''[T]he application must be as complete as possible in the light of information that is reasonably available at the time of docketing.'' The Commission addressed the step-wise licensing approach in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55738–55739, November 2, 2001) in which it stated:

> Part 63 provides for a multi-staged licensing process that affords the Commission the flexibility to make decisions in a logical time sequence that accounts for DOE collecting and analyzing additional information over the construction and operational phases of the repository. The multi-staged approach comprises four major decisions by the Commission: (1) Construction authorization; (2) license to receive and emplace waste; (3) license amendment for permanent closure; and (4) termination of license. The time required to complete the stages of this process (*e.g.*, 50 years for operations and 50 years for monitoring) is extensive and will allow for generation of additional information. Clearly, the knowledge available at the time of construction authorization will be less than at the subsequent stages. However, at each stage, [the] DOE must provide sufficient information to support that stage. DOE has stated its intent to submit, and NRC expects to receive, a reasonably complete application at the time of construction authorization to allow the Commission to make a construction authorization decision. This is reflected in the requirement at Section 63.24(a) that the application be as complete as possible in light of information that is reasonably available at the time of docketing. The

Commission believes the regulations, as proposed, provide the necessary flexibility for making licensing decisions consistent with the amount and level of detail of information appropriate to each licensing stage. However, we agree with DOE that the proposed requirement at Section 63.24(a) speaks to the content of the initial application, as well as to all subsequent updates, and, therefore, it has been included at the end of Section 63.21(a).

The information provided at each stage should be sufficient for NRC staff to make the requisite findings for the licensing action being contemplated, whether, for example, it be issuance of a construction authorization or a license to receive and possess waste.

The Yucca Mountain Review Plan has been revised, as appropriate, to clarify the step-wise approach to licensing a geologic repository for high-level waste at Yucca Mountain and the information required for each licensing step.

9.3 Organization of the Yucca Mountain Review Plan

Issue 1: Should the Yucca Mountain Review Plan be reorganized to better support both preparation of an application and a licensing review?

Comment. Commenters noted that having a license application correspond to the structure of the Yucca Mountain Review Plan is important for NRC staff's review. Similarly, since the DOE will have to prepare and maintain a safety analysis report throughout the lifetime of a repository, a structure that most efficiently presents the required information is also important. The commenters suggested that a Yucca Mountain Review Plan more similar in structure to a reactor license application would facilitate license preparation by DOE, review of the application by NRC, and maintenance of the safety evaluation report over the lifetime of the facility. The commenters also suggested that restructuring of some areas of the Yucca Mountain Review Plan, such as the performance confirmation section, would enhance the transparency and traceability to DOE's supporting technical information. Specific recommendations to achieve this restructuring were provided for the preclosure safety; postclosure safety; and general information sections of the plan. The commenters also suggested that NRC state in the Yucca Mountain Review Plan that DOE may use a format different from that presented in the Yucca Mountain Review Plan.

With respect to the preclosure safety section of the Yucca Mountain Review Plan, one commenter suggested that a logical format would be to present design information followed by the preclosure safety analysis. This format would allow design information relevant to each structure, system, and component to be presented in its own subsection, rather than being split into separate areas as in the Yucca Mountain Review Plan. The commenter noted that as low as is reasonably achievable requirements are typically addressed as a design requirement for normal operations rather than as a consequence of hazards. Therefore, the commenter recommended that the as low as is reasonably achievable requirements be addressed in a new subsection of the Yucca Mountain Review Plan that provides a comprehensive review of the radiation protection program proposed for the facility. This new section would cover the as low as is reasonably achievable design aspects as well as the commitment to these principles during operations.

With respect to the postclosure safety section of the draft Yucca Mountain Review Plan, commenters noted that the draft Yucca Mountain Review Plan structure differs from that used previously by DOE and could make it difficult to present a cohesive story regarding total system performance while demonstrating compliance with the five acceptance criteria for each model abstraction. The commenter recommended that the Yucca Mountain Review Plan be rewritten to generally state that the five review methods (and corresponding acceptance criteria) are to be applied to the model abstractions as DOE determines. The commenter notes that, in previous documents, DOE communicated its postclosure safety approach in terms of the movement of water from the surface through the mountain to the accessible environment, which is different from the structure currently presented in the Yucca Mountain Review Plan.

Commenters identified locations in the draft Yucca Mountain Review Plan relevant to their concerns.

Response. The Yucca Mountain Review Plan should provide a structure for the license application as a means to promote efficiency in both preparation of an application by DOE and the license application review by NRC staff. Long-term maintenance of the safety analysis report might also be enhanced. The structure of the Yucca Mountain Review Plan was intended to provide this structure and to inform the prospective applicant as to the preferred organizational structure of the license application.

Organization of the application along the lines of a power reactor application may not be appropriate for a potential repository for high-level waste. Among the considerations that defined the structure of the Yucca Mountain Review Plan are: (i) The requirements for the content of a license application at 10 CFR 63.21; (ii) the need to focus a licensing review on compliance with risk-informed, performance-based performance objectives being implemented in 10 CFR part 63; and (iii) the specification, in 10 CFR part 63, of techniques to be used to demonstrate compliance both during operations and after permanent closure.

Because regulatory guidance cannot impose regulatory requirements, DOE is not required to use the format presented in the Yucca Mountain Review Plan, however, a different format could prolong the duration of the NRC licensing review.

As for the suggestion that the preclosure safety section (Section 4.1 of the draft Yucca Mountain Review Plan) first present design information followed by the preclosure safety analysis, the approach currently in the plan is consistent with the steps required for a preclosure safety analysis. These techniques are based on hazard and consequence analysis methodologies that are widely accepted for complex facilities. The purpose of the preclosure safety analysis is to determine whether the preclosure performance objectives will be met. Consequently, the review steps in the Yucca Mountain Review Plan logically lead from hazard identification through consequence analyses to assessment of compliance with performance objectives. Related to this approach is the need to use risk information to focus the NRC staff review. The preclosure safety analysis will be used by DOE to identify those structures, systems, and components important to safety. Since these structures, systems, and components have not yet been identified, the Yucca Mountain Review Plan is not structured around the design of the repository.

As low as is reasonably achievable requirements are typically addressed as a design requirement for normal operations rather than as a consequence of hazards. However, for a preclosure safety analysis for a repository meeting these requirements can appropriately be linked to the radiological risks of a repository. Since these risks will be evaluated as part of the preclosure safety analysis process, NRC staff prefers to evaluate them as part of its review of DOE's preclosure safety analysis.

Comments on the postclosure safety section of the Yucca Mountain Review Plan may have misinterpreted the review approach. NRC staff is aware that

the current DOE Total System Performance Assessment uses nine process level models (similar to NRC's model abstractions) that are based on the flow of water through a repository to the location of the reasonably maximally exposed individual. In light of the key role performance assessment will play in demonstrating and determining compliance, NRC staff has been developing an independent performance assessment capability for a Yucca Mountain repository and discussed the published results with DOE at numerous public meetings. The NRC total system performance assessment incorporates 14 model abstractions that represent its independent conceptual model of a Yucca Mountain site. The Yucca Mountain Review Plan describes how NRC staff will determine compliance, and its independently developed total system performance assessment code will be an important tool in assessing whether DOE has satisfied regulatory requirements. Therefore, the Yucca Mountain Review Plan facilitates the use of this tool in the license application review. DOE's compliance demonstration method may use similar, or different, conceptual models. NRC staff review, based on its 14 model abstractions, is described in detail in the Yucca Mountain Review Plan. This detail is useful because NRC staff has learned a great deal about the features, events, and processes of the Yucca Mountain site, and this knowledge is reflected in the technical information specific to each of the 14 model abstractions.

Although specific details of the postclosure portion of the Yucca Mountain Review Plan have been revised to address this comment, the general structure has not been changed. The Yucca Mountain Review Plan was revised, as appropriate, to clarify the matters raised in these comments.

Issue 2: Should quality assurance requirements be specifically addressed in each section of the Yucca Mountain Review Plan?

Comment. One commenter stated that quality assurance requirements should be identified and specified in the review methods and acceptance criteria for each section of the Yucca Mountain Review Plan. The commenter argued that Section 3.2, ''Proposed Schedules for Construction, Receipt, and Emplacement of Waste,'' Review Method 1, and Acceptance Criterion 1, of the draft Yucca Mountain Review Plan, should explicitly mention quality assurance compliance, since state-of-the-art quality assurance begins with preliminary scheduling and includes impacts on schedules, work interdependence, and work flow, particularly during construction. The commenter also suggested four specific changes to this section of the Yucca Mountain Review Plan that would incorporate quality assurance requirements.

Response. The quality assurance requirements in 10 CFR part 63 apply to aspects of repository construction, operation, or closure that are important to safety or to waste isolation. While quality assurance is an integral part of almost all aspects of a licensing review for a high-level waste repository, the Yucca Mountain Review Plan includes a single section on quality assurance, which will be applied to each of the other review activities.

To clarify the importance of quality assurance, the Yucca Mountain Review Plan integrates quality assurance into the entire licensing review by using the review methods and acceptance criteria in the ''Quality Assurance Program'' section of the Yucca Mountain Review Plan and applying them to reviews conducted for other Yucca Mountain Review Plan sections.

No changes to the Yucca Mountain Review Plan were made as a result of this comment.

Issue 3: Should the distinction between a licensing review and inspection activities be specifically addressed in each section of the Yucca Mountain Review Plan?

Comment. One commenter stated that the distinction between licensing review and inspection activities should be highlighted in each section of the Yucca Mountain Review Plan.

Another commenter suggested that NRC staff conduct a comprehensive review of the plan to ensure that the level of detail being specified is appropriate for a licensing review, rather than an inspection review. The commenter also suggested that Figure 1.1 in the plan be clarified for this purpose and that the ''Introduction'' to the Yucca Mountain Review Plan be revised to more explicitly outline this principle.

Response. It is not necessary to draw a distinction between licensing review and inspection in each section of the Yucca Mountain Review Plan in that it would substantially lengthen the review plan without adding significant benefit or clarity to the licensing review. This approach would also be inconsistent with other agency review plans.

As part of NRC's inspection program for a high-level waste repository at Yucca Mountain, NRC staff would prepare an Inspection Manual inspection procedures and would train additional inspectors. Inspection would thus be addressed separately.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

Issue 4: Is the Yucca Mountain Review Plan excessively redundant and difficult to understand?

Comment. One commenter stated that although the Yucca Mountain Review Plan meets the purpose for which it was written and explains the bases for activities and roles of various entities, it is repetitive particularly with respect to ''Areas of Review,'' ''Review Methods,'' ''Acceptance Criteria,'' ''Evaluation Findings,'' and ''References.'' The commenter noted that such headings, along with common verbiage, is repeated for topics, which are separately discussed for both preclosure and postclosure safety reviews. Although the commenter indicated that this approach may support the uniformity of the NRC review, it makes the document quite long. The commenter suggested that a table could be used as an abbreviated form of what currently appears as narrative under the headings (*e.g.*, ''Acceptance Criteria,'' ''Evaluation Findings,'' *etc.*) for each of the topics involved and for each major section of the review plan.

Response. The Yucca Mountain Review Plan is lengthy and somewhat redundant. The structure and format of the review plan, however, is intended to guide NRC staff reviewers from various disciplines to perform an efficient and complete review in discrete areas and provide the relevant information in each section. The structure of the Yucca Mountain Review Plan is also consistent with other NRC review plans.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 5: Should the Yucca Mountain Review Plan include an example of how a review would be completed and the results documented?

Comment. One commenter noted that the Yucca Mountain Review Plan sections dealing with postclosure issues reflect the risk perspectives of 10 CFR part 63 appropriately, but cautioned that implementation of the Yucca Mountain Review Plan will determine whether a risk perspective is followed. The commenter noted that the review plan identifies the need to maintain flexibility in review guidelines at the expense of specificity and acceptance criteria contain guidance to NRC staff for evaluating such aspects as: (1) Whether sufficient data are available to adequately define relevant parameters and conceptual models; (2) whether models use parameter values, assumed

ranges, probability distributions, and bounding assumptions that are technically defensible; and (3) whether the technical bases for the parameter values are consistent with data from the Yucca Mountain region. The commenter argued that the critical issue will be how items such as data sufficiency and model adequacy are determined and suggested adding an appendix to the Yucca Mountain Review Plan, which provides an abbreviated illustration of a review of a specific issue. This might be achieved using one of the integrated subissues, with specific reference to the prelicensing agreements between NRC staff and DOE staff as to how questions about sufficiency and adequacy would be addressed in the review process. The commenter noted that such an example might be very useful. In providing such an example, NRC staff could clarify what might lead to a conclusion that the license application was inadequate.

Response. An example of a review and the documentation of the results would be helpful to users of the Yucca Mountain Review Plan. One has been incorporated in Appendix A.

Issue 6: Will the Yucca Mountain Review Plan be revised in the future?

Comment. One commenter acknowledged that the Yucca Mountain Review Plan is a living document and agreed that physical protection is a potential area of change. The commenter questioned whether, considering the expected length of time between initial emplacement of waste and repository closure, it is reasonable to anticipate and accommodate change.

Response. Because the document is intended to address several steps in licensing of a high-level waste repository, the Yucca Mountain Review Plan will be revised in the future, if appropriate.

No changes to the Yucca Mountain Review Plan were made as a result of this comment.

9.4 Content of Yucca Mountain Review Plan Glossary

Issue: Should the Yucca Mountain Review Plan glossary include terms that are not defined in the text?

Comment. One commenter identified approximately forty terms that are used in the Yucca Mountain Review Plan text, but are not defined. The commenter suggested that these terms be added to the glossary.

Response. The glossary should define the terms used in the Yucca Mountain Review Plan. The glossary, however, provides general definitions and is not intended to be exhaustive as to all technical terms that may be used by a reviewer of a license application.

In response to this comment, the glossary has been revised to add terms that would be useful to a general reader.

9.5 Use of a Risk-Informed, Performance-Based Yucca Mountain Review Plan

Issue 1: Is the Yucca Mountain Review Plan sufficiently risk-informed, and performance-based?

Comment. One commenter noted the NRC commitment to conduct a risk-informed, performance-based licensing review for a potential high-level waste repository at Yucca Mountain. However, the commenter stated that the application of risk-informed, performance-based principles in the Yucca Mountain Review Plan was uneven. The commenter cited examples from the ''Introduction'' (now Appendix A) to the Yucca Mountain Review Plan that indicated risk-informed, performance-based principles were applied only where there was some reason to do so. The commenter argued that application of such principles should be a fundamental part of all NRC review activities. The commenter cited several specific examples from the Introduction to make the point that risk-informed, performance-based principles were unevenly applied in the Yucca Mountain Review Plan.

In addition, the commenter defined three items needed to consistently apply risk-informed, performance-based principles in the Yucca Mountain Review Plan: (i) Recognition that DOE has the latitude to make risk-informed, performance-based judgments as to what should be included in a license application and that NRC will determine whether it agrees with these judgments; (ii) revision of sections of the Yucca Mountain Review Plan that contain an excessive level of detail, particularly those sections dealing with repository design and Commission assumptions about the relative importance of specific features, events, and processes; and (iii) recognition that risk-informed, performance-based principles are especially important in a step-wise licensing process.

In support of these arguments, that commenter stated that consistent application of risk-informed, performance-based licensing principles would allow flexibility and would encourage the learning and development that would occur over a repository lifetime, thereby improving the protection of health and safety.

Finally, the commenter identified specific locations in the draft Yucca Mountain Review Plan that are inconsistent with risk-informed, performance-based principles; contain an excessive level of detail or prescription; or preclude necessary licensee flexibility. These locations are summarized here.

(1) Section 3, ''Review Plan for General Information,'' is, in general, overly detailed and prescriptive.

(2) Section 3 does not adequately recognize that, at the construction authorization stage, information in some areas may not be as highly developed as in others.

(3) Section 4.2.1.3, ''Model Abstraction,'' could be significantly streamlined. Rather than redundantly repeating the five generic Acceptance Criteria and related guidance, this material could be stated once and then applied to each of the 14 model abstractions. (This comment was made by another commenter on the review plan as well). The commenter stated that making this change would require a rewrite of the entire section, resulting in approximately 10 pages, rather than 109 pages, which could be applied with improved consistency and flexibility.

(4) Section 4.4, ''Performance Confirmation Program,'' is inconsistent with the risk-informed, performance-based nature of 10 CFR Part 63, would be impractical to implement, and contradicts what has been learned about total system performance assessment and subsystem performance requirements by placing detailed stipulations on the specific scientific and technical measures that must be taken to meet the already stated expectations of the ''Performance Confirmation Program.'' (Responses to comments received on Section 4.4 of the draft Yucca Mountain Review Plan are consolidated in Section 7 of this comment response document).

(5) Section 4.5.1, ''Quality Assurance,'' is too restrictive, inconsistent with other NRC criteria for Quality Assurance Program Descriptions, and will necessitate continual implementation of the Quality Assurance Program Description change process. (Responses to comments received on Section 4.5.1 of the draft Yucca Mountain Review Plan are consolidated in Section 8 of this comment response document.)

One commenter suggested that ''risk-informed,'' and ''performance-based'' be specifically defined in the Yucca Mountain Review Plan.

Response. Changes have been made throughout the Yucca Mountain Review Plan to address these and other comments. For example, the review plan explains that DOE may make risk-informed, performance-based judgments as to what should be included in a license application, and NRC has to

assess these judgments. NRC staff has revised sections of the Yucca Mountain Review Plan that contain an excessive level of detail, particularly those sections dealing with repository design and NRC assumptions about the relative importance of specific features, events, and processes. The Yucca Mountain Review Plan recognizes that risk-informed, performance-based principles are especially important in a step-wise licensing process.

Some specific comments, however, were not incorporated.

Regulations at 10 CFR part 63 were specifically written to implement a risk-informed, performance-based approach to licensing. Quantitative performance measures for the repository are found in the radiation health and protection standards that are implemented in 10 CFR part 63. In addition, 10 CFR part 63 specifies use of multiple barriers, performance confirmation, and other requirements in demonstrating performance. There are some techniques, programs, and guidance for regulating the use of radioactive material, however, that have proven to be efficient and effective for a wide range of licensees and that were adopted in 10 CFR part 63. Among these areas are operational health physics, material control and accountability, and emergency preparedness. For these reasons, the Yucca Mountain Review Plan does not reflect major changes in the way these programs would be implemented at other facilities regulated by NRC.

An applicant may propose approaches to areas such as operational health physics, physical protection, material control and accountability, and emergency preparedness that depart from those outlined in the guidance of the Yucca Mountain Review Plan. If DOE otherwise demonstrates it satisfies regulatory requirements, that is, that the public health and safety, as well as the environment, would be protected, NRC staff would find those approaches acceptable.

Section 4.2.1.3, ''Model Abstraction,'' of the draft Yucca Mountain Review Plan is lengthy and somewhat redundant, but was structured to best reflect how NRC staff would conduct its licensing review. Each of the 14 model abstractions has its unique technical and regulatory issues. Although the five generic acceptance criteria are applicable to each of the model abstraction reviews, for the convenience of the reviewer, the review procedures and acceptance criteria are listed separately for each model abstraction. Accordingly, the multidisciplinary team that conducts each model abstraction review will be able to use a separate section of the review plan.

In summary, changes have been made throughout the Yucca Mountain Review Plan to more effectively implement a risk-informed, performance-based licensing review, but brevity has not been the primary goal.

Issue 2: To what extent should NRC staff rely on the applicant in developing risk insights?

Comment. One commenter noted that findings of compliance or noncompliance will need to be substantiated, suggesting that NRC staff performs a detailed review or a simplified review of a particular feature will be decided by how important DOE's safety analysis considers the feature to be to the overall repository performance. On the other hand, the Yucca Mountain Review Plan contains language that suggests that the scope of the review will be determined in part by what DOE deems important, but also in part by risk insights developed by NRC staff from using its own knowledge of the site and its own analyses of performance assessment models. The commenter strongly favored the latter approach.

The commenter urged NRC staff not to be guided solely by the applicant on the depth of the review of an application and to continue to build agency insights about important contributors to risk at the proposed repository.

Response. One purpose of the Yucca Mountain Review Plan is to provide guidance to NRC staff on how to conduct a risk-informed, performance-based licensing review for a potential high-level waste repository at Yucca Mountain. The review plan, as revised, clarifies that the risk-informed, performance-based review, is not dictated solely by DOE.

Issue 3: How will risk-informed, performance-based principles be applied in a Yucca Mountain licensing review?

Comment. Several comments addressed the use of risk insights, to focus the review on those areas most important to repository performance. One commenter asked how NRC would decide which areas are most important to repository performance, and how the extent of the review of a given portion of the license application would be determined.

One commenter noted that Section 4.2.1.2.2, ''Identification of Events with Probabilities Greater Than 10^{-8} Per Year,'' of the draft Yucca Mountain Review Plan does not mention the risk-informed, performance-based review approach, and suggested that this section should be combined with Section 4.2.1.2.1, ''Scenario Analysis,'' of the draft Yucca Mountain Review Plan.

Another commenter asked whether NRC staff was aware that DOE's results were being probability weighted.

Response. Practical experience in conducting iterative performance assessments for the Yucca Mountain site has provided NRC staff with valuable insight regarding areas that are most likely to be important to health and safety. Until DOE submits a license application, however, it is premature to identify those areas of the postclosure performance assessment that would require the most detailed review. The review of DOE's scenario analysis and event probability described in Section 4.2.1.2 of the draft Yucca Mountain Review Plan would provide an initial foundation for focusing on credible events affecting repository performance. The review methods and acceptance criteria in Section 4.2.1.3, ''Model Abstraction,'' of the draft Yucca Mountain Review Plan provide a mechanism for evaluating the different sections of DOE's postclosure performance assessment. NRC staff would focus its review accordingly based on information in the DOE application and the areas that are most important to health and safety.

The concept of a risk-informed, performance-based review has been reiterated in this section and the text has been modified to clarify that establishing a probability range is an aspect of a risk-informed approach.

Section 4.2.1.2.2 has not been combined with Section 4.2.1.2.1. Section 4.2.1.2.2 addresses the specific requirements of 10 CFR 63.114(a)(4), and Section 4.2.1.2.1 addresses the specific requirements of 10 CFR 63.114(a)(5) and (6).

NRC staff review will determine whether probability weighting of results is mathematically and technically used appropriately in the license application.

Section 4.2.1.2.2 of the Yucca Mountain Review Plan has been clarified and modified in response to this comment.

9.6 Use of Guidance and Experience From Regulating Other Nuclear Facilities

Issue: To what extent should NRC rely on guidance and experience from regulating other nuclear facilities when evaluating a license application for a potential high-level waste repository at Yucca Mountain?

Comment. One commenter expressed concern that, because 10 CFR part 63 does not have performance objectives for administrative and programmatic

aspects, NRC staff relied on experience from regulating other nuclear facilities, including nuclear power plants, in developing these parts of the Yucca Mountain Review Plan. The commenter also noted that some of the preclosure sections of the draft Yucca Mountain Review Plan apparently rely on experience with fuel cycle facilities and nuclear power plants, but urged that the operations at the proposed Yucca Mountain repository have little in common with nuclear power plants and, hence, many reactor-related guidance documents may not be transferable. The commenter argued that repeated references to reactor-based documents (*e.g.*, NUREGs–2300 and 1278; Regulatory Guides 1.109 and 8.38; and references to the design of systems that are important to safety) support the observation that the Yucca Mountain Review Plan relies heavily on NRC documents prepared for and used in conjunction with the licensing of nuclear power plants.

The commenter suggested that NRC staff reevaluate inclusion of material from nuclear power plant reviews, and delete material and requirements that are not relevant to the safety of the proposed Yucca Mountain repository. For material deemed relevant, NRC staff should explain in the Yucca Mountain Review Plan, the use and relevance of reactor-based guides and policies, and should indicate where use of such material has been modified to account for differences between high-level waste disposal and nuclear power plant operation.

Response. The Yucca Mountain Review Plan has been modified to clarify that only applicable guidance, or portions of that guidance, are proposed for use in a licensing review for a high-level waste repository.

9.7 Use of Graphics

Issue: Could use of graphics clarify the purposes and use of the Yucca Mountain Review Plan?

Comment. Commenters stated that a process diagram that illustrates how decisions are made and how inadequacies are addressed would be helpful. Commenters noted that Figure 1–3 in ''Components of Performance Assessment Review'' provided information on how the potential for engineered barrier failure would be addressed and asked how other topics would be addressed.

One commenter recommended the use of tables, charts, and graphics to give the reader a high-level overview of activities under the Yucca Mountain Review Plan. The commenter suggested that an ''activity network,'' which diagrams how the Yucca Mountain Review Plan would be used would help identify linkages among plan sections. The commenter argued that an activity network diagram would also help communicate the completeness of the Yucca Mountain Review Plan and make the report more understandable to stakeholders.

Another commenter suggested that an appendix that referenced requirements from 10 CFR part 63 to the Yucca Mountain Review Plan would be useful.

Response. Graphics could be useful in promoting understanding of the Yucca Mountain Review Plan, and two have been added. One depicts the steps of the licensing process, and one describes how review of a license application section would be conducted using the Yucca Mountain Review Plan. Accompanying text in the review plan explains the graphics.

An appendix that cross-references requirements from 10 CFR part 63 to the Yucca Mountain Review Plan was not included because the related regulatory requirements are already identified in the evaluation findings portion of each review plan section.

Changes to address aspects of these comments were added to the new Appendix A (Licensing Review and the Yucca Mountain Review Plan) of the review plan.

9.8 Completeness of the Yucca Mountain Review Plan

Issue: Is the scope of the Yucca Mountain Review Plan adequate to evaluate the health and safety of a potential high-level waste repository at Yucca Mountain?

Comment. Several commenters had concerns regarding the adequacy of the scope of the Yucca Mountain Review Plan. The concerns included omission of potentially significant features, events, and processes; the nature of information that would be reviewed using the Review Plan for General Information; requirements for the size of restricted areas; the adequacy of the scope of a preclosure safety analysis; specificity of required design information; and the possibility that acceptance criteria were too lenient and subjective.

Response. The scope of the Yucca Mountain Review Plan is adequate and allows flexibility to evaluate whatever methods DOE might choose to demonstrate compliance.

The purpose of the ''Review Plan for General Information'' section of the Yucca Mountain Review Plan is to ensure that the requirements of 10 CFR 63.21(b) have been met. The General Information section of a license application should provide a general understanding of the engineering design concept for the repository and of the aspects of the Yucca Mountain site and its environs that influence repository design and performance. Information provided by DOE in response to the requirements of 10 CFR 63.21(b) for the General Information section should be at the level of an executive summary and is not expected to be detailed. The level of detail requested for the site characterization description in the General Information section of the Yucca Mountain Review Plan has been substantially reduced. Detailed information would be evaluated with respect to its importance to health and safety in sections that address review of DOE's Safety Analysis Report.

The probability and consequences of features, events, and processes would be subjected to a detailed review using review methods and acceptance criteria in the section of the Yucca Mountain Review Plan that examines Repository Safety After Permanent Closure.

There is no regulatory requirement mandating the size of restricted areas. However, general practice is that these areas are as small as operationally feasible to facilitate monitoring and control. A DOE physical protection plan would have maps and diagrams associated with physical protection methods and procedures inside restricted areas as required by 10 CFR 73.51.

The Yucca Mountain Review Plan identifies the methods and criteria NRC staff would use to determine regulatory compliance. The review methods and acceptance criteria in the Yucca Mountain Review Plan are flexible rather than prescriptive because: (i) NRC regulations at 10 CFR part 63 are risk-informed and performance-based, (ii) prescriptive review methods and acceptance criteria could foreclose the license applicant from using the most effective approaches to regulatory compliance, and (iii) DOE has not yet presented a preclosure safety analysis.

The Yucca Mountain Review Plan has been modified throughout, as appropriate, to clarify the scope of the risk-informed, performance-based review methods and acceptance criteria.

10 Selected Topics

10.1 Consistency With Regulations

Issue 1: Should the terminology in the Yucca Mountain Review Plan be made more consistent with regulations and be used in a more consistent manner?

Comment. Several commenters stated that the draft Yucca Mountain Review Plan uses terms that are inaccurate or

are inconsistent with the applicable regulations. The commenters recommended that the Yucca Mountain Review Plan be revised to more closely reflect the applicable regulations to minimize questions of interpretation. The commenters also suggested that the Yucca Mountain Review Plan directly reference appropriate regulations rather than paraphrasing them.

For example, the term ''safety case'' is used throughout the draft Yucca Mountain Review Plan, but is not defined either within the review plan or in 10 CFR part 63. One commenter stated that this term generally addresses more than a compliance demonstration, and confusion about its use may adversely affect both preparation and review of an application.

Commenters noted that terms used in the draft Yucca Mountain Review Plan were confused with common industry terms. For example, the terms ''technical specifications'' and ''license specifications'' are erroneously used interchangeably. ''License specifications'' is used and defined in 10 CFR part 63 and its use in the Yucca Mountain Review Plan should be consistent with this definition. Also, the term ''license conditions'' is used interchangeably with the term ''license specifications.'' In 10 CFR 63.43, license specification is defined in terms of license condition, but the Yucca Mountain Review Plan does not provide sufficient distinction between the two terms.

One commenter recommended replacing the term ''performance-based'' with ''experimental'' due to the lack of experience in storage for thousands of years. The commenter noted that use of the phrases ''risk-informed'' and ''performance-based'' was problematic because risk should mean probability times consequence, but this was not apparent in the Yucca Mountain Review Plan. The commenter further noted that the phrase ''risk-informed, performance-based,'' as applied over a period of thousands or millions of years require a workable definition.

Two commenters expressed concern with the discussion of ''open items'' or ''confirmatory items'' that might result from the licensing review. One argued that these items could be used to inappropriately accommodate licensing deficiencies and asked for assurance that such action would be prevented.

Another commenter requested that the term ''important to performance'' be defined consistent with 10 CFR part 63 and that the terms ''important to safety'' and ''important to waste isolation'' be included in the Yucca Mountain Review Plan glossary.

The commenters included a number of additional suggestions for improving Yucca Mountain Review Plan consistency and the effectiveness of the glossary.

Response. Terminology should be used consistently throughout the Yucca Mountain Review Plan and should be consistent with regulations. Revisions were made to the Yucca Mountain Review Plan, as appropriate, to address terminology concerns raised by commenters.

The term ''safety case'' has been removed from the Yucca Mountain Review Plan and, generally, has been replaced with the term ''license application.'' This change is more consistent with language in 10 CFR part 63; however, the removal of the term ''safety case'' should not be viewed as a lessening of an emphasis on health and safety for the repository.

Discussion and use of the terms ''technical specifications,'' ''license specifications,'' and ''license conditions'' have been clarified throughout the Yucca Mountain Review Plan to be consistent with 10 CFR 63.42 and 62.43. License conditions include license specifications that are derived from analyses and evaluations included in the application.

In developing 10 CFR part 63 and the Yucca Mountain Review Plan, NRC staff sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulations. [''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities—Final Policy Statement'' (60 FR 42622, August 16, 1995).] Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (*e.g.*, defense in depth), and performance history are used to: (i) Focus attention on the most important activities; (ii) establish objective criteria for evaluating performance; (iii) develop measurable or calculable parameters for monitoring system and licensee performance; (iv) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes; and (v) focus on the results as the primary basis for regulatory decision-making.

NRC defines risk as probability times consequence. Further, 10 CFR part 63 establishes the regulatory period of interest for a Yucca Mountain repository at 10,000 years, consistent with the Nuclear Waste Policy Act.

With respect to the concerns about possible misuse of ''open'' and ''confirmatory'' items, NRC will review the application to determine whether the requisite regulatory showing has been made and impose conditions, as necessary to address confirmatory items. ''Open'' items that relate to information required for regulatory findings must be addressed by DOE during the review.

The term ''important to performance'' has been replaced with ''important to safety'' or ''important to waste isolation,'' as appropriate, consistent with 10 CFR part 63.

These and other changes were made throughout the Yucca Mountain Review Plan to clarify the guidance and provide consistency with regulatory requirements.

Issue 2: Is the Yucca Mountain repository program being conducted consistent with legal requirements?

Comment. One commenter stated that the Yucca Mountain Review Plan violates a number of legislative mandates, Federal laws, an executive order, State and local constitutions, and an international treaty. Such documents include: The Nuclear Waste Policy Act; the National Environmental Policy Act; the Federal Administrative Procedures Act; the Safe Drinking Water Act; the Federal Facilities Management Act; Executive Order 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Population''); the Ruby Valley Treaty of 1863; and regulations related to uncompensated takings.

Response. The Yucca Mountain Review Plan is a guidance document that sets forth an approach for NRC staff to determine whether the regulatory requirements of 10 CFR part 63 have been met. The regulations at 10 CFR part 63 were adopted in accordance with the laws of the United States. Any challenges to those regulations should be raised in the appropriate forum and are not appropriate for comment here.

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

10.2 Nature of Wastes To Be Disposed of in a High-Level Waste Repository

Issue: What types of radioactive wastes may be emplaced in a repository for high-level radioactive waste at Yucca Mountain?

Comment. One commenter asked several questions regarding the types and forms of waste that would be eligible for disposal in a repository for high-level radioactive waste at Yucca Mountain, Nevada. The questions included: (i) Whether liquid wastes could be interred; (ii) whether low-level or intermediate-level wastes could be interred; (iii) whether contaminated

operations equipment could be disposed of; (iv) whether radioactive chemical wastes could be interred; and (v) whether contaminated soils or contaminated mine tailings could be disposed of.

Response. The types and forms of waste that could be disposed of in a repository for high-level radioactive waste at Yucca Mountain are based on Section 2 of the Nuclear Waste Policy Act, as amended, and are defined in NRC regulations at 10 CFR 63.2. High-level waste means: (i) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material, derived from such liquid waste, that contains fission products in sufficient concentrations; (ii) irradiated reactor fuel; and (iii) other highly radioactive material that the Commission, consistent with existing law, determines, by rule, requires permanent isolation. Also, 10 CFR 63.2 defines radioactive waste as high-level waste and radioactive materials other than high-level waste that are received for emplacement in a geologic repository.

The Commission addressed the question of liquid wastes in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55773, November 2, 2001), which states:

> Because of processing in the nuclear fuel cycle, some high-level waste can occur in the liquid (aqueous) state. However, this waste type is not expected to be disposed of at Yucca Mountain. Rather, liquid high-level waste will be vitrified—mixed with molten glass and solidified—to reduce the actual volume of waste and make it easier to handle.

DOE would have to demonstrate in its license application that wastes that are not the highly radioactive material resulting from the reprocessing of spent nuclear fuel (including liquid waste produced directly in reprocessing and solid material derived from such liquid waste that contains fission products in sufficient concentrations) or irradiated reactor fuel, are wastes that the Commission, consistent with existing law, determines, by rule, requires permanent isolation.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

10.3 The Meaning of Safety

Issue: Will results of a review conducted using the Yucca Mountain Review Plan adequately protect health and safety?

Comment: One commenter questioned whether a licensing review for a high-level waste repository at Yucca Mountain that is based on the regulatory requirements in 10 CFR part 63, and that uses the review methods and acceptance criteria in the Yucca Mountain Review Plan, would protect health and safety.

The commenter referred to a dictionary definition of safety as meaning free from danger and involving no risk. The commenter contended that this is the public interpretation of safety, and that agencies of the Federal government use different definitions since the Yucca Mountain Review Plan glossary does not define safety. The commenter assumed that the dictionary definition applies.

The commenter further noted that, when Yucca Mountain was selected as the sole site for characterization as a geologic repository, officials of DOE promised not to build the site if it was unsafe. The commenter stated that DOE often referred citizens to site suitability guidelines that included qualifying and disqualifying conditions. Also, NRC regulations included sub-system requirements that would ensure the site could be licensed only if safety could be assured. The commenter noted that these regulatory provisions have been eliminated and that a safety decision would now be based on the results of performance assessment. The commenter also stated that DOE has redefined safe in terms of satisfying regulations.

Response. A decision on whether to authorize construction of a high-level waste repository at Yucca Mountain will be based on whether DOE demonstrates it has satisfied applicable regulatory requirements. The standards for issuance of a construction authorization, for example, include a determination that (1) There is reasonable assurance that the types and amounts of radioactive materials described in the application can be received in the repository without unreasonable risk to public health and safety and (2) there is reasonable expectation that materials can be disposed of without unreasonable risk to public health and safety.

Among the requirements that must be met are the preclosure and postclosure performance objectives that are defined in NRC regulations at 10 CFR part 63. Simply stated, these performance objectives are quantitative radiation exposure limits. The Commission addressed the adequacy of performance assessment for evaluating compliance in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55746–55747, November 2, 2001) as follows.

> Although repository postclosure performance is evaluated with respect to a single performance measure for individual protection, the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (*e.g.*, qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the postclosure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain. The Commission believes the approach for performance assessment in the proposed rule is appropriate and it is retained in the final rule. However, requirements for QA, multiple barriers, and performance confirmation have been revised to clarify the Commission's intent for these requirements * * *
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> The Commission believes that there have been significant advances in, and experience with, risk assessment in the past 20 years (see Commission's white paper on Risk-Informed and Performance-Based Regulation, March 1999). The Commission continues to believe that a performance assessment, developed with sufficient credibility, is the best means to provide useful information to the Commission for making an informed, reasonable licensing decision. The Commission recognizes, however, the uncertainties inherent in evaluating a first-of-a-kind facility like the repository and in estimating system performance over very long time periods (*i.e.*, 10,000 years). Thus, proposed Part 63 contained requirements to ensure that: (1) Uncertainties inherent in any performance assessment are thoroughly articulated and analyzed or addressed; (2) DOE's performance assessment is tested (corroborated) to the extent practicable; and (3) there are additional bases, beyond the performance assessment, that provide confidence that the postclosure performance objectives will be met.

In essence, safety is defined by 10 CFR part 63. A determination as to whether a repository for high-level radioactive waste at Yucca Mountain can be operated safely will be based on the information presented in a license application, and the evidence presented in the adjudicatory proceeding before the NRC.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

10.4 Reasonable Assurance and Reasonable Expectation

Issue: Does the difference in the meanings of the terms ''reasonable assurance'' and ''reasonable expectation'' need to be clarified?

Comment. One commenter asked that the meanings of the terms reasonable assurance and reasonable expectation be clarified. The commenter stated that, as used in the draft Yucca Mountain Review Plan, these terms seem to mean approximately the same thing. The commenter argued that this was not the intent of NRC when it promulgated 10 CFR part 63.

The commenter agreed that use of reasonable assurance as a measure of compliance for preclosure safety was appropriate and consistent with NRC regulation of other nuclear facilities. However, the commenter opined that reasonable expectation implies a different standard that recognizes the inherent uncertainties in predicting repository performance far into the future. The differences include the need for realistic, rather than bounding, modeling approaches, and for taking into account the stepwise nature of repository licensing. According to the commenter, a reasonable expectation standard should allow for considerable information to be added after a license is initially granted, but before repository closure. The commenter argued that reasonable expectation should allow gaps in understanding to exist at the time a license is initially granted, provided adequate efforts to address these gaps are implemented.

The commenter added that the U.S. Environmental Protection Agency defined reasonable expectation in 40 CFR part 197 with the intent that it be explicitly different from reasonable assurance and allowed NRC the flexibility to determine how the term would be applied. Since the Yucca Mountain Review Plan is the key NRC implementation guidance, the distinction between reasonable assurance and reasonable expectation should be clear in the Review Plan.

Response. The Commission addressed its adoption and use of the reasonable expectation and reasonable assurance regulatory compliance standards in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55739–55740, November 2, 2001) where it stated:

> Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process. It is the Commission's responsibility to determine whether DOE has or has not demonstrated compliance. The Commission does not believe that NRC's use of ''reasonable assurance'' as a basis for judging compliance compels focus on extreme values (*i.e.*, tails of distributions) for representing the performance of a Yucca Mountain repository. Further, if DOE is authorized to file a license application, and if the Commission is called on to make a decision, irrespective of the term used, the Commission will consider the full record before it. That record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) contained in Subparts E, K, and L. The Commission could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public. To avoid any misunderstanding and to achieve consistency with final EPA standards, the Commission has decided to adopt EPA's preferred criterion of ''reasonable expectation'' for purposes of judging compliance with the postclosure performance objectives. The Commission is satisfied that a standard of ''reasonable expectation'' allows it the necessary flexibility to account for the inherently greater uncertainties in making long-term projections of a repository's performance. The Commission agrees with EPA and others that it is important to not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. By adopting what EPA has characterized as a more flexible standard of ''reasonable expectation'' for determining compliance with postclosure performance objectives, the Commission hopes to make clear its expectations. The Commission expects that the required analyses of postclosure performance will focus on the full range of defensible and reasonable parameter distributions, and that they should not be constrained only to extreme physical situations and parameter values. For other determinations regarding compliance of the repository with preclosure objectives, the Commission will retain a standard of ''reasonable assurance,'' consistent with its practice for other licensed operating facilities subject to active licensee oversight and control.
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> As stated previously, in order to avoid further misunderstanding of its intent, the Commission will adopt EPA's preferred standard of ''reasonable expectation'' for purposes of judging compliance with the numerical postclosure performance objectives. However, the Commission wants to make clear that its proposed use of ''reasonable assurance'' as a basis for judging compliance was not intended to imply a requirement for more stringent analyses (*e.g.*, use of extreme values for important parameters) or for comparison with a potentially more stringent statistical criteria (*e.g.*, use of the 95th percentile of the distribution of the estimate of dose).

No changes have been made to the Yucca Mountain Review Plan as a result of this comment.

11 Other Comments

11.1 Codes and Standards

Issue: Should the Yucca Mountain Review Plan identify specific codes and standards to be used by the applicant?

Comment. One commenter stated that the draft Yucca Mountain Review Plan refers to codes and standards that are not compatible with the risks from a geologic repository. The commenter recommended that the Yucca Mountain Review Plan be revised to clarify that the applicant has the flexibility to use codes, standards, and methodologies it demonstrates to be applicable. Another commenter noted that some referenced codes and standards were outdated.

Commenters identified locations in the draft Yucca Mountain Review Plan related to their concerns.

Response. The risk-informed, performance-based regulations at 10 CFR part 63 give the applicant the responsibility to select codes, standards, and methodologies; demonstrate that they are appropriate for use with a geologic repository for high-level waste; and then use them appropriately. When specific codes, standards, or methodologies were listed in the Yucca Mountain Review Plan, they were included only as examples or to indicate the kinds of approaches that have been successfully used in other licensing programs.

The Yucca Mountain Review Plan has been revised to clarify that references to specific codes, standards, methodologies, or outdated codes have been deleted.

11.2 General Comments on the License Application and the Licensing Process

Issue 1: Will NRC ignore mistakes in a DOE license application?

Comment. Two commenters asked whether NRC would ignore mistakes in DOE's license application and how the Commission would address major problems in DOE's work. One commenter also stated that NRC must have the power to reject a license application.

Response. A DOE license application must demonstrate compliance with applicable regulations. Editorial mistakes that prevent NRC from understanding the compliance demonstration may have to be corrected. Technical mistakes could even invalidate a DOE analysis to demonstrate compliance. The nature, extent, and effects of mistakes in a license application would be considered in the NRC review.

NRC has the statutory authority as well as the responsibility to reject a license application if the applicant fails to show that applicable regulatory requirements are satisfied.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 2: Does a DOE license application exist?

Comment. One commenter asked whether a DOE license application already existed.

Response. It is NRC's understanding that DOE had not yet prepared a license application.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 3: Will NRC hold DOE to appropriate standards in a licensing review?

Comment. One commenter asked whether NRC would hold DOE to the same standards that produced failures of high-level waste storage at other sites. Other commenters asked whether DOE's past research, organizational structure, and organizational culture would be considered in a licensing review for a high-level waste repository at Yucca Mountain.

Response. NRC has promulgated regulatory requirements for a high-level waste repository at 10 CFR part 63. These regulations require protection of public health and safety, and the environment. If DOE's license application demonstrates compliance with regulatory requirements at 10 CFR part 63, and applicable requirements in 10 CFR part 51, for high-level radioactive waste repository at Yucca Mountain, NRC staff would recommend issuance of a construction authorization or license to receive and possess waste, as appropriate.

DOE organization and qualifications are addressed in the following three sections of the draft Yucca Mountain Review Plan: (i) 4.5.3.1, ''DOE Organizational Structure as it Pertains to Construction and Operation of Geologic Repository Operations Area''; (ii) 4.5.3.2, ''Key Positions Assigned Responsibility for Safety and Operations of Geologic Repository Operations Area''; and (iii) 4.5.3.3, ''Personnel Qualifications and Training Requirements.'' A licensing review using these sections of the Yucca Mountain Review Plan would support a conclusion as to whether DOE may receive a license for a high-level waste repository at Yucca Mountain.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 4: Will NRC regulations be rewritten to accommodate a Yucca Mountain license application?

Comment. One commenter asked whether NRC would change its regulations to accommodate a Yucca Mountain license application. One commenter asked whether performance bases are expected to change as waste is processed and interred at a repository. Another commenter stated that NRC modified the standards for Yucca Mountain because DOE could not meet them.

Response. NRC regulations at 10 CFR part 63 were promulgated to specifically address an application for a potential repository at Yucca Mountain and were developed through a public rulemaking process. There are no plans to revise these regulations.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 5: What level of conservatism is appropriate in licensing a high-level waste repository at Yucca Mountain?

Comment. One commenter stated the statement in the draft Yucca Mountain Review Plan ''Introduction'' (now Appendix A) that NRC cannot require a different or additional proposal if the application satisfies applicable regulations to encourage an applicant to demonstrate compliance using non-conservative methods. The commenter noted that this approach is unacceptable for a repository with a disposal period of 10,000 years, and that the U.S. Department of Energy should be required to use the most conservative approach for demonstrating compliance.

Another commenter expressed the opposite concern that the very reliance on the use of ''bounding values'' is not consistent with a reasonable expectation compliance standard. The commenter noted that it may be necessary to use expert judgement in some cases and that the Yucca Mountain Review Plan should explicitly allow use of such judgement, or other accepted techniques, in certain circumstances. The commenter suggested that NRC staff adopt an ''expected behavior approach'' similar to that used by the commercial nuclear power industry, noting the similarities and differences in power reactor and repository licensing issues and acknowledging that the time and spatial scales for a repository limit the use of direct frequency data. To address this concern, the commenter suggested the use of natural analogue data, and the collection of data over longer time periods, to confirm models.

The same commenter suggested a dual modeling approach that uses the ''expected behavior'' model followed by application of conservative assumptions in areas where it might be difficult to accurately define the expected conditions. The intent would be that a conservative model would be used for the licensing decision, while the expected behavior model would be used to provide regulatory insight.

Response. NRC's regulations at 10 CFR part 63, are protective of health and safety and the environment. Therefore, ensuring compliance with them would protect health and safety and the environment and accomplish the mission of NRC.

Regulation of nuclear facilities requires realistic or reasonably conservative approaches that take into account importance to safety, technical complexity, and the degree and nature of associated uncertainty. These concepts underlie the ''reasonable assurance'' and ''reasonable expectation'' bases that would be applied in NRC staff's review of a license application for a high-level waste repository at Yucca Mountain.

The Commission addressed the issue of conservatism in the ''Statements of Considerations'' for 10 CFR part 63 (66 FR 55732, November 2, 2001). In ''Statements of Considerations,'' the Commission stated, in part

> Confidence that DOE has, or has not, demonstrated compliance with EPA's standards is the essence of NRC's licensing process * * *. The Commission does not believe that NRC's use of ''reasonable assurance,'' as a basis for judging compliance compels focus on extreme values (*i.e.*, tails of distributions) for representing the performance of a Yucca Mountain repository. Further * * * if the Commission is called on to make a decision * * * the Commission will consider the full record before it. That record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) * * * The Commission could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public.
>
> The Commission is satisfied that a standard of ''reasonable expectation'' allows it the necessary flexibility to account for the inherently greater uncertainties in making long-term projections of a repository's performance. The Commission agrees with EPA and others that it is important to not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence * * *. The Commission expects that the required analyses of postclosure performance will focus on the full range of defensible and reasonable parameter distributions, and that they should not be constrained only to extreme physical situations and parameter values. For other determinations regarding compliance of the repository with preclosure objectives, the Commission will retain a standard of ''reasonable assurance'' consistent with its practice for other licensed operating facilities subject to active licensee oversight and control.

Changes have been made throughout the Yucca Mountain Review Plan, as necessary, to ensure that the use of conservatism is clearly stated.

Issue 6: How should requests for additional information be managed?

Comment. Commenters expressed concern about the NRC staff goal to limit requests for additional information to one round. One commenter stated that it is unacceptable for NRC staff to impose such a limit. Considering the complexity of issues associated with a potential high-level waste repository at Yucca Mountain, NRC staff should prepare requests for additional information as necessary until the licensing information is adequate. One commenter stated that DOE's performance record implies that one round will not be sufficient and asked (1) If a limited number of requests for additional information would be allowed and (2) if NRC would allow DOE to submit an incomplete license application and then tell it how to make it acceptable. Another commenter asked for information on how DOE's responses to requests for additional information would be addressed.

Response. Imposing a limit of one round of requests for additional information is not necessary. The Yucca Mountain Review Plan does not impose such a limit, but provides guidance that the goal is to complete an effective review with only a single round of requests for additional information. This is a goal in other NRC regulatory programs as well.

DOE responses to requests for additional information would be evaluated during the NRC licensing review.

The Yucca Mountain Review Plan has been revised to clarify that preparing a single round of requests for additional information is a goal for the licensing review.

Issue 7: Is there a timing constraint on the NRC licensing review and preparation of a safety evaluation report?

Comment. One commenter stated that it would be premature to publish a draft safety evaluation report before the licensee has produced the information necessary for a license. The commenter went on to state that early publication of a safety evaluation report would indicate a rush to judgement before necessary information is available. Two commenters questioned the schedule for a high-level waste repository licensing review. One commenter asked when the 3-year time limit begins. Another commenter noted that DOE should be prepared for one or more application rejections if the application is inadequate and that the licensing process could require several 3-year cycles.

Response. The NRC detailed technical licensing review begins after the license application is found acceptable for review and is docketed. NRC plans to decide whether to docket the tendered application within 90 days from the receipt of the license application. If the license application is incomplete and not sufficient to support a detailed technical review, the application could be rejected or DOE could be informed of the deficiencies and given an opportunity to correct them. If DOE is unable to correct them within a reasonable period, the license application could be rejected. Section 114 of the Nuclear Waste Policy Act requires the Commission to issue a final decision approving or disapproving the issuance of a construction authorization not later than the expiration of three years after the date of submission of an application. A one-year extension from Congress may be requested by the NRC.

Preparation of a safety evaluation report depends on whether NRC staff has reached conclusions regarding whether the applicant has satisfied applicable regulatory requirements. The entire detailed licensing review need not be complete before NRC staff may begin preparation of the safety evaluation report. Conclusions on compliance with discrete regulatory requirements may be possible early in the review period and associated portions of the safety evaluation report may be prepared if those conclusions can be independently reached. Conclusions related to regulatory requirements that require complex, multidisciplinary, or integrated assessment may not be possible until late in the licensing review and would be documented in a safety evaluation at that time.

A safety evaluation report could conclude that a license should not be granted. In any event, a draft safety evaluation report, if published, would not contain final NRC staff conclusions on regulatory compliance and would be subject to revision.

The Yucca Mountain Review Plan text has been modified, as necessary, to clarify provisions regarding preparation of a safety evaluation report.

Issue 8: Would a license for a high-level waste repository at Yucca Mountain include an option to store wastes temporarily?

Comment. One commenter asked whether a license for a high-level waste repository at Yucca Mountain would include an option to store wastes temporarily.

Response. Since the NRC has not yet received a license application for a high-level waste repository at Yucca Mountain, it would be speculation to state whether the license would authorize temporary storage of wastes.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 9: What would be the term of a license for a high-level waste repository at Yucca Mountain and would the license be renewable?

Comment. One commenter asked that NRC define the period over which a license for a high-level waste repository at Yucca Mountain would be in effect and to state whether license renewal would be allowed.

Response. Requirements for issuance of a license for a high-level waste repository at Yucca Mountain are specified in 10 CFR part 63, subpart B. There are no provisions for renewal of a license. Rather, unless such a license is revoked or suspended, it would be in effect until an application for license termination satisfies the requirements of 10 CFR 63.52(c). At that time, NRC would terminate the license and NRC oversight of the site would end.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 10: Would a licensing review conducted using the Yucca Mountain Review Plan adequately consider available information about the Yucca Mountain site?

Comment. Two commenters expressed several concerns regarding the potential for and effects of the Yucca Mountain site failing to perform properly. The commenters noted a concern, shared by farmers in Amargosa Valley, that the potential damage from contaminated groundwater to the agricultural resource in well-irrigated land around Yucca Mountain has not been adequately evaluated, especially considering that the population is expected to double in 40 years.

The commenters stated that DOE ignored results of water surveys, by Lawrence Livermore National Laboratory, that proved the existence of interbasin groundwater flow from an aquifer under Yucca Mountain to the water supplies for Los Angeles and Las Vegas.

In a related concern, one commenter stated that DOE scientists had objected to the recent Yucca Mountain site recommendation because they needed at least six more years to complete enough scientific work to make a responsible rejection or recommendation. The commenter also urged that NRC consider the concerns of the Nuclear

Waste Technical Review Board, and Dr. Victor Gilinsky that deep geologic disposal of nuclear waste carries with it the possibility of irretrievable and irremediable error. The commenter stated that NRC, under the Nuclear Waste Policy Act, should reject the license application, because Yucca Mountain is unsuitable as a repository site because of water issues and earthquakes.

Response. NRC will evaluate the information submitted in a license application and any accompanying documents to determine whether the application satisfies regulatory requirements, *i.e.*, whether health and safety, and the environment will be protected. The regulations in 10 CFR part 63 and 10 CFR part 51 are protective of health and safety and the environment.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 11: Have the key technical issues related to the Yucca Mountain site been omitted from the scope of the Yucca Mountain Review Plan?

Comment: Two commenters expressed concern that the key technical issues that were supposed to be addressed by DOE have been omitted from the Yucca Mountain Review Plan.

Response. Nine key technical issues which were identified during the prelicensing consultation period are largely centered on individual scientific or engineering disciplines. The Yucca Mountain Review Plan has 14 physical processes (called model abstractions) that NRC staff considers most important to health and safety. These 14 model abstractions are multidisciplinary and are derived from the uncertainties associated with the key technical issues.

NRC staff would use these 14 model abstractions as the foundation for conducting its assessment of DOE's performance assessment during a licensing review. Therefore, the portion of the Yucca Mountain Review Plan that examines postclosure performance has been structured around these abstractions. Technical concerns associated with the key technical issues have been incorporated in the model abstractions.

No changes to the Yucca Mountain Review Plan have been made in response to this comment.

Issue 12: Is there a difference between requests for additional information prepared during an acceptance review and those prepared during a detailed technical review?

Comment. One commenter noted that Section 1.2.1, ''Acceptance Review Objectives,'' (now Appendix A, Section A1.2.1) of the Yucca Mountain Review Plan directs NRC staff to identify additional information needed to make the application complete. The commenter noted that Section 1.2, ''General Review Procedure,'' (now Appendix A, Section A1.2) states that gaps in information necessary to make a licensing conclusion should serve as the basis for NRC staff requests for additional information. The commenter asked if there are differences between these two types of information needs.

Response. These two types of information request have slightly different purposes. Requests for information stemming from an acceptance review generally would identify deficiencies in the application and ask the DOE to provide information that would make a license application complete enough to begin a detailed technical review. Examples might be missing maps of facility structure locations or missing historical meteorological data.

Requests for additional information prepared during detailed technical review would provide NRC staff with sufficient information to determine whether regulatory requirements have been met.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 13: How can information from prelicensing interactions be used during a licensing review for a high-level waste repository at Yucca Mountain?

Comment. One commenter noted that the many years of DOE and NRC prelicensing interactions have given NRC a considerable opportunity to review the breadth and depth of DOE's work related to a Yucca Mountain repository. The commenter suggested that the Yucca Mountain Review Plan explicitly recognize the progress made during prelicensing reviews and communicate the extent to which NRC staff should consider the results of these prelicensing interactions.

Response. During prelicensing issue resolution activities with DOE, NRC staff has become knowledgeable about technical issues associated with the repository and prepared to conduct a licensing review. No licensing decisions have been reached during prelicensing interactions. NRC staff will conduct a licensing review for a proposed high-level waste repository at Yucca Mountain and make findings based on the information and compliance demonstrations presented in the license application and any other information submitted by DOE.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 14: Will NRC staff have adequate resources to conduct a licensing review for a potential high-level waste repository at Yucca Mountain?

Comment. One commenter expressed concern regarding whether NRC staff would have adequate numbers of qualified staff to conduct a licensing review for a potential high-level waste repository at Yucca Mountain. Other commenters expressed concerns that NRC would be unable to obtain qualified reviewers or that all qualified reviewers would retire by the time a license application is submitted.

Response. NRC is taking steps to ensure that it has qualified staff sufficient to conduct a licensing review for a potential high-level waste repository at Yucca Mountain.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

Issue 15: Are requirements on DOE for data traceability, transparency, retrievability, reproducibility, and consistency adequate?

Comment. One commenter raised several concerns related to requirements on DOE for data traceability, transparency, retrievability, reproducibility, and consistency. These concerns included: (i) Whether the license application would be hypertext linked to supporting documentation; (ii) whether access to DOE data tracking numbers is adequate; (iii) whether reference materials are kept updated and interrelated; (iv) whether historically defined quality system weaknesses are to be corrected; (v) whether data can be located; (vi) whether calculation or modeling results can be duplicated; and (vii) whether adequate technical bases will be available. The commenter suggested the use of DOE ''road maps,'' to help resolve these concerns.

Response. There is a publicly available record of NRC and DOE interactions during the prelicensing consultations on the commenter's concerns. Responses to similar comments on the Quality Assurance Program section of the Yucca Mountain Review Plan are addressed in response to issues above. Separate guidance is under development addressing the usage of hyperlinks in the license application.

NRC staff will continue to observe DOE's quality assurance program and will require compliance with quality assurance requirements in 10 CFR part 63, subpart G, ''Quality Assurance

Program'' during the license application review.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 16: What are the penalties for exceeding radiation exposure limits?

Comment. One commenter asked what the penalties would be for exceeding radiation protection limits. The commenter also asked for the criteria for revocation of a repository license.

Response. NRC has a rigorous inspection and enforcement program for licensed facilities. The enforcement program reflects a hierarchy of violations and penalties based on the severity of a violation. Depending on the circumstances, enforcement actions could include the imposition of civil penalties or revocation of a license. If warranted, violations would be referred to the U.S. Department of Justice for prosecution. Information on the NRC inspection program can be obtained by visiting NRC's Web site at *http://www.nrc.gov.*

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 17: What enforcement action will be taken if the DOE violates NRC regulations?

Comment. One commenter asked whether the Yucca Mountain Review Plan states the actions NRC would take if DOE violated regulations or was untruthful.

Response. The Yucca Mountain Review Plan is guidance for the NRC staff review of a DOE license application and does not address possible enforcement actions. Pursuant to 10 CFR 63.10, information provided to NRC, or required to be maintained by law, by a license, or license applicant, must be complete and accurate in all material aspects. Deliberate violations of NRC requirements are addressed in 10 CFR 63.11. Enforcement action depends on the severity of a violation and could range from issuance of a notice of violation to the issuance of an order to impose a civil penalty (or to modify, suspend, or revoke a license), or other appropriate action.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 18: What would be the extent of NRC on-site presence at the repository and the NRC staff role after the licensing process?

Comment. One commenter stated that NRC should provide personnel for site monitoring on a continuous basis from the time the Yucca Mountain project starts until it is completed. The commenter also asked whether NRC staff conducted unexpected on-site inspections during the various stages of a project. One commenter asked that NRC staff specify its role after the licensing process.

Response. The Commission discussed the nature of its on-site activities at Yucca Mountain in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55768, November 2, 2001) by stating:

> The NRC maintains a local onsite representative's office, with a small staff, in Las Vegas, Nevada, as a means of keeping abreast of DOE activities and interacting with other stakeholders. This office allows our onsite representatives physical proximity to the site and the opportunity to interact on various site characterization activities. At this time, the NRC has no plans to expand the size of the onsite representative's office. However, the size of the office, as well as the scope of NRC's activities conducted there, is [are] subject to reexamination.

If a license is granted for a high-level waste repository at Yucca Mountain, NRC staff will carry out its statutory and regulatory responsibilities to ensure adequate protection of health and safety, to promote the common defense and security, and to protect the environment. NRC staff plans to have onsite representatives based in Las Vegas, Nevada, and would implement an inspection program that would continue for the operational lifetime of a repository. These measures are similar to those employed at other nuclear facilities.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 19: What is NRC staff's plan if it cannot complete the licensing review for a high-level waste repository at Yucca Mountain within the legally mandated time frame?

Comment. One commenter asked whether NRC staff had a plan for the possibility that it might not complete a Yucca Mountain licensing review within the legally mandated time frame.

Response. NRC staff plans to complete its review of an application for a proposed repository at Yucca Mountain in sufficient time to enable the Commission to decide whether to issue a construction authorization within the legally mandated three-four year time frame. If additional time is needed to fully consider issues raised in the adjudicatory proceeding, NRC will seek appropriate relief.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 20: How will NRC staff handle a change to repository design or operations during the licensing proceeding?

Comment. One commenter asked how NRC staff would respond if, during the licensing process, DOE requested more space for a larger repository footprint.

Response. NRC response to this hypothetical situation would depend on whether the change was encompassed by the analysis in the license application and was addressed in the environmental impact statement. NRC would expect DOE to revise or supplement its application to address such changes. NRC would then determine whether the application, as revised, satisfies regulatory requirements.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

Issue 21: Why would radioactive wastes be generated during operations at a high-level waste repository at Yucca Mountain?

Comment. One commenter expressed concern that NRC is expecting DOE to reprocess spent fuel or to operate a nuclear reactor at a Yucca Mountain repository. The commenter cites a portion of Review Method 1 in the draft Yucca Mountain Review Plan, 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,'' which notes that a license application must include adequate consideration of ''* * * means to control radioactive waste and radioactive effluents * * * such as: * * * liquid waste management system to handle the expected volume of potentially radioactive liquid waste generated during normal operations * * *.'' The commenter stated that the public does not expect the Yucca Mountain site to be generating radioactive waste during normal operations and asked if there was another explanation for this review method.

Response. A license for a geologic repository at Yucca Mountain would not authorize the reprocessing of spent fuel or operation of a nuclear power reactor at the site. Experience from other nuclear facilities where high-level radioactive waste and spent fuel handling and packaging take place, however, indicates that small amounts of radioactive waste (*e.g.*, gloves) will be generated during fuel handling, packaging, testing, and decontamination activities. These materials generally may be classified as low-level waste and would be disposed of appropriately. This review method addresses a regulatory requirement at 10 CFR 63.112, ''Requirements for Preclosure Safety Analysis of the Geologic

Repository Operations Area,'' Subsection (e)(10), which requires an analysis that includes ''* * * means to control radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency * * *.''

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 22: Would emergency response capability to respond to potential radiological accidents at a high-level waste repository at Yucca Mountain be adequate?

Comment. One commenter expressed several concerns regarding emergency response planning including: (i) Whether local emergency response personnel would have to be mobilized to respond to radioactive waste spills; (ii) whether NRC intends to fund the purchase of equipment necessary to neutralize the effects of a radiation spill; (iii) whether NRC will educate the public on self-protection during radiation emergencies; and (iv) whether drills would be conducted for evacuation of a large population threatened by radiation exposure.

Response. The Commission addressed issues related to emergency preparedness and response in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55745–55746, November 2, 2001) as follows:

> Part 63 (Subpart I) requires DOE to submit an emergency plan for coping with radiological accidents. NRC's review of DOE's emergency plan will evaluate the adequacy of the plan including such things as the capability to respond to accidents and medical assistance for treatment of radiological injuries. Where DOE's emergency plan is found to be inadequate, NRC, if necessary, can impose license conditions that require DOE to correct any deficiencies. * * *
>
> Additionally, U.S. Federal Emergency Management Agency (FEMA) regulations, as well as DOE orders, require that DOE have an emergency response capability that is adequate to meet anticipated accidents, including potential radiological accidents. DOE is responsible for ensuring that the emergency treatment capability exists and is documented in its emergency plan, which is subject to NRC review in accordance with Section 63.161.

In response to a comment regarding the required scope of emergency plans the Commission stated (66 FR 55746, November 2, 2001):

> The rule requires DOE to have plans to cope with radiological accidents (emergency planning at section 63.161) and provide for physical protection (Section 63.21(b)(3)). These plans are required to address a number of criteria to ensure that DOE is prepared to respond, both on site and off site, to accidents, and that DOE has the capability to detect and respond to unauthorized access and activities that could threaten the physical protection of high-level waste. As noted * * *, NRC and [U.S. Federal Emergency Management Agency] regulations, as well as DOE orders, require that DOE have adequate plans and procedures in place to address any potential accidents and incidents. DOE's emergency plan and physical protection plan are subject to NRC review. The Commission believes that the requirements for DOE's plans for emergencies and physical protection expressed in the proposed Part 63 are appropriate and has retained them in the final rule. In light of the terrorist attacks of September 11, 2001, the Commission has directed the staff to conduct a comprehensive reevaluation of NRC physical security requirements. If this effort indicates that NRC's regulations or requirements warrant revision, such changes would occur through a public rulemaking or other appropriate methods.
>
> Section 63.161 requires DOE to develop an emergency plan based on the criteria of Section 72.32 (*i.e.*, criteria provided for an Emergency Plan for an Independent Spent Fuel Storage Installation (ISFSI)). The required Emergency Plan includes: Identification of each type of accident; description of the means of mitigating the consequences of each type of accident; prompt notification of offsite response organizations; and adequate methods, systems, and equipment for assessing and monitoring actual or potential consequences of a radiological emergency condition. If particular types of accidents require evacuation procedures to ensure the protection of public health and safety, they will be included in the Emergency Plan.
>
> Section 63.21(b)(3) requires DOE to submit a detailed plan to provide physical protection of HLW in accordance with § 73.51 (requirements for physical protection of stored spent nuclear fuel and HLW). The requirements for physical protection include: (1) Capabilities to detect and assess unauthorized access or activities and protect against loss of control of the facility; (2) limiting access to HLW by means of two physical barriers; (3) providing continual surveillance of the protected area in addition to protection by an active intrusion alarm; and (4) providing a primary alarm station located within the protected area and have [having] bullet-resisting walls, doors, ceiling, and floor. These requirements provide high assurance that physical protection of the repository includes appropriate measures to prevent and respond to unauthorized access and activities, including the potential for armed intruders (*e.g.*, terrorist activity).

The Commission also addressed infrastructure requirements for emergency response (66 FR 55746, November 2, 2001).

> Section 180(c) of the Nuclear Waste Policy Act requires DOE to provide technical assistance and funding for training State and local governments and Tribes for safe routine transportation and emergency response. However, NRC's responsibility for oversight and review of DOE's emergency plans * * * does not include responsibility for how DOE provides for technical assistance and funding. Additionally, under NEPA, the potential for (environmental) impacts due to transportation, including accidents, is the responsibility of DOE to assess and mitigate.

Section 4.5.7, ''Emergency Planning,'' of the draft Yucca Mountain Review Plan provides guidance regarding the review of DOE's application with respect to emergency planning regulations.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

11.3 Issue Resolution

Issue: When will the 293 agreements regarding key technical issues be resolved?

Comment. Commenters asked when the 293 identified unresolved issues would be resolved and whether the repository would be licensed if the issues were unresolved. One commenter stated that if NRC staff uses the technical understanding and basis for issue resolution developed during prelicensing, it must explicitly reference to the supporting documentation. One commenter was concerned that haste in issue resolution would result in some issues not being properly resolved. Another commenter stated that DOE's site recommendation is premature and that years are still required to amass information necessary for a license application. Another commenter asked whether issues identified by the U.S. Government Accounting Office would be included in the licensing process.

Response. In 293 agreements with NRC, DOE agreed to provide additional information to NRC regarding key technical issues as part of the prelicensing issue resolution process. NRC staff expects that this prelicensing issue resolution will continue up to the time that DOE submits an application for a construction authorization for a repository at Yucca Mountain and that DOE will address the 293 agreements before submitting the application. During prelicensing interactions with DOE, NRC staff has stayed informed on issues related to DOE's site characterization and the repository design process and identified concerns regarding these issues in public meetings and documents. Issues identified by the U.S. Government Accounting Office were taken from issues raised by NRC staff.

NRC staff has made clear that a licensing decision will be based on information contained in the DOE application. Issues may be reopened, or new issues may be identified, during the

review of the license application. A construction authorization for a repository at Yucca Mountain will not be issued unless DOE demonstrates, and NRC staff determines, that applicable regulatory requirements have been met. NRC staff will document the basis for its conclusions on the application in a safety evaluation report.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

11.4 Public Participation

Issue 1: What is the public role in activities under the Nuclear Waste Policy Act related to Yucca Mountain?

Comment. Commenters identified approximately 20 questions about the nature and extent of public participation in a Yucca Mountain licensing proceeding and questioned whether the public participation process was valid. Some commenters asked about the extent of public participation in the process and others argued that public participation was required. One commenter stated expectations that NRC staff will adequately advertise public hearings in advance. Another commenter stated that all interactions between NRC and DOE should be in public meetings or by conference calls that include the public.

Other commenters urged that there be a continuing program of interaction, training, and progress reviews for the public and questioned whether the public has adequate access to the Yucca Mountain site.

Response. NRC staff has offered numerous opportunities for the public to stay informed about activities related to the proposed repository at Yucca Mountain. The extensive program of public involvement has included meetings in Nevada on the mission of NRC, the development of 10 CFR part 63, the review of DOE's draft environmental impact statement, and the development of the Yucca Mountain Review Plan. Formal periods of public comment were provided for development of 10 CFR part 63 and the Yucca Mountain Review Plan. NRC has had public interactions with DOE consistent with a prelicensing agreement and the Commission's Open Meeting Policy (59 FR 48340, September 20, 1994; 65 FR 56964, September 20, 2000), and the public has been given the opportunity to ask questions. Notice of public meetings with DOE is provided in advance and that practice will continue.

In addition, as required by NRC regulations in 10 CFR part 2, ''Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,'' an opportunity for a formal adjudicatory hearing will be provided on the license application for high-level waste repository at Yucca Mountain. Members of the public, including representatives of the State of Nevada, local counties, and Indian Tribes, may participate in a hearing on the application provided they are admitted as parties or interested governmental participants to the proceeding.

Substantial documentary material related to the license application will be available to the public and participants in the licensing proceeding via the Licensing Support Network, which is accessible over the Internet, as required by 10 CFR part 2, subpart J, ''Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High-Level Radioactive Waste at a Geologic Repository.''

If the Yucca Mountain Review Plan is revised or updated in the future, NRC will decide, depending on the nature and extent of the changes, whether to circulate it for public comment.

No changes were made to the Yucca Mountain Review Plan in response to these comments

Issue 2: What assistance will NRC staff provide to Native American Tribes with respect to the licensing of the potential high-level waste repository at Yucca Mountain?

Comment. A commenter stated that NRC staff was not interested in helping or working with members of Native American Tribes and asked that the hearing process be extended for 10–15 years to enable tribal members to prepare to participate in the proceeding.

Response. NRC recognizes the unique status of Native American Tribes. Consistent with the Nuclear Waste Policy Act, NRC regulations in 10 CFR part 63, subpart C, require that any ''affected Indian Tribe'' (a status conferred by the Department of the Interior) be kept informed concerning activities regarding the proposed repository and also provide opportunities for affected Indian Tribes to participate in the review of the license application under certain circumstances. Further, as noted in response to Issue 1, above, Indian Tribes may also seek permission to participate in the adjudicatory proceeding pursuant to 10 CFR part 2, subpart J.

As a general matter, representatives of Indian Tribes, as well as other members of the public, have been notified of public interactions concerning the proposed repository and have had access to the Yucca Mountain Review Plan and other documents related to the repository.

The requested, lengthy extension of the hearing process would be inconsistent with three- to four-year statutory deadline for a NRC decision on the construction authorization for the proposed repository.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

11.5 U.S. Department of Energy Responsibilities

Issue 1: What are DOE's responsibilities at the proposed repository?

Comment. One commenter asked whether DOE would be allowed to transfer responsibilities and liabilities to corporate vendors.

Response. Under NRC regulations, the license applicant or licensee is responsible for safety and regulatory compliance with NRC regulations, even if some activities are performed by a contractor. Thus, DOE is responsible for ensuring that the proposed repository is constructed, and waste handling and disposal activities are conducted, in compliance with NRC requirements, NRC will conduct the necessary inspection and review activities to determine compliance with NRC regulations, and take action, as necessary, to enforce those requirements, including modifying, suspending or revoking any license issued, if warranted.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 2: Who is financially responsible for the safe operation of a repository?

Comment. One commenter asked who would be financially responsible for limiting radioactive release from the repository. Another commenter expressed concern that the costs of cleaning up after an accident or sabotage would be astronomical and asked who would be responsible for these costs. Another commenter stated that there are no stewardship funds for Yucca Mountain.

Response. Federal statutes provide that DOE would be licensed by NRC, if appropriate, to construct and operate the high-level waste repository at Yucca Mountain. Thus, DOE, an agency of the Federal Government, would be financially responsible for ensuring that activities at the repository are conducted safely.

As the Commission stated in its ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55771, November 2, 2001):

> Part 63 does not alter whatever liability the Federal Government may have for damage to

health or property caused by its activities. It is possible that compensation could be available for certain types of damage to health or property under Federal law, but it would be speculative to suggest that compensation would be available in any particular case.

No changes to the Yucca Mountain Review Plan were made in response to this comment.

Issue 3: How does DOE provide material control and accountability for nuclear materials at the Nevada Test Site?

Comment. One commenter asked about the material control and accounting by DOE at the Nevada Test Site.

Response. The Nevada Test Site is under DOE jurisdiction and is not regulated by NRC. The commenter should contact DOE for information regarding material control and accounting at the Nevada Test Site.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

Issue 4: Who is responsible for identifying structures, systems, and components important to safety?

Comment. One commenter expressed concern that the Yucca Mountain Review Plan directs that NRC staff should focus its review proportionally on high-risk-significant structures, systems, and components important to safety. The commenter argued that NRC, as the regulator, should not defer to DOE judgments as to which components are most important to safety, and should perform a separate analysis of what the Commission views as high-risk-significant structures, systems, and components important to safety.

Response. Regulations at 10 CFR 63.142(c)(1) require DOE to identify the structures, systems, and components to be covered by the quality assurance program. DOE must identify structures, systems, and components important to safety or to waste isolation and to assess their risk significance. NRC will evaluate whether DOE has adequately performed this identification and assessment.

Commensurate with implementation of risk-informed, performance-based regulation for a high-level waste repository, NRC staff would focus its review proportionately on those structures, systems, and components that are important.

NRC staff has developed an independent capability to conduct a preclosure safety analysis. Consistent with risk-informed, performance-based regulation, this independent capability will be focused on those structures, systems, and components important to health and safety.

No changes were made to the Yucca Mountain Review Plan as a result of this comment.

11.6 Role of the Licensing Support System Advisory Review Panel (Now the Licensing Support Network Advisory Review Panel)

Issue: What is the role of the Licensing Support Network Advisory Review Panel in the review of licensing issues?

Comment. One commenter asked whether the Licensing Support System Advisory Review Panel (now the Licensing Support Network Advisory Review Panel) will continue to perform a review role on licensing issues.

Response. Under 10 CFR 2.1011(e), the Licensing Support Network Advisory Review Panel provides advice to NRC on issues related to, among other things, the type of computer system necessary to access the Licensing Support Network, and computer format standards for providing electronic access to the documentary material made available via the Licensing Support Network, and procedures and formats for electronic transmission of filings and orders in the adjudicatory proceeding on the DOE application. The Licensing Support Network Advisory Review Panel basically provides advice on issues related to the means by which information about the proposed high-level waste repository will be made electronically available and has no role in the review of DOE's application.

No changes have been made to the Yucca Mountain Review Plan in response to this comment.

11.7 The U.S. Department of Energy Environmental Impact Statement

Issue: How will the Yucca Mountain Review Plan provide for review of a Yucca Mountain environmental impact statement?

Comment. Several commenters questioned whether the Yucca Mountain Review Plan adequately addressed review of the Yucca Mountain environmental impact statement.

Some commenters questioned the adequacy of the environmental impact statement in evaluating property values along the transportation routes, flooding analysis, environmental justice, cumulative effects, impacts on affected Native American Tribes (economic, cultural, and social) and responses to public comments on the environmental impact statement.

Other commenters recommended modification of the environmental impact statement to incorporate designs presented in the license application, the preparation of a Record of Decision, and any need to prepare a supplemental environmental impact statement.

Response. Comments regarding DOE's Final Environmental Impact Statement are not related to the Yucca Mountain Review Plan, which is a guidance document for NRC staff to use to conduct a review of whether the DOE license application, if submitted, satisfies NRC regulations in 10 CFR part 63.

Under Section 114 of the Nuclear Waste Policy Act, NRC (in connection with the issuance of a construction authorization and license for a repository) is required to adopt, to the extent practicable, any environmental impact statement prepared in connection with a repository. If the DOE submits an application, NRC staff would publish a notice of hearing in the **Federal Register** and state whether it is practicable to adopt DOE's environmental impact statement. The notice would provide a 30-day opportunity for parties and petitioners to file contentions regarding whether it is practicable to adopt the environmental impact statement. The presiding officer in the hearing would rule on any petition to intervene and, to the extent raised by an admitted contention, resolve disputes concerning NRC staff determination regarding adoption of the environmental impact statement. The decision of the presiding officer would be reviewable by the Commission.

The standards, set forth in 10 CFR 51.109(c), require that NRC find it practicable to adopt any environmental impact statement prepared by DOE unless: (1) The action proposed to be taken by the Commission differs from the action proposed in the DOE license application and this difference may significantly affect the quality of the human environment, or (2) Significant and substantial new information or new considerations render DOE's final environmental impact statement inadequate.

Unless either of the above criteria were met, NRC would find it practicable to adopt the environmental impact statement.

No changes were made to the Yucca Mountain Review Plan were made in response to these comments.

11.8 Transportation

Issue: Are transportation concerns, including protection of nuclear materials during transport, adequately addressed in the Yucca Mountain Review Plan?

Comments. Several commenters identified issues relating to U.S. Department of Transportation and NRC transportation regulations and the adequacy of DOE's Environmental Impact Statement in evaluating the transportation of storage casks to a geologic repository at Yucca Mountain.

A number of commenters also expressed concerns about physical protection and security during transport of nuclear materials from current storage locations to Yucca Mountain.

Response. The Yucca Mountain Review Plan is guidance for NRC staff in conducting a review of the license application submitted under 10 CFR part 63. Reviews of transportation of nuclear materials is addressed by other NRC guidance. Section 180 of the Nuclear Waste Policy Act, 42 U.S.C. 10175, requires DOE to use NRC-certified package designs to transport spent nuclear fuel and high-level waste to a permanent geologic repository. The design of casks that would be used by DOE to transport spent nuclear fuel to a proposed repository must be reviewed and approved by NRC in accordance with 10 CFR part 71. The applicable NRC review guidance is in NUREG–1617, the ''Standard Review Plan for Transportation Packages for Spent Nuclear Fuel.'' If and when DOE submits a design, or designs, for shipping casks, NRC would perform a safety review, and if the designs are found to comply with NRC regulations, then NRC would issue a Certificate of Compliance that is a license to use the cask(s) for shipping the specified fuel contents.

Review of transportation activities for Yucca Mountain will depend on whether they will be conducted by an NRC licensee other than DOE. If DOE takes custody of spent fuel at the site of an NRC licensee, DOE regulations would govern the security of spent fuel shipments. If an NRC licensee ships spent fuel to the geologic repository, 10 CFR part 71, 10 CFR part 73, and U.S. Department of Transportation regulations apply. The impacts of transportation to and from the facility have been evaluated in the DOE environmental impact statement that may be adopted by NRC under 10 CFR 51.109.

NRC's regulations for physical protection of the shipment of irradiated reactor fuel (*i.e.*, spent nuclear fuel) by NRC licensees are located in 10 CFR 73.37. Shipments made by NRC licensees to a future high-level waste repository would be subject to NRC security regulations. NRC staff would review the proposed routes for shipments. For shipments that are subject to NRC's authority, the regulations in 10 CFR 73.37 require licensees to develop and implement security procedures to meet performance objectives, including minimizing the possibilities for radiological sabotage. These procedures provide information on how licensees comply with NRC's spent nuclear fuel shipment physical protection requirements, including advance notification of each shipment to Governors, the establishment of redundant communication capability with the shipment vehicle, the arrangement of law enforcement contacts along the route, and provisions for armed escorts. Section 180 of the Nuclear Waste Policy Act requires DOE to abide by NRC's advance notifications to state and local governments associated with transporting spent fuel and high level waste.

For NRC-licensed shipments, NRC reviews and approves in advance the routes used for road and rail shipments of irradiated reactor fuel, with respect to physical protection requirements. The U.S. Department of Transportation regulations at 49 CFR part 397 establish the requirements for the designation of preferred routes for highway shipment of hazardous material (*e.g.*, spent nuclear fuel). A shipper must choose routes that meet U.S. Department of Transportation-specified criteria that are intended to minimize the risk of exposure of the public to radiation. There is no formal U.S. Department of Transportation route approval processes as long as routes are consistent with U.S. Department of Transportation guidelines. The U.S. Department of Transportation regulations set the standards for packaging, transporting, and handling radioactive materials (including labeling, shipping documents, placarding, loading, and unloading), and specify training that is required for personnel who handle and transport hazardous materials.

Since the events of September 11, 2001, NRC has taken actions to impose additional security requirements on shippers of spent nuclear fuel. In addition, NRC is sponsoring vulnerability studies to determine the potential effects on a cask subject to attack, by terrorists, beyond current regulatory assumptions, including the crash of a jumbo jet filled with fuel. NRC staff would use results of this study to determine if its security regulations should be modified.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

11.9 Terrorism

Issue: Does the Yucca Mountain Review Plan adequately address terrorism and related acts?

Comment. One commenter questioned whether NRC staff was going to mandate ''mock attack'' drills on the Yucca Mountain site as a test of the physical protection system. Another commenter inquired whether NRC staff was going to consider protection from insider threats as well as the outsider threat to a repository. Other commenters questioned the perceived lack of security at nuclear facilities in the wake of the September 11, 2001, attacks and argued that the Yucca Mountain site would be a prime target for terrorists. A commenter asked that the schedule for the U.S. Nuclear Regulatory comprehensive review of physical security be placed in the Yucca Mountain Review Plan.

One commenter stated that the technical bases and assumptions for identifying initiating events need to include acts of terrorism, sabotage, and acts of war. The same commenter stated that for calculating Category 2 event sequences, sabotage in the repository, acts of war directed at the repository, sabotage in the operations area, acts of war in the operations area, accidental criticality, intentional criticality, dirty bombs, and permanent contamination of the operations area need to be considered.

Response. NRC staff has taken actions regarding security at NRC-licensed facilities in the wake of the September 11, 2001, attacks. Numerous security advisories have been issued to site security managers keeping them updated on the threat environment. NRC staff monitors the threat environment and shares information and analysis with other law enforcement and intelligence agencies. Compensatory Measures have been issued to NRC licensees outlining mandatory enhancements to physical protection in areas such as access control, physical barriers, detection, assessment, and response. The Compensatory Measures are designed to enhance and strengthen physical protection until the Commission-ordered comprehensive review of physical protection is complete.

The purpose of the Yucca Mountain Review Plan is to ensure the quality and uniformity of NRC staff licensing reviews under 10 CFR part 63. The NRC comprehensive review of safeguards and security is a separate activity. The NRC safeguards and security review encompasses all types of licensed facilities and includes information and

personnel security programs. Additionally, the review schedule may need to be modified based on the changing threat environment. NRC staff review of the physical protection aspects of a license application for a high-level waste repository at Yucca Mountain would be consistent with results from the comprehensive review.

Protection against terrorism and sabotage were discussed by the Commission in the ''Statement of Considerations'' for 10 CFR part 63 (66 FR 55771, November 2, 2001):

> As regards the potential risk of radiological sabotage to the repository during the preclosure phase of operations, the Commission's regulations for Yucca Mountain at Section 63.21(b)(3) require that licensees have in place adequate physical security plans and attendant procedures to protect against radiological sabotage, consistent with Section 73.51—NRC's requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste. In light of the terrorist attacks of September 11, 2001, the Commission has directed the staff to conduct a comprehensive reevaluation of NRC physical security requirements. If this effort indicates that NRC's regulations or requirements warrant revision, such changes would occur through a public rulemaking or other appropriate methods.

The physical security plan required by 10 CFR 63.21(b) and 10 CFR 73.51 would not be made publicly available, but would be reviewed to determine whether the regulatory requirements are met.

The technical bases and assumptions for identifying initiating events and evaluating Category 2 event sequences do not need to include acts of war. As the Commission stated in issuing 10 CFR part 63 (66 FR 55776, November 2, 2001), ''[c]onsideration of the effects of wars and military actions is beyond the scope of NRC's responsibility. NRC has not taken into account the effects of war in developing Part 63.''

Events such as criticality and contamination of the operations area are addressed in responses to other comments.

No changes were made to the Yucca Mountain Review Plan in response to this comment.

11.10 Editorial Comments

Issue: Will editorial corrections be made to the Yucca Mountain Review Plan?

Comment. Several commenters suggested editorial improvements to the Yucca Mountain Review Plan.

A partial list of these comments follows.

(1) Remove review plan Section 1, ''Introduction,'' and Section 2, ''Acceptance Review,'' from the front of the plan and include them as appendixes, to avoid detracting from the actual licensing review.

(2) Change the bullet and dash system to a numerical outline format similar to that in other NRC staff guidance documents.

(3) Clarify the language of Review Method 3 in Section 3.1, ''General Description,'' of the draft Yucca Mountain Review Plan, regarding the basis for the Commission's licensing authority.

(4) Make specific provisions in the Yucca Mountain Review Plan for evaluating information that is classified, such as the characteristics of naval fuel.

(5) Update the Yucca Mountain Review Plan to reflect the current status of activities under the Nuclear Waste Policy Act.

Response. NRC staff has incorporated those editorial comments that add clarity to the Yucca Mountain Review Plan.

Dated at Rockville, Maryland, this 23rd day of July 2003.

For the Nuclear Regulatory Commission.

Janet R. Schlueter,

Chief, High-Level Waste Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

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