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Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada; Final Rule

Enclosure 1

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 19, 20, 21, 30, 40, 51, 60, 61, 63, 70, 72, 73, and 75

RIN 3150–AG04

Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, NV

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing licensing criteria for disposal of spent nuclear fuel and high-level radioactive wastes in the proposed geologic repository at Yucca Mountain, Nevada. As mandated by law, this final rule changes the Commission's technical requirements and criteria, as necessary, to be consistent with final environmental standards for Yucca Mountain issued by the U.S. Environmental Protection Agency (EPA). The criteria address how a repository system at Yucca Mountain must perform and specify that the system must comprise both natural and engineered barriers. The final rule includes licensing criteria; participation in license reviews by the State, affected units of local government, and Indian Tribes; records and reporting; monitoring and testing programs; performance confirmation; quality assurance; personnel training and certification; and emergency planning. Criteria set out in this final rule apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission is also changing its generic criteria for disposal of spent nuclear fuel and high-level radioactive wastes in geologic repositories. These changes make clear that the generic criteria, specified elsewhere in the regulations, do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

EFFECTIVE DATE: December 3, 2001.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7285, e-mail tjm3@nrc.gov; Janet Kotra, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6674, e-mail jpk@nrc.gov; or Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6203, e-mail cwp@nrc.gov.

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I. Background

On February 22, 1999 (64 FR 8640), the Commission published a proposed rule for public comment that would establish licensing criteria for disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, Nevada. The Energy Policy Act of 1992, Pub. L. 102–486 (EnPA) directed the Commission to make its requirements for geologic disposal consistent with new standards for Yucca Mountain the Environmental Protection Agency (EPA) would develop. The legislation also specifies the type of standards the NRC is to implement [that is, standards which limit individual dose and which are based on and consistent with the National Academy of Sciences' (NAS) 10 recommendations]. The Commission proposed a new, separate part of its regulations, 10 CFR part 63, that would apply only to the proposed repository at Yucca Mountain. The Commission also proposed to leave its existing, generic regulations at Part 60 in place, changed only to state that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

In setting forth these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for a Yucca Mountain facility that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation. Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria based upon risk insights for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, and (4) focus on the results as the primary basis for regulatory decision making. The Commission believes that creating a new part of its regulations accomplishes these objectives better than modifying the generic requirements. The Commission prefers a wholly new part 63 that reflects the fundamentally different approach laid out for Yucca Mountain by EnPA and the final EPA standards, an approach unlike that contemplated when the generic criteria were issued. Specifically, EnPA defined an approach that requires the performance of a Yucca Mountain repository to comply with health-based standards, developed by EPA and based on the recommendations of the NAS. EPA has established standards for Yucca Mountain that consider risk to a hypothetical individual and are to be the only such standards for the postclosure performance of the repository. This approach differs from that taken in the existing generic criteria which relies on quantitative, subsystem performance standards.

The public comment period, originally ending on May 10, 1999, was

extended to June 30, 1999, in response to many requests for extension (64 FR 24092; May 5, 1999). During the public comment period, the NRC staff held a series of public meetings in Nevada to discuss the proposed rule and solicit public comment. Meetings were held at Las Vegas and Beatty, Nevada, on March 23 and 25, respectively. Later, NRC held more meetings at Amargosa Valley, Las Vegas, and Caliente, Nevada, on June 15, 16, and 17, respectively. In developing this final rule, NRC considered comments received at these meetings along with written comments sent to NRC. The NRC also held a facilitated round table discussion on defense in depth as applied to a possible repository at Yucca Mountain on November 2, 1999, in Las Vegas.

The EPA published final radiation protection standards for the potential Yucca Mountain repository (40 CFR part 197) on June 13, 2001 (66 FR 32073). The EPA standards differ from the performance objectives proposed by the Commission at 10 CFR part 63. EPA established an annual individual protection dose limit of 0.15 mSv (15 mrem), and EPA included separate ground-water protection criteria in its final standards for the purpose of protecting ground water. In formal comments on EPA's proposed standards, dated November 3, 1999, the NRC staff supported a somewhat different approach. The NRC approach, which the Commission believes is adequately protective of public health and safety and ground water, used a comprehensive, all-pathway limit. However, the ultimate decision was EPA's to make and, as called for under the EnPA, the Commission will change its technical requirements and criteria to be consistent with EPA's final standards.

II. Implementation of the Environmental Protection Agency Final Standards

The U.S. Environmental Protection Agency (EPA) published Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, at 40 CFR part 197 on June 13, 2001 (66 FR 32073). The Energy Policy Act of 1992, Pub. L. 102–486 (EnPA) directs the Commission to modify its technical requirements and criteria to be consistent with these standards. The Commission has imported the EPA standards into its final 10 CFR part 63 regulations in as transparent a manner as possible. Three categories of changes were necessary to accomplish this. First, the two subparts of the EPA standards—subpart A for storage and subpart B for disposal—have been added to part 63 as subparts K and L, respectively. Second, in most cases, the Commission adopted wording precisely as it appears at 40 CFR part 197. The Commission also made nonsubstantive changes that conformed to the regulatory style of the proposed part 63, and other U.S. Nuclear Regulatory Commission (NRC) regulations; removed unnecessary references to NRC; and adapted or removed redundant definitions. Lastly, as the implementing authority for the EPA standards, we have provided additional specifications and requirements based on the proposed part 63 rule and public comments we received in the areas where it is appropriate to do so. Indeed, EPA has acknowledged NRC's authority to add implementing requirements. As part of its rulemaking process, the Commission proposed and received comments on many aspects of radiation exposure scenarios, including several matters relevant to implementation of the EPA standards. Although EPA publication of the standards postdated the formal comment period for proposed part 63, the Commission has provided further specifications in subpart L, where needed, for clarification. We believe these additions are consistent with EPA's intent and are responsive to public comments we received. A brief summary of key aspects of the Commission's implementation of EPA's Standards in the final part 63 regulations appears below.

Radiation Standards for Storage

NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for members of the public, during the storage period, and the associated requirements for determining compliance with the standards. The EPA standards identify the standards for storage as applicable at Yucca Mountain during the time period before closure of the proposed repository. In proposed part 63, NRC characterized this phase as "preclosure." Therefore, we are implementing EPA's standards for storage to apply to the preclosure time period.

Radiation Standards for Disposal

The NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for the reasonably maximally exposed individual, during the disposal period, and the associated requirements for determining compliance with the standards.

Ground-Water Protection Standards

NRC has adopted the ground-water protection standards and the associated requirements for determining compliance with the standards.

Radiation Standards for Human Intrusion

NRC has adopted the 0.15 mSv/year (15 mrem/year) dose limit for the reasonably maximally exposed individual as a result of a human intrusion and the associated requirements for determining compliance with the standards. One aspect of EPA's final standards is the specification of the characteristics of a postulated scenario for evaluating the consequences of human intrusion. NRC fully supports and has adopted the characteristics of the human intrusion scenario as specified in 40 CFR part 197 and has specified one additional requirement to further characterize the scenario. Specifically, part 63 provides that no particulate waste material falls into the borehole, and that DOE should assume the exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone). This change responds to a public comment seeking clarification of this aspect of the human intrusion scenario in proposed part 63. The Commission considers the additional requirement to be appropriate for addressing the comment and to be a matter of implementation of the EPA final standards. Further, the requirement is consistent with the human intrusion scenario as specified in 40 CFR part 197.

Reference Biosphere

The EPA standards for Yucca Mountain specify criteria that pertain to the characteristics of a reference biosphere, for use in the performance assessments that are required to show compliance with the postclosure standards for disposal. NRC fully supports and has adopted, in part 63, the characteristics of the reference biosphere as specified in 40 CFR part 197 and has included an additional requirement on characteristics of the biosphere that are consistent with EPA's final standards and that were discussed in proposed part 63 (64 FR 8640; February 22, 1999). Specifically, part 63 provides a further requirement for biosphere pathways by stating these pathways * * * "must be consistent with arid and semi-arid conditions." This addition, from proposed part 63 (64 FR 8677), clarifies the bounds on what DOE needs to consider and is consistent with present knowledge of

how the climate could change over the next 10,000 years.

Reasonably Maximally Exposed Individual

The EPA standards specify characteristics of the reasonably maximally exposed individual (RMEI) for use in the performance assessments used to demonstrate compliance with standards for disposal. The NRC fully supports and has adopted the characteristics of the reasonably maximally exposed individual from 40 CFR part 197, and has included requirements specifying additional characteristics that are consistent with the EPA standards and were discussed in proposed part 63 (64 FR 8640). First, part 63 provides that the reasonably maximally exposed individual * * * "is an adult with metabolic and physiological considerations consistent with present knowledge of adults." This addition, suggested for the average member of the critical group in proposed part 63 (64 FR 8677), clarifies assumptions DOE must make in estimating the radiation exposure to the reasonably maximally exposed individual. This addition is considered to be consistent with EPA's standards because: (1) The standards specify a consumption rate for water (i.e., 2 liters per day) that corresponds with that of an adult; and (2) a dose limit of 0.15 mSv (15 mrem) for an adult is protective of children as well as other age groups. The requirement that metabolic and physiological considerations are consistent with present knowledge of adults is consistent with EPA's final standards, which state that DOE should not project changes in human biology (66 FR 32133).

Second, although the EPA standards specify a representative volume approach for demonstrating compliance with the separate ground-water protection standards, they leave to NRC the approach for demonstrating compliance with the individual protection standard for disposal. EPA's approach for ground-water protection specifies a representative volume of 3,000 acre-feet for estimating the concentrations of radionuclides. The 3,000 acre-feet representative volume of ground water is consistent with assumptions for the critical group described in proposed part 63 (64 FR 8646). Specifically, in the proposed part 63, we suggested consideration of a farming community of up to 100 individuals, living on 15 to 25 farms. Fifteen to 25 farms are consistent with current conditions in the town of Amargosa Valley, Nevada, and would be the number needed to produce the range of locally produced food that is currently consumed in this area. The purpose of identifying 15 to 25 farms and specifying 100 individuals was to provide DOE with flexibility in determining an appropriate water demand consistent with a farming community of that size. A community of 15 to 25 farms would pump a sufficiently large volume of water and involve a broad range of exposure pathways. Of primary importance is the ingestion pathway, through consumption of water, crops, and animal products. The Commission considers that the water demand of between 15 and 25 farms can be represented by a volume of at least 3,000 acre-feet and, thus, is consistent with the farming community proposed for comment in part 63. Additionally, the preamble to EPA's final standards stated the NRC could use an approach to assess water usage in the hypothetical community, in which the RMEI resides, that was similar to the representative volume approach used for ground-water protection (i.e., consider a representative volume of 3,000 acre-feet). Therefore, the Commission removed the flexibility provided DOE to determine an appropriate water demand. This revised approach limits speculation on water demand and provides DOE with a specific value for the water demand that the NRC staff finds acceptable to estimate the RMEI dose. Part 63 specifies that the reasonably maximally exposed individual uses well water with an average concentration of radionuclides based on a representative volume of water of 3,000 acre-feet.

Unlikely Features, Events, and Processes

The EPA standards exclude unlikely features, events, and processes (including sequences of events and processes) from analyses for estimating compliance with the standards for human intrusion and ground-water protection. However, the EPA standards do not specify a frequency for unlikely features, events, and processes, and acknowledge that a value is to be specified by NRC (66 FR 32135). NRC fully supports excluding unlikely features, events, and processes from analyses for estimating compliance with the standards for human intrusion and ground-water protection. Although we have provided no specific quantitative value for determining when exclusion of unlikely features, events, and processes is appropriate, the final regulations require DOE to exclude unlikely features, events, and processes from the specified analyses upon prior approval of the Commission for the probability limit used for unlikely features, events, and processes. The Commission recognizes that specification of a probability limit for unlikely features, events, and processes, as is done for "very" unlikely features, events, and processes, would be a more direct approach. Although the Commission considers a frequency for unlikely features, events, and processes would fall somewhere between 10^{-8} to 10^{-4} per year, the Commission has decided not to specify a value in the regulations at this time. The Commission plans to conduct an expedited rulemaking to quantitatively define the term "unlikely." Consideration will be given to whether a range of values or a single specific value should be used as well as the appropriate numerical value(s). The expedited rulemaking will provide an opportunity for public comment to assist the Commission in determining an appropriate approach.

Total Effective Dose Equivalent

The EPA and the NRC use different quantities to assess the total dose to exposed members of the public (including the RMEI). EPA uses the annual committed effective dose equivalent (annual CEDE), defined as the sum of the committed effective dose equivalent from internal doses resulting from one year's exposure to radioactive materials, and the effective dose equivalent from external radiation exposure during the year. The NRC uses the total effective dose equivalent (TEDE) for the same purpose. There are differences between TEDE and annual CEDE in some contexts. Specifically, in determining the external dose component of TEDE, NRC specifies use of the deep-dose equivalent at 10 CFR 20.1003. The deep-dose equivalent is a point measurement that does not sum the doses to the organs or tissue through use of weighting factors. This approach may reflect the fact that compliance with part 20 is customarily assessed using a Thermo-Luminiscent Device (TLD) or a film badge, and the results of such measurements reflect deep-dose equivalent. By contrast, in determining annual CEDE, the external dose component is determined using the effective dose equivalent, which involves summing the products of organ doses and weighting factors. In those situations in which the two measures of external dose differ, the effective dose equivalent approach probably provides a better estimate for measuring radiation risk.

Nonetheless, NRC's part 20 does allow for consideration of weighting factors for individual organs in the case of external exposures on a case-by-case

basis. *See* 10 CFR 20.1003, Footnote 2 to Table on Organ Dose Weighting Factors. In practice, computer codes used by NRC in decommissioning and HLW disposal currently calculate external doses using effective dose equivalent and not deep-dose equivalent. *See* NUREG/CR 6676, "Probabilistic Dose Analysis Using Parameter Distributions Developed for RESRAD and RESRAD-Build Codes," 3–1 (July 2000); NUREG–1464, "NRC Iterative Performance Assessment," 7–5 (October 1995); and NUREG/CR–5512, "Residual Contamination from Decommissioning, User's Manual DandD Version 2.1," Vol. 2, E–1 (April 2001). Consequently, use of organ doses and organ weighting factors, from Federal Guidance Report 12 and ICRP in its Publication 26, for external doses in assessing compliance with dose limits for members of the public in the general environment and the individual protection standard in connection with a geologic repository will yield exactly the same result as applying annual CEDE. As a result, in assessing compliance with the individual protection standard, the staff intends to use effective dose equivalent for assessing external exposure.

For purposes of assessing actual doses to workers at the Yucca Mountain repository, however, the Commission has directed that deep-dose equivalent be used in determining TEDE. This ensures consistency with NRC's regulations for limiting doses to occupationally exposed workers.

Requirements for Environmental Impact Statement

EPA's standards require DOE to estimate peak dose under the evaluations for individual protection and human intrusion. The results of these evaluations are to be included in DOE's environmental impact statement (EIS). The Commission has modified part 63 to include the provision that DOE must include peak dose estimates in its EIS, but notes that there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain. However, DOE still must carry out its responsibilities under the National Environmental Policy Act in accordance with the final EPA standards.

Definitions

Barriers

Proposed part 63 and EPA's final standards define "barriers" slightly differently. The Commission believes there is no substantive difference between the two definitions and has adopted the EPA definition at § 63.2. The EPA definition, among other things, provides that the Commission would determine a time period over which a material, structure or feature would perform its intended function. The regulation at § 63.115 requires DOE to describe the capability of each barrier to isolate waste. The description would include information on the time period over which DOE asserts that each barrier will perform its intended function including any changes during the compliance period. This information on expected performance will enable NRC to determine the period of time that any particular material, structure or feature 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.

Ground Water

Proposed part 63 and EPA's final standards define "ground water" differently. To implement the EPA standard, part 63 has adopted the EPA definition for ground water and revised the use of the term "ground water" in the proposed rule accordingly. The single definition for ground water is provided at § 63.302.

High-Level Waste

Proposed part 63 and EPA's final standards define "high-level waste" slightly differently. The Commission believes there is no substantive difference between the two definitions and has modified its definition to more closely reflect the definition provided in the Nuclear Waste Policy Act of 1982 and the final standards.

Important to Waste Isolation

Proposed part 63 defined "important to waste isolation" in the context of meeting the individual dose limit for the postclosure period of the repository (i.e., disposal). This use of the term is important in defining the scope of the requirements for: DOE's quality assurance program (specified at subpart G); multiple barriers (specified at 10 CFR 63.113); performance confirmation (specified at subpart F); and changes, tests, and experiments (specified at 10 CFR 63.44). The Commission has expanded the definition of the term, "important to waste isolation" to include both the dose limit and the separate ground-water protection limits contained in the EPA standards.

Performance Assessment

Proposed part 63 and EPA's final standards define "performance assessment" slightly differently. The Commission believes there is nosubstantive difference between the two definitions and has adopted the EPA definition at § 63.2.

III. Public Comments and Responses

In preparing the final rule, the NRC staff carefully reviewed and considered more than 700 discrete comments enclosed in about 160 individual letters received during the public comment period. The NRC staff also identified and evaluated an additional 193 comments made at public meetings. To simplify the analysis, the NRC staff grouped all written and oral comments on the rule into the following six major topic areas:

(1) Regulatory Process and Licensing Process;

(2) Requirements for the Preclosure Period;

(3) Requirements for the Postclosure Period;

(4) General Requirements;

(5) Selected Topics; and

(6) Beyond the Scope of This Rulemaking.

1 Regulatory Process and Licensing Process

1.1 Promulgation in Advance of EPA Standards

Issue 1: Is NRC's action in promulgating part 63 in advance of EPA standards beyond the scope of its authority?

Comment. Many of those who commented on the NRC's proposed part 63 expressed concern that NRC was "usurping" EPA's authority by declaring its own standards and technical requirements in advance of EPA's issuance of final standards. For example, the State of Nevada pointed out the EnPA does not mandate a new Commission rule specific to Yucca Mountain to replace its general rule for licensing geologic repositories. It only requires modification of NRC's technical requirements and criteria, as necessary, to be consistent with new EPA standards once they are published. Further, the State pointed out that EnPA does not authorize the Commission to expand its licensing jurisdiction to include proposing standards for human safety and environmental protection

that are within the statutory mandate and jurisdiction of EPA.

Response. The Commission acknowledges the statutory role given to EPA for setting standards for Yucca Mountain. It is with full recognition of that role that the Commission is publishing final criteria that are consistent with EPA's published standards. In the supplementary information published with the proposed rule, the Commission stated clearly that "* * * the authority and responsibility for setting public health and safety standards for radioactive waste disposal rest with EPA" (64 FR 8643; February 22, 1999). The Commission went on to say that "* * * [w]hen EPA issues final standards for Yucca Mountain or if new HLW legislation is enacted into law, the Commission will amend its criteria at 10 CFR part 63, if necessary, to be consistent with the final standards" (ibid. 8644).

It is true the EnPA did not direct the NRC to develop a new rule specific to Yucca Mountain to replace its general rule for licensing geologic repositories. It is also true the EnPA does not diminish NRC's authority under the Atomic Energy Act to conduct rulemaking nor to select the manner in which it will revise regulatory requirements. In the proposed rule, the Commission explained that since the initial technical criteria at 10 CFR part 60 were promulgated more than 15 years ago, there has been notable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain. The Commission stated that "(t)hese new methods were not envisioned when the part 60 criteria were established and their implementation for Yucca Mountain will avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the Commission's generic requirements at 10 CFR part 60" (64 FR 8641). The Commission recognized that its generic part 60 requirements will need updating if applied to sites other than Yucca Mountain. However, the Commission elected not to conduct an update of part 60 now but, instead, decided to place all the regulations needed for the licensing of a repository at Yucca Mountain in a separate CFR part. *See* Response to Issue 3. The Commission explained that it "believes this to be the most direct and time-efficient approach to the specification of concise, site-specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with forthcoming EPA standards that must also apply solely to Yucca Mountain" (64 FR 8643). Consistent with the views expressed by most commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain and has changed its technical requirements and criteria to conform to EPA's standards, as required by law.

Issue 2: Should NRC wait for EPA to release final standards before completing part 63?

Comment. Commenters differed on the issue whether NRC should proceed with proposed part 63 or wait until after EPA publishes final standards. Commenters in favor of NRC moving forward with the proposed part 63 supported the proposed approach as protective of public health and safety and the environment. They cited timely specification of NRC regulations for the potential repository as a benefit for the national program. Others, however, believed that it was premature for NRC to publish final regulations. They felt that doing so would be contrary to the sequence set by Congress in the EnPA which directs EPA to issue radiation standards first and then for NRC to conform its technical requirements to those standards. These commenters saw no reason for NRC to act outside this time sequence and favored withdrawal of the proposed rule and resubmittal with any necessary adjustments after promulgation of EPA standards.

Response. The EnPA specified that EPA was to publish radiation standards for Yucca Mountain not later than 1 year after receipt of the findings and recommendations of the National Academy of Sciences (NAS). It also directed NRC to modify its technical requirements and criteria not later than 1 year after EPA publishes final standards. The Commission believes that this schedule reflects Congress' intent to have a final regulatory structure before DOE would start preparation of a license application if Yucca Mountain were recommended as a site for a geologic repository. The NAS published its recommendations in August 1995. The NRC explained when it published its proposed rule, on February 22, 1999, that it had decided to proceed, even in the absence of EPA standards, because of the short time period allotted NRC to conduct its own rulemaking. In one year, NRC would have to modify its standards and requirements and to implement certain assumptions in the EnPA related to the effectiveness of postclosure oversight of the repository. The Commission also believed it was in the best interest of the national program to proceed, given that DOE could be in a position to submit a license application to NRC in 2002 (64 FR 8641). It is important to recognize that most of the requirements proposed at part 63 involve matters that are unaffected by the final EPA standards (e.g., licensing procedures, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning). Now that EPA has published final standards, NRC is prepared to complete its implementing regulations at part 63 with due regard to the requirement in EnPA to be consistent with EPA's standards.

Issue 3: Why is there a need to develop a site-specific disposal regulation for the Yucca Mountain site?

Comment. Several commenters questioned NRC's need to develop a whole new body of site-specific regulations as opposed to revising its generic regulations at part 60, as necessary, to conform to the new, site-specific standards to be developed by EPA. These same commenters noted that certain portions of proposed part 63 depart significantly from part 60 (e.g., there are no quantitative subsystem requirements) and, in the view of several commenters, weaken the safety requirements for any proposed repository at Yucca Mountain.

Response. The Commission is establishing a new, separate part of its regulations (at part 63) that would apply only to the proposed repository at Yucca Mountain. The Commission will leave existing, generic regulations at part 60 in place, modified only to state that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain. The Commission believes this to be the most direct and efficient approach for specifying concise, site-specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with EPA standards that apply solely to Yucca Mountain.

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. The Commission believes that creating a new part of its regulations to accomplish these objectives is preferable to modifying its generic requirements, given that EnPA and NAS laid out a fundamentally different approach for Yucca Mountain than was contemplated when the generic criteria were promulgated. Specifically, EnPA and NAS outlined an approach that would require the performance of a Yucca Mountain repository to comply with health-based standards established in consideration of risk to individuals in a hypothetical group. The law also stated that the new health-based standards were to be the only quantitative standards for the postclosure performance of the repository. This approach departs from the approach taken in the existing generic criteria which rely on compliance with cumulative release limits and separate, quantitative, subsystem performance objectives. Further, the Commission's current approach is consistent with EPA standards for Yucca Mountain. Therefore, after carefully considering the public comments, the Commission remains of the view that it is best to develop site-specific regulations—regulations that reflect an improved scientific understanding of the site; are based on state-of-the-art analyses; are consistent with the Commission's philosophy to implement risk informed regulation; and implement the separate, site-specific standards that EPA has issued for Yucca Mountain.

Commenters correctly pointed out that there are significant differences between part 60 and part 63. In the Commission's view, the part 63 regulations do not in any way lessen DOE's responsibility to site, design, and operate the proposed repository safely. Much has been learned regarding the expected performance of geologic repositories in general (Nuclear Energy Agency, Lessons Learnt from Ten Performance Assessment Studies, Paris, France, NEA/OECD Working Group on Integrated Performance Assessments for Geologic Repositories, 1997), and a potential Yucca Mountain repository in particular over the nearly two decades since part 60 was written. Part 63 reflects and incorporates much of this new information. The risk-informed, performance-based approach used to develop the rule (see SECY–97–300, "Proposed Strategy for Development of Regulations Governing Disposal of High-Level Radioactive Wastes in a Proposed Repository at Yucca Mountain," U.S. NRC, December 24, 1997) eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives. That being said, however, part 63 still requires DOE to demonstrate reliance on multiple barriers and defense in depth, preservation of the retrieval option, implementation of a performance confirmation program, transparency in decision making, and application of rigorous quality assurance (QA). Moreover, as a result of public comments, other provisions have been added to part 63 to ensure the adequacy and sufficiency of DOE's compliance demonstrations. (See Multiple Barriers and Defense in Depth for additional discussion on quantitative subsystem requirements.)

1.2 Differences Between Part 63 and EPA Standards for WIPP

Issue: Why is there a difference between the performance objectives in NRC's proposed 10 CFR part 63 for Yucca Mountain and EPA's 40 CFR part 191 standards used to certify the Waste Isolation Pilot Project (WIPP)?

Comment. Many commenters expressed concern that NRC's proposed regulations for Yucca Mountain provided less protection than EPA's standards for WIPP. They regarded NRC's proposed regulations as less stringent than the standards for WIPP. Many cited the absence of separate criteria for protection of ground water in NRC's proposed regulation as evidence that the WIPP standards, which include separate requirements for protection of ground water, are more restrictive. Commenters also cited the differences in the individual protection limits [0.15 mSv/year (15 mrem/year) for WIPP compared to 0.25 mSv/year (25 mrem/year) limit for Yucca Mountain], and the compliance location (5 km for WIPP compared to approximately 20 km for Yucca Mountain). Generally, commenters asked NRC to set standards similar to, or more stringent than, those for WIPP. Some argued that a greater level of protection for people near Yucca Mountain was needed to offset potential exposures from other sources in the region (i.e., the Beatty low-level waste site and the Nevada Test Site, NTS).

Response. Final EPA standards adopted numerical limits that are comparable to those applied at WIPP. Consistent with the views expressed by a majority of commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain and is adopting final part 63 criteria that are consistent with those limits, as required by law.

1.3 Multi-Staged Licensing

Issue 1: Should DOE be allowed to begin to place waste in the repository or to store waste in surface facilities once NRC has determined that there is enough space for initial operations, or should DOE have to wait until site construction is complete?

Comment. Many commenters indicated that NRC should not allow DOE to place waste in the repository until construction is complete. These commenters had general concerns that only after construction is completed would emergency equipment and safety precautions be available in case of an accident; and that any waste, if emplaced before completing construction, may pose an unnecessary risk to the construction workers. Alternatively, other commenters suggested that storage of waste at the repository should be allowed during construction as long as it does not pose any additional health or safety risk. The Nuclear Energy Institute (NEI) suggested that part 63 should be changed so that NRC could authorize DOE to construct all or part of the geologic repository operations area (GROA), and could authorize early use of the surface facilities to store waste.

Response. The proposed rule retained the licensing phases as described at part 60. Once construction of the GROA is substantially complete (as specified at § 63.41), DOE may update its application and the Commission may issue a license to receive and possess source, special nuclear, or byproduct material at the GROA. Prior to issuing such a license, the Commission must make certain findings, such as: (1) Activities to be conducted at the GROA comply with the rules and regulations of the Commission, which will include radiation protection for workers; (2) adequate protective measures can and will be taken in the event of a radiological emergency; (3) there is no unreasonable risk to the health and safety of the public; and (4) construction of the GROA has been substantially completed. Construction is deemed

substantially complete, for this purpose, if among other things, DOE has completed construction of sufficient underground storage space for *initial* operations. Thus, part 63 provides DOE flexibility to plan for efficient repository operations for receipt and emplacement of waste because of the significant length of time required to complete excavation of the entire underground facility.

The DOE has not indicated to the Commission any intention to seek an authorization for early use of the surface facilities for storage of spent nuclear fuel. Such an authorization likely would necessitate a change to (or an exemption from) the regulations. Before NRC would make changes of this type to its regulations, NRC would need to publish the proposed changes and seek public comment.

Issue 2: Should DOE have to prepare a second EIS to support a decision to issue a license amendment for permanent closure, as this may constitute a major Federal action?

Comment. Commenters stated that the license amendment for permanent closure is a major Federal action and should require a new EIS (i.e., not rely upon the EIS prepared for the license application). They expressed the view that a decision to issue an amendment for permanent closure would include a decision that retrieval of the waste is not necessary and that the expected impacts of the waste affecting the environment far into the future and far beyond the site are acceptable. They also pointed out that the decision to issue the license amendment will be based, in part, on performance confirmation data collected after the original EIS is submitted. One commenter was concerned that the proposed requirement at § 51.67 did not explicitly state the need to include measures to mitigate impacts including transportation.

Response. The regulations require DOE to supplement its EIS, if necessary, when the application for the license amendment for permanent closure is submitted [§ 63.51(b)]. The decision involved in granting the amendment would be a subset of decisions made in the original EIS and any supplements. A supplement to the EIS would need to address such things as substantial changes to the proposed action or significant new circumstances or information relevant to environmental concerns. The Commission believes the commenters' request for requiring DOE to consider these matters at the time of permanent closure is adequately covered by the regulations.

The Commission did not adopt the suggested change to § 51.67 to include a specific requirement to consider mitigation measures that the Council on Environmental Quality (CEQ) regulations dictate for the contents of the EIS, which include requirements for consideration of measures to mitigate impacts including transportation. DOE would need to comply with applicable CEQ requirements, and the Commission does not believe any regulatory changes are necessary to ensure compliance by DOE.

Issue 3: Is there any limit on the types and amounts of radioactive materials (e.g., tons of HLW) that DOE would be allowed to receive and possess at Yucca Mountain if these materials were for site characterization activities or testing during construction?

Comment. EPA suggested that, under the proposed rule (§§ 63.7(a) and 63.74(a)(1)), DOE could take any types and amounts of radioactive materials onto the site if it claimed that the materials were for site characterization activities.

Response. EPA correctly notes that proposed part 63 does not place any specific quantitative limit on the amount of radioactive materials DOE might use for site characterization or testing. However, a specific numerical limit is unnecessary. Section 113(c)(2)(A) of the NWPA prohibits the DOE from using radioactive material in conducting site characterization activities unless the Commission concurs that such use is necessary. Under § 63.16(a), if DOE's planned site characterization activities include onsite testing with radioactive material, the Commission must determine whether the proposed use of radioactive material is necessary. The Commission would not concur in any DOE proposal to bring radioactive materials on site unless it was convinced that both the types and amounts were needed for site characterization. The proposed part 63 would not have allowed DOE to receive and possess "any types or amounts" of radioactive materials as suggested by EPA. Thus, changes to the proposed regulations are not needed.

Issue 4: In a multi-staged licensing approach, does the NRC require that all information be available at the first stage (i.e., construction authorization) or will DOE be allowed to provide certain information in a "staged" manner consistent with that particular stage of the licensing process?

Comment. DOE commented that it intends to provide a sufficient level of information to allow the NRC to make a finding of reasonable assurance at the time of the construction authorization in accordance with § 63.31. However, DOE stated that it would be helpful if the Commission would clarify its intent regarding the level of information required in the license applicati[illegible] In particular, DOE recommende[illegible] [illegible]ree changes to proposed subpart B: (1) The language of § 63.2[illegible])(3) calling for "a detailed plan" to provide physical protection for HLW should be changed to a "description of the plan" to provide physical protection for HLW because this would be more consistent with the language used in other provisions of § 63.21(b) and would reflect what DOE believes to be an adequate level of detail on this subject; (2) the proposed § 63.24(a) requirement that the application be as complete as possible at the time of docketing based on reasonably available information should be moved to § 63.21(a) because this section provides requirements for the content of the license application; and (3) the proposed finding that the Commission would make to authorize construction at § 63.31(a)(6) that "DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate" should be changed to "DOE's proposed plan to develop operating procedures" because, at the time of construction authorization, details of the repository design will not, in some cases, be sufficient to support development of operating procedures and DOE does not believe that the procedures need to be in place at this stage of the licensing process. Another commenter suggested that the regulations for each licensing stage should be modified to state explicitly that the corresponding Commission finding must take into account "the scope of the authorization requested and the information available."

Response. 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, 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 § 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 § 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 § 63.21(a).

Regarding DOE's recommendation that the requirement for a "detailed plan" to provide physical protection be changed to require a "description of the plan," the Commission agrees that the suggested revision provides greater consistency with other provisions of § 63.21(b) and with § 72.24(o) and has revised § 63.21(b)(3) to require "(a) description of the detailed security measures for physical protection of high-level radioactive waste in accordance with § 73.51 of this chapter." Notwithstanding this change, DOE must provide sufficient information at each stage of the licensing process to support that stage, and DOE must provide sufficient detail necessary to allow NRC to review DOE's design.

Regarding DOE's recommendation that the requirement that "DOE's proposed operating procedures" are adequate be changed to require the adequacy of "DOE's proposed plan to develop operating procedures," the Commission believes a proposed plan to develop operating procedures is not sufficient to meet the requirement at § 63.31(a)(6). However, to support the construction authorization, the DOE must provide a sufficient level of information to allow NRC to review DOE's design, which would include any operating procedures that affect design.

Issue 5: Is there any control over the site after license termination?

Comment. Commenters expressed general concern regarding oversight of the site after license termination. One commenter supported the approach in proposed part 63 that leaves a single agency (DOE) responsible for control over the site after license termination.

Response. License termination represents the end of NRC involvement with the repository. However, the Commission would not terminate the license unless and until all requirements have been met by DOE. License termination removes NRC oversight of the Yucca Mountain site, leaving DOE as the single Federal authority responsible for the site. Under the proposed part 63, the license amendment for permanent closure must include a DOE program for continued oversight to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers or increasing radiation exposure of individual members of the public beyond allowable limits. The final part 63 continues to retain these same requirements. This is consistent with statutory direction in section 801(b)(2) of EnPA that the Commission's requirements assume that, following repository closure, the inclusion of engineered barriers and DOE's postclosure oversight will be sufficient to prevent any activity at the site that poses an unreasonable risk of breaching the repository's engineered or geologic barriers, and prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits. The NRC will review the adequacy of DOE's program for continued oversight at the time DOE submits an application to amend the license for permanent closure.

Issue 6: Are the standards for issuance of a license sufficiently clear?

Comment. EPA asked why the term "unreasonable risk" was used at § 63.41(c) and suggested that reference to the dose limit may be more appropriate. EPA also asked what the basis was for judging what is necessary for "common defense and security" at § 63.42.

Response. The standards for issuance of a license specified at § 63.41 and conditions of the license at § 63.42 provide a general description of standards and conditions that the Commission will apply to a license application for an HLW repository at Yucca Mountain. They would include, among other things, compliance with dose limits established by EPA in its final standards for Yucca Mountain. Although the terms identified by EPA (i.e., "unreasonable risk" and "common defense and security") are general terms, clarification for what is required is provided earlier in the regulation. In particular, requirements for the content of the license application (specified at § 63.21) describe and clarify the types of analyses and information that would be necessary for DOE's demonstration of compliance with these standards and conditions including, among other things, reference to dose limits and physical protection of the repository (i.e., common defense and security). Revision of § 63.21 in the proposed rule to provide additional clarification of these terms is considered unnecessary.

1.4 Reasonable Assurance

Issue 1: Should a concept other than "reasonable assurance" be incorporated into the implementing regulations for Yucca Mountain?

Comment. EPA commented that generic disposal standards at 40 CFR Part 191 require compliance to be demonstrated with "reasonable expectation," and that proposed NRC implementing regulations for Yucca Mountain at Part 63 require demonstration with "reasonable assurance." EPA believes that a connotation has developed around "reasonable assurance" that could lead to an extreme approach of selecting worst case values for important parameters. EPA believes that "reasonable assurance" is appropriate for operating facilities or in the context of the nuclear power plant licensing program where facilities operate under active institutional controls during their lifetime. It is not appropriate, in EPA's view, for the licensing of a repository where projections of performance have inherently large ranges of uncertainty. EPA prefers "reasonable expectation" because it believes "reasonable assurance" has come to be associated with a level of confidence that is not appropriate for the very long term analytical projections that will be necessary for evaluating Yucca Mountain.

Another commenter expressed the view that the majority of people in the HLW field view "reasonable assurance" as being more stringent than "reasonable expectation." This commenter expressed the concern that it is likely that by requiring "reasonable assurance" the NRC will be seen as implementing EPA's standards in a manner more stringent than intended by the EPA. The commenter also indicated that if it is NRC's position that the two terms are synonymous in the context of HLW disposal, then this should be made more explicit.

Response. 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.

Issue 2: Does the term "reasonable assurance" denote a specific statistical parameter related to either the probability distribution of calculated individual doses or important variables used in that calculation?

Comment. EPA commented that a connotation has developed around "reasonable assurance" that could lead to an extreme approach to selecting worst case values for important parameters used to calculate individual dose (for example, precipitation rates, seepage rates, and flow in the unsaturated zone). According to the EPA, that approach, coupled with an equally extreme approach in selecting engineered barrier performance factors, would lead to assessments that represent situations with little or no probability of occurring but which become the basis for licensing decisions. The EPA concludes that the application of the "reasonable assurance" standard: (1) Is inconsistent with the NAS recommendation to use "cautious, but reasonable" assumptions when projecting the performance of the geologic repository; and (2) would result in applying margins of safety beyond the standard for individual protection set by EPA, which, in effect, alters that standard.

Another commenter noted that the proposed part 63 makes it clear that compliance is to be based on calculations of "expected annual dose" and that this requirement is completely consistent with the recommendation in the NAS report on "Technical Basis for Yucca Mountain Standards," which recommends that the mean values of calculations be the basis for comparison with the NAS recommended standards. However, the commenter was concerned that "reasonable assurance" may be interpreted to be more stringent than the mean values of calculations of individual dose and recommended that it be made clear that, in the context of Yucca Mountain, "reasonable assurance" refers to the mean or expected value of the relevant probability distribution.

Response. 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).

2 Requirements for the Preclosure Period

2.1 Preclosure Safety Analysis

Issue 1: Is the use of an Integrated Safety Assessment (ISA) appropriate for evaluation of the preclosure safety of a repository at Yucca Mountain?

Comment. One commenter questioned the use of an ISA, as derived from chemical process safety analyses, to evaluate preclosure safety because there is not yet much experience in regulating with the ISA and suggested that requirements for monitored retrievable storage (as contained in part 72) should be applicable to the GROA and should be used in place of the proposed requirements of part 63.

Response. The Commission considers necessary the analysis referred to in the proposed rule as an "integrated safety analysis". However, for clarity, in the final rule, the Commission has changed the name of the analysis to "preclosure safety analysis" (PSA).

The proposed rule identifies the need for, and general scope of, the analysis to be done to demonstrate compliance with the performance requirements for the operational phase of the repository (§§ 63.111(a) and (b) and 63.112(e)). The Commission did not intend to imply, however, that a particular approach, such as that used for chemical process safety analyses, was required. The Commission's intention was to identify ISA as a broad category of analyses to be used by DOE in its evaluation of repository operations and design in the context of meeting the preclosure performance objectives. ISA was proposed as a general term for these preclosure analyses, much as the general term "performance assessment" is used to denote the analyses used to evaluate postclosure performance. To avoid confusion with any particular type of analysis associated with other industrial facilities, the term "ISA" will be replaced by the more general term "preclosure safety analysis (PSA)." The Commission intends that DOE have broad flexibility in structuring its PSA for purposes of demonstrating compliance with the requirements at § 63.112.

The Commission recognizes that there are similarities between a facility regulated by Part 72 and the GROA facilities proposed for Yucca Mountain. However, there are important differences (e.g., Part 72 does not consider a mined facility) that make it impractical to merely adopt the requirements of the current part 72. The Commission has used and adopted relevant portions of existing regulations (e.g., part 50), including part 72, to the

extent practical, during the development of proposed part 63.

Issue 2: Is the probability of a design basis event (DBE) based on the event sequence or just an initiating event? Are the criteria for Category 2 DBEs too stringent?

Comment. DOE suggested that the rule should be clarified as to whether event sequences or single initiating events are to be used in determining the probabilities of DBEs. DOE also noted that the proposed rule would define Category 2 DBEs as those that have one chance in 10,000 of occurring before permanent closure of the repository or an annual probability of about 10^{-6}. DOE stated that:

> Designing to this probability is a reasonable goal in general, but that there are specific concerns with applying the definition to natural events, which have existing precedent for the magnitude and frequency of events to be included *ensp;* *ensp; A 1010^{-6} earthquake is far beyond normal design considerations.

DOE suggested the following definitions of DBEs:

Definition for Category 1 DBEs should be revised to read: "natural events and human-induced event sequences."

Definition for Category 2 DBEs should be revised to read: "other human-induced event sequences that have at least one chance in 10,000 of occurring before permanent closure of the geologic repository, and (b) appropriate consideration of natural events (phenomena) that have been historically reported for the site and the geologic setting (referred to as Category 2 events)."

Response. 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 considers that the changes to the rule suggested by DOE are not sufficiently clear and has not adopted these changes in the final rule. However, 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) § 63.102(f) is revised to clarify the scope of the PSA and the requirements for the inclusion or exclusion of specific, naturally-occurring, and human-induced hazards in the safety analysis.

The proposed rule described the ISA (referred to as PSA in final part 63) as a systematic examination of the hazards and their potential consequences [see § 63.102(f)]. In the Supplementary Information for the proposed rule, Category 2 design basis events were discussed as follows:

> The analysis of a specific Category 2 design basis event would include an initiating event (e.g., an earthquake) and the associated combinations of repository system or component failures that can potentially lead to exposure of individuals to radiation. An example design basis event is a postulated earthquake (the initiating event) which results in (1) the failure of a crane lifting a spent fuel waste package inside a waste handling building, (2) damage to the building ventilation (filtration) system, (3) the drop and breach of the waste package, (4) damage to the spent fuel, (5) partitioning of a fraction of the radionuclide inventory to the building atmosphere, (6) release of some radioactive material through the damaged ventilation (filtration) system, and (7) exposure of an individual (either a worker or a member of the public) to the released radioactive material.

The Commission intended that the probability of the entire event sequence, including initiating event(s) and the associated combinations of repository system or component failures, be considered in dose calculations. The proposed rule has been revised by replacing the previous term "design basis event" with new terms "initiating event" and "event sequence" and associated definitions. These changes clarify that the appropriate probability is based on the entire event sequence, which includes the initiating event(s) and associated combinations of repository system or component failures relating to the potential release of radioactive material.

The two critical aspects of the PSA in the context of this issue are (1) the identification of the event sequences that have probabilities greater than or equal to one chance in 10,000 of occurring before permanent closure and (2) the associated dose consequences. Following the intent of risk-informed performance-based regulation, designation of specific design basis criteria in the regulation is not appropriate. The goal of the DOE design activity should be to demonstrate that the dose limits expressed in § 63.111 will be met, taking into consideration site-specific information regarding the geologic setting and human activities in the surrounding environs. For example, if a hazard (or the low probability events of the hazard spectrum) is deemed unreasonable for the Yucca Mountain site, DOE can exclude it from consideration in the PSA provided proper technical justification is presented in accordance with § 63.112(d). Thus, while the regulation specifies a lower limit on the probability of event sequences, the risk-informed NRC regulation anticipates that DOE will develop a clear technical basis for the event sequences included/excluded from the PSA. The Commission did not intend to specify cut-off probabilities for initiating events but recognizes that certain initiating events may not be appropriate for inclusion in the PSA. Therefore, the rule, at § 63.102(f), has been revised to include the following description of considerations that can be used by the DOE to limit the inclusion of initiating events in the PSA:

> 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).

Issue 3: How should doses be estimated in evaluating repository operations during the time before permanent closure? Can different approaches be used for evaluating Category 1 and Category 2 DBEs (event sequences)?

Comment. Further clarification is needed on the scope of the dose calculations associated with DBEs (event sequences).

For Category 1 DBEs [event sequences], DOE recommended a realistic or best-estimate analysis for direct exposures from a single event. For airborne pathways, DOE proposed including submersion, inhalation, and ingestion. DOE also recommended that the doses from all Category 1 DBEs (event sequences) be aggregated.

For Category 2 DBEs (event sequences), DOE recommended dose calculations be based on suitably conservative values for direct exposure and airborne pathways including submersion, and inhalation, but not ingestion. DOE recommended that ingestion not be considered because the focus is on an acute dose, not a dose that occurs slowly over time as is the case for ingestion. Also, the emergency planning would mitigate, if necessary, contamination relevant to ingestion. DOE also recommended that Category 2 DBEs [event sequences] be analyzed on an event sequence by event sequence basis.

Response. The Commission has revised the proposed rule, at § 63.111(b)(1) and (2), to clarify that (1) the doses from consequence analyses for Category 1 event sequences are to be aggregated to a single estimate and (2) the dose from the consequence analysis for each Category 2 event sequence is to be estimated for that specific event sequence only. Thus, each Category 2 event sequence dose is to be evaluated

separately. The doses from Category 2 event sequences that might occur at differe[illegible]mes during the preclosure period are not to be aggregated.

DOE raised a number of concerns with the scope of the dose calculations associated with event sequences. Generally, DOE called for details that are typically found in regulatory guidance rather than regulation. Although such guidance is expected to be included in the Yucca Mountain Review Plan (YMRP) rather than in the regulation, the NRC staff response to DOE's concerns regarding dose calculations associated with event sequences is summarized below.

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.

DOE suggested that a "realistic or best-estimate" analysis is appropriate for Category 1 event sequences, and a "suitably conservative" analysis is appropriate for Category 2 event sequences. Once again, the approach in the rule is to provide DOE flexibility to select the type of analysis it believes most appropriate for the license application. Whatever approach DOE uses will need to be supported, taking into account uncertainties. Therefore, analyses relying on point values (e.g., best estimate values) will need to discuss how uncertainties are taken into account.

DOE suggested that dose estimates for Category 1 DBEs (event sequences) should be aggregated into a single annual dose estimate. This approach is consistent with historical practices and is acceptable to NRC. DOE also suggested that the potential dose arising from the occurrence of each Category 2 DBE (event sequence) should be estimated separately (i.e., not be aggregated). The Commission agrees that each Category 2 event sequence is to be evaluated individually, as this approach is consistent with historical practices. Also, analyzing each event sequence separately provides a high degree of transparency in the analysis, thus allowing NRC to evaluate the postulated events, the associated event sequences, and the engineered components that affect the likelihood and magnitude of potential releases of radioactive material. The Commission has revised the rule at § 63.111(b)(1) and (2) to clarify that dose estimates for Category 1 event sequences are to be aggregated, but those of Category 2 event sequences are to be analyzed and documented individually.

DOE also suggested that, for Category 2 DBEs (event sequences), dose calculations for ingestion are not necessary. The Commission sees no compelling logic for the specific pathways for dose calculations being different for Category 1 and Category 2 event sequences. Dose should be calculated considering all pathways relevant to an event sequence. Consistent with the Commission requirements elsewhere, the DOE must consider all pathways in demonstrating compliance with § 63.111. The risk-informed regulation anticipates that DOE will present in its license application the magnitude of, and the technical basis for, the dose contribution of various pathways, including the technical bases for eliminating any pathway.

Issue 4: What precedents, if any, do NRC regulatory guides developed for other applications, such as nuclear power plants, have for use in developing DBEs (event sequences) for a potential repository at Yucca Mountain?

Comment. DOE asked for clarification about the role of precedents in other regulatory guides (e.g., consideration of earthquakes, aircraft crashes, tornadoes, and flooding) in determining what should be considered in the development of DBEs (event sequences) (especially for Category 2). DOE also commented that development of credible natural events, for Category 2 DBEs (event sequences), would require only following applicable regulatory precedents and considering severe natural phenomena that have been historically reported for the site and geologic setting.

Response. The applicability of regulatory guidance developed for facilities other than a high-level waste repository will need to be considered on a case-by-case basis for applicability to high-level waste disposal at Yucca Mountain. For the guidance to be appropriate, it should be generally applicable to nuclear facilities with comparable or higher risks to workers and the public than the potential repository at the Yucca Mountain site (see discussion under Issue 2).

Issue 5: What is the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in part 63?

Comment. DOE inquired about the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in Part 63.

Response. DOE's Topical Reports 1 and 2 on Seismic Design for Yucca Mountain were provisionally accepted prior to NRC's issuance of proposed requirements at part 63. The applicability of DOE's seismic design methodology will be reviewed after final part 63 requirements are in place and DOE has completed Topical Report 3.

Issue 6: Should there be an explicit requirement for an analysis of the effects of any plans for use of the air space above the GROA?

Comment. One commenter recommended an analysis of the effects of any plans for use of the air space above the GROA.

Response. Any plans for use of the air space above the GROA that would affect compliance with the performance objectives should be included in the PSA. The Commission finds no reason for a separate requirement for such an analysis.

Issue 7: Will NRC have its own experts to evaluate what can happen during repository operations or will NRC rely on the DOE analysis?

Comment. One commenter inquired whether NRC had independent experts to develop probabilities for DBEs, or would NRC simply rely on DOE analyses.

Response. The Commission will perform an audit review of the DOE license application including a review of the technical basis for initiating events and event sequences. In performing the audit review, the NRC will use a variety of its technical staff with appropriate technical experience and skills, and experience with comparable activities for other facilities (handling of nuclear fuel at nuclear reactors and fuel fabrication facilities) regulated by NRC. Additionally, the NRC's HLW contractor (The Center for Nuclear Waste Regulatory Analyses, CNWRA) has a wide range of technical expertise to assist NRC staff in any review conducted.

Issue 8: Is the terminology in the rule consistent and adequate to convey what is required?

Comment. DOE identified instances where particular words or phrases in Part 63 lacked clarity and suggested the following changes:

Section 63.112(b) should be revised to read: "An identification and systematic analysis of naturally-occurring and

human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential design basis events" (The definition of DBEs makes no link to consequence, whereas § 63.112(b) inappropriately implies such a link).

The word "accidents" in § 63.112(e) should be replaced with "design basis events" (the word "accidents" is not defined (also in § 63.161)—use of DBE is consistent with language elsewhere in part 63).

Response. The Commission agrees that the use of the word "accident" in § 63.112(e) is vague and will replace "accident" by "event sequence." Additionally, the Commission has revised the language at § 63.112(b) to remove the inappropriate reference to consequences.

Issue 9: Should the proposed rule prescribe requirements for the ISA (PSA)?

Comment. DOE noted that prescribing requirements for the ISA (PSA) at § 63.112 was inconsistent with the overall performance-based approach in the rule.

Response. The rule identifies topics that need to be included in the PSA but does not prescribe either the methodology to use or the depth to which these topics need to be addressed. part 63 appropriately identifies the topics that need to be included in the PSA to ensure DOE's analysis is complete and yet gives DOE flexibility to determine the level of detail needed to address each topic properly. This performance-based approach provides DOE latitude to adjust the technical rigor of its evaluation of any particular topic in a manner that is consistent with the topic's importance to safety.

2.2 Retrievability

Issue 1: Will NRC require DOE to demonstrate that the waste package is retrievable?

Comment. 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.

Response. 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 Rule 10 CFR [illegible] 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.

Issue 2: Why did NRC set an upper limit for retrieval at 50 years after waste emplacement operations are initiated?

Comment. 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.

Response. 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 110-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 upon (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 (see "Supplement to the Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada," Office of Civilian Radioactive Waste Management, DOE/EIS–0250DS, May 2001). 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 HLW 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.

Issue 3: If retrieval is necessary, what happens to the retrieved waste?

Comment. One commenter inquired as to the disposition of the waste if it is determined that retrieval is necessary.

Response. Proposed Part 63 does not specifically address any required actions for the handling of retrieved waste from an operating geologic repository, but § 63.21(c)(19) [moved to § 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.

2.3 Performance Confirmation

Issue 1: What is the objective of the performance confirmation program?

Comment. DOE commented that the general requirements for performance confirmation at § 63.131(a) and requirements for confirmation of geotechnical and design parameters at § 63.132(a) do not reflect the Commission's risk-informed, performance-based approach to regulation because the requirements do

not explicitly focus the performance confirmation program on data linked to the performance assessment. DOE stated that the performance confirmation program, when tied to a performance-based approach, should focus on the verification of the performance assessment. DOE stated that this approach would allow DOE and NRC to focus attention and resources on those parameters and processes that are significant contributors to repository performance and to uncertainties in that performance.

Response. The objective 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 the wastes. Consistent with NRC's performance-based approach, the NRC will make findings with respect to each of the performance objectives in Part 63, Subpart E, and not just the postclosure performance objective specified at § 63.113(b). The general requirements for the performance confirmation program at § 63.131(a)(1) and (a)(2) state that the program must provide data that indicate whether: (1) Subsurface conditions encountered and changes in those conditions during construction and waste emplacement are within limits assumed in the licensing review and (2) natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated. These requirements are intended to encompass subsurface conditions and design assumptions related to both operational (preclosure) and postclosure repository performance. Should the Commission authorize construction of a geologic repository at Yucca Mountain, the NRC staff will conduct an ongoing, performance-based inspection program to evaluate DOE's compliance with the performance objectives and any conditions established in that construction authorization per § 63.75.

The general requirements at § 63.131(a) explicitly link the performance confirmation program to DOE's performance assessment, albeit in terms of the barriers designed or assumed to function after permanent closure. Although the primary focus of the performance confirmation program is on postclosure performance of the repository, and the NRC recognizes DOE's desire to focus on verifying the performance assessment (e.g., postclosure performance), it is important that the general requirements also include consideration of operational aspects of repository performance, for example, the ability to retrieve waste as required at § 63.111(e). An organized program of collecting subsurface information during repository construction and operation that confirms the design assumptions regarding the ability to retrieve waste is therefore an important performance confirmation activity. The NRC believes that the general requirements at § 63.131(a) allow DOE the flexibility to develop and implement an effective performance confirmation program focused on confirming assumed subsurface conditions and assumed functionality of geologic and engineered systems and components important to postclosure performance (i.e., performance of barriers important to isolation) and/or preclosure repository operations (e.g., retrievability). In the proposed rule, the definition of performance confirmation in § 63.2 and the discussion of performance confirmation in § 63.102(m) do not clearly reflect the intent of § 63.131(a) and have been revised accordingly in the final rule. To adopt the changes to §§ 63.131(a) and 63.132(a) requested by DOE would remove consideration of operational aspects of repository performance from the performance confirmation program. For these reasons, the Commission does not agree that these changes are appropriate and has not adopted them.

Issue 2: Are the requirements for the performance confirmation program too prescriptive?

Comment. Some commenters were concerned with the level of detail provided in the requirements for the performance confirmation program. NEI commented that the regulation should provide for ongoing programs of monitoring and testing to improve information but also stated that the specified requirements should be made less prescriptive. NEI stated that §§ 63.132–134 (respectively, Confirmation of geotechnical and design parameters, Design testing, and Monitoring and testing waste packages) were inconsistent with the overall performance-based nature of the regulation. NEI recommended that these requirements be deleted because they are unnecessary and counterproductive to § 63.131 in that they provide more detail and remove flexibility already in the rule. NEI also recommended minor word changes to the definition of performance confirmation in § 63.2 and the discussion of performance confirmation in § 63.102(m) to lessen the potential for overly prescriptive interpretations of what is expected of the performance confirmation program. DOE commented that the minimum list of geotechnical parameters in § 63.132(c) is overly prescriptive and is not needed or appropriate. DOE recommended revising the requirement to state that DOE will determine the parameters, measurements, and observations appropriate for inclusion in the program. DOE also recommended revising § 63.133, which restricted design testing to in situ testing, to allow performance of some of the design testing at other locations, such as laboratories, other test facilities, or boreholes outside of the repository block. In addition, DOE also suggested revising the wording of § 63.133(c) to make it clear that testing of backfill is required only if backfilling the emplacement drifts is planned. Another commenter noted that while § 63.134 requires a program to monitor and test waste packages, the commenter found no statement of objectives or criteria for the monitoring and test program. The commenter was concerned that the regulation could be used to drive a very large and costly full scale test program and recommended that the objectives and criteria be stated.

Response. The Commission agrees with the commenters that §§ 63.132–134 were too prescriptive and has modified these sections accordingly. However, the Commission does not agree with the comment that §§ 63.132–134 are inconsistent with the overall performance-based nature of the rule and therefore should be deleted. The Commission believes the requirements for performance confirmation set forth in §§ 63.132–134 are consistent with the overall performance-based approach to part 63. Consistent with this approach, the rule does not prescribe specific subsystem requirements. The absence of subsystem requirements is a concern to a number of commenters. Some commenters believe that the rule places too much reliance on the total system performance assessment (refer to discussion of issues under Postclosure Safety Assessment and Multiple Barriers and Defense in Depth). The Commission believes these concerns are partly addressed through an effective performance confirmation program focused on confirming assumed subsurface conditions and assumed functionality of geologic and engineered systems and components important to postclosure performance and the related performance assessment. Specific concerns that these requirements are either too prescriptive or too limiting are discussed in the following paragraphs.

Section 63.132 (Confirmation of geotechnical and design parameters)

provides additional requirements related to the underground facility including comparing the original design bases and assumptions to information obtained during construction and operation, determining their significance to performance, and reporting this information, including recommended design changes, to the Commission. Section 63.132(c) does prescribe specific measurements and observations to be made by DOE. Because the design of the repository is evolving, it is not clear that, in the future, this list will be an acceptable minimum list of measurements and observations to be made. For the same reason, it is not clear that, in the future, all items in the list will be technically justifiable within the context of operational and postclosure performance of the repository. 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, the NRC staff will provide guidance to DOE in this area through pre-licensing interactions and/or the YMRP. Section 63.132(c) has been revised to reflect these considerations.

Section 63.133 (Design testing) provides requirements for in situ testing of seals and backfill and the thermal interaction effects of waste packages, backfill, rock, and ground water. DOE's recommendation that § 63.133 be revised so as to not limit testing to in situ testing only is reasonable. Section 63.133(a) has been revised accordingly. The NRC has also revised § 63.133(a) to generally reference "engineered systems and components," with examples, so as to not limit tests to specific features that may or may not be included in the final design of the repository. Finally, the Commission has revised § 63.133(c) to require specific testing of the effectiveness of backfill placement and compaction only if backfill is included in the repository design.

Section 63.134 (Monitoring and testing waste packages) provides specific requirements for monitoring and testing waste packages consistent with the objectives of the performance confirmation program established at § 63.131(a). Waste packages are important engineered components designed to operate as barriers after permanent closure. Because the assumed long-term performance of waste package materials is based on short-term experimental data, monitoring waste package performance and related laboratory experiments are appropriate performance confirmation activities. Although the NRC recognizes the need for reasonable cost constraints, it is important to note that it is DOE's responsibility to develop the details of a performance confirmation plan that focuses on those natural and engineered systems and components important to repository performance and operation. The requirements allow DOE the flexibility to develop a focused and effective performance confirmation program. An alternative approach would be to prescribe in detail the specifics and limits of that program. The Commission does not want to limit DOE's options regarding testing methodologies and has chosen not to follow that approach. Note, however, that NRC will evaluate the adequacy of the performance confirmation program in the course of its review of the license application.

Issue 3: Is the performance confirmation data required to be used in the updating of the performance assessment?

Comment. EPA recommended that performance confirmation data should be explicitly identified as information to be included in the update of the performance assessment required at the time of the amendment for permanent closure [§ 63.51(a)(1)].

Response. The Commission agrees with the commenter and has modified the rule accordingly.

2.4 Preclosure Operations Activities

Issue: Should the proposed rule specify environmental monitoring requirements for regulating releases from the preclosure operational activities?

Comment. The EPA commented that requirements for environmental monitoring during the operational phase of the repository were not in the proposed rule and there were no methods stated in the rule for enforcement of the preclosure requirements.

Response. The Commission considers that proposed part 63 has sufficient requirements for environmental monitoring during the operational phase of the repository and is not revising the rule on this issue. The Commission has included environmental monitoring requirements for radioactive releases in part 63. Sections 63.111 and 63.112 require DOE to account for, design against, and monitor any potential event sequences that could lead to radioactive releases. As part of the PSA (§ 63.112), for example, DOE is to describe its design and operating procedures for monitoring and controlling radioactive releases. Consistent with its National Environmental Policy Act (NEPA) responsibilities, DOE has already described its plans and procedures for the monitoring (and mitigation) of environmental impacts due to the operation of the geologic repository, including radioactive releases, in its DEIS for Yucca Mountain.

Regarding the comment on the lack of enforcement methods in the rule, subpart J of part 63 addresses enforcement at a level of detail that the Commission has typically used in all its regulations. Specific policy and procedure issues for enforcement activities are described in NRC's "General Statement of Policy and Procedure for NRC Enforcement Actions," the NRC enforcement manual, and supplemental guidance. The Commission believes this is an appropriate approach for its regulations and will retain the current language as in the proposed rule under subpart J. The Commission plans to develop specific changes to the enforcement policy and procedures as part of development of inspection and oversight plans for implementation of part 63.

2.5 Emergency Planning Criteria

Issue 1: If local emergency first-responder capabilities and emergency medical services are not sufficient for reacting to nuclear accidents at the geologic repository, will the NRC require DOE to enhance existing local capabilities in the Yucca Mountain region?

Comment. Commenters expressed concern that current local emergency and medical services are not adequate to respond to potential nuclear accidents at a geologic repository at Yucca Mountain. Accordingly, it was suggested that NRC include, as a license condition to operate the repository, a requirement that DOE enhance local capabilities for responding to potential nuclear accidents.

Response. 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, the NRC, if necessary, can impose license conditions that require DOE to correct any deficiencies. (See also response to Issue 3 below.)

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 § 63.161.

Issue 2: Will DOE's emergency plans be sufficiently comprehensive to include such scenarios as emergency evacuation procedures and responses to terrorist activity?

Comment. Some commenters were concerned whether DOE would have adequate, effective, and sufficiently comprehensive plans and procedures to address most, if not all, potential accidents, incidents, and/or contingencies.

Response. The rule requires DOE to have plans to cope with radiological accidents (emergency planning at § 63.161) and provide for physical protection (§ 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 HLW. As noted in the previous response, NRC and FEMA 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 § 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 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).

Issue 3: Will Federal funding be available to upgrade emergency first-responders and emergency medical services so as to allow local communities to be better prepared to respond to potential transportation accidents?

Comment. Counties in the Yucca Mountain region expressed concern with their ability to respond to medical emergencies resulting from a transportation accident involving nuclear waste. Local communities suggested that DOE be required to enhance local emergency capabilities for responding to transportation accidents.

Response. Section 180(c) of the NWPA 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 (see discussion under Issues 1 and 2) 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.

3 Requirements for the Postclosure Period

? 'ostclosure Safety Assessment

Issue 1: Can performance assessments be relied on as the sole quantitative technique for evaluating compliance with postclosure safety requirements?

Comment. DOE and NEI supported the risk-informed, performance-based approach. Additionally, NEI supported requirements in proposed Part 63 intended to ensure that DOE conducts and documents a high-quality performance assessment (e.g., features, events, and processes (FEPs) be described; relevant conceptual models be considered) and NEI also expressed a need for the NRC to effectively and clearly articulate this approach in future regulatory efforts. However, other commenters indicated that, although performance assessment is a highly informative methodology, its capability to model complex, coupled geologic systems over extended time periods has yet to be demonstrated. Confidence in performance assessments could be improved through testing on actual geologic systems and conducting suitable, long-term studies.

Response. 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 (see discussion under Quality Assurance, Multiple Barriers and Defense in Depth, and Performance Confirmation for more details).

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. For example:

1. Requirements for Addressing Uncertainty in Performance Assessment

Section 63.114 provides a number of requirements for DOE's performance assessment to thoroughly address uncertainty. Part 63 requires consideration of uncertainties in DOE's representation of the repository (uncertainty and variability in parameter values must be taken into account—§ 63.114(b)) and the events that can happen during the compliance period (consideration of potentially disruptive events with a probability of occurrence as low as one chance in 10,000 of occurring over 10,000 years—§ 63.114(d)) to be directly included in the quantitative estimate of performance. Additionally, DOE is required to provide additional assurances that uncertainty in the information (e.g., evaluation of site characterization data) used to develop the performance assessment have been evaluated by consideration of alternative conceptual models of features and processes that are consistent with available data and current scientific understanding (§ 63.114(c)); and the basis for inclusion or exclusion of FEPs that would have a significant effect on performance (§ 63.114(e) and (f)). (See discussion under Issue 2 for further details on uncertainty in performance assessment.)

2. DOE's Performance Assessment Is Tested (Corroborated) to the Extent Practicable

DOE must test or corroborate, to the extent practicable, the confidence in (validity of) the performance assessment models. Part 63 requires DOE to provide the technical basis for the models used in the performance assessment (§ 63.114(g)). Approaches for providing the technical basis would include comparisons of these models with information relevant to the conditions of geologic disposal and time periods of the assessment (e.g., results from detailed process-level models, field investigations, and natural analogs). Additionally, a performance confirmation program is required (part 63, subpart F) to confirm that the behavior of the barriers of the repository system is consistent with what has been assumed in the performance assessment (see discussion under Performance Confirmation for more details).

3. Basis for Confidence That the Postclosure Performance Objectives Will Be Met

As a basis for confidence that the postclosure performance objectives will be met, the Commission plans to rely on requirements in addition to that for the performance assessment. Specifically, part 63 requires a multiple barrier approach for the repository, and a QA program. A requirement that multiple barriers make up the repository system ensures that repository performance is not wholly dependent on a single barrier. As a result, the system is more tolerant of failures and external challenges such as disruptive events (see discussion under Multiple Barriers and Defense in Depth for more details). The required QA program enhances confidence in the design and characterization of barriers important to waste isolation.

In summary, any determination that the postclosure performance objectives will be met will be based on a comprehensive set of regulatory requirements. Thus, reliance on the performance assessment for assisting regulatory decisions is supported by a range of considerations. The Commission believes this comprehensive approach (i.e., requirements for addressing uncertainty, providing technical basis for models, and additional requirements, beyond expected performance, for increasing confidence that the performance objectives will be met) is appropriate and it is retained in the final rule.

Issue 2: Should a requirement for the level of uncertainty and performance that is acceptable for performance assessment of the proposed repository be included in part 63?

Comment. A number of comments were received concerning uncertainty in estimating postclosure performance of the repository. Commenters were concerned with the level or degree of uncertainty in performance calculations and approaches for analyzing uncertainty in performance calculations. Some specific concerns were: (1) The acceptable level of uncertainty should be clearly stated in part 63 (results that depend mainly on assumptions rather than actual properties are unacceptable); (2) the many orders of magnitude of uncertainty in performance projections are, and will continue to be, too high for assuring long-term safety; and (3) whether DOE is required to predict "actual" performance.

Response. The first-of-a-kind nature of the repository and the evaluation over a very long time period result in significant uncertainty being included in the performance assessment. Part 63 not only requires DOE to account for uncertainty in its performance assessment but also contains a number of other requirements (e.g., use of multiple barriers, performance confirmation program) to compensate for residual uncertainties in estimating performance. 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.

The previous response under Issue 1, discussed the requirements for the performance assessment. Many of these requirements address uncertainty in the performance assessment. Some of these uncertainties will be directly included in the DOE's estimate of performance. For example, DOE is expected to conduct uncertainty analyses (i.e., evaluation of how uncertainty in parameter values affects uncertainty in the estimate of dose), including the consideration of disruptive events and associated probability of occurrence. Other uncertainties are not necessarily quantified but are considered during the development of the conceptual models for the performance assessment (e.g., consideration of alternative models, inclusion and exclusion of FEPs). 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 eval[illegible]d; and (3) differences in the types of uncertainties (e.g., variability in measured parameters, modeling assumptions, expert judgment, etc.) complicate the specification. The approach defined in part 63, which requires DOE to fully address uncertainties in its performance assessment rather than requiring DOE to meet a specific level of uncertainty, is appropriate. The treatment of uncertainty in DOE's performance assessment will be an important part of NRC's review.

Regardless of the uncertainty in the performance assessment, part 63 contains additional provisions to increase confidence that the postclosure performance objectives will be met. These provisions include requirements for multiple barriers, a performance confirmation program, and implementation of a QA program (see discussion under Issue 1). However, it should be kept in mind that the performance assessment evaluates "potential" doses, not "actual" doses. For example, part 63 requires the performance assessment to assume for the next 10,000 years that the reasonably maximally exposed individual (RMEI) is a member of a community that: (1) Exists where it will intercept potential releases from the repository and (2) uses ground water but never tests the quality of this water nor treats the ground water to remove any contaminants. This specification is considered appropriately conservative for evaluating performance but most likely is not an "accurate" prediction of what will happen during the next 10,000 years (see discussion under RMEI Characteristics and Reference Biosphere for more information on the RMEI). 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). 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.

Issue 3: Do known conditions at the Yucca Mountain site and/or the potential for other adverse conditions make Yucca Mountain an unacceptable location for an HLW repository?

Comment. Commenters expressed opinions/concerns regarding the impact of certain FEPs (e.g.; Yucca Mountain lies in an area that is seismically and tectonically active; volcanic activity in the recent geologic past; potential for fast ground-water pathways to the water table; the effect of heat and radiation on the surrounding rock; microbial-induced corrosion of the waste package; and the potential for a significant rise of the water table as the water table may rise and interact with the proposed repository) that could have a deleterious effect on repository performance. Given these concerns, many of the commenters recommended the Yucca Mountain site be withdrawn from further consideration as a potential repository.

Response. Consideration of all FEPs, especially those with the potential to have an adverse effect on performance, is an important part of the evaluation of repository performance. Commenters have correctly identified a number of conditions that have been or are being considered by DOE in performance assessments for Yucca Mountain, such as seismic activity, thermal effects, volcanic activity, microbial-induced corrosion of the waste package, and the potential for a significant rise of the water table. Section 63.114 requires DOE to consider all FEPs pertinent to a repository at Yucca Mountain and fully justify how they are treated in the performance assessment. In reviewing DOE's performance assessment, the NRC will evaluate how well DOE has accounted for those FEPs that could have an adverse effect on the repository. Based on current information, the Commission is not aware of any specific feature, event, or process that so adversely affects repository performance that Yucca Mountain must be withdrawn from further consideration by DOE as a potential repository site.

Issue 4: How will NRC ensure DOE properly documents its performance assessment?

Comment. One commenter discussed the need for DOE to provide a traceable and transparent analysis in support of its demonstration of compliance with the performance standard. The commenter recommended that plain English should be used to document the performance assessment to improve overall understanding of the risks.

Response. The Commission agrees that DOE's performance assessment needs to be clearly documented. Part 63 provides the requirements for DOE's performance assessment at § 63.114 and requirements for the content of the application at § 63.21. These requirements provide a general description of the types of information that need to be included in the license application but do not prescribe specific details for the format of the documentation. The Commission believes it is inappropriate and unnecessary to prescribe, in the regulations, further details for DOE's documentation. The performance assessment is DOE's analysis, and DOE needs flexibility in deciding how best to document its analysis. However, the NRC staff is developing a YMRP to provide guidance to DOE on approaches for documenting performance assessment results that are both transparent and traceable. The Commission agrees with improving overall understanding of performance assessment through better documentation and will interact with the public and DOE to improve the YMRP in this important area.

Issue 5: Why does NRC require DOE to evaluate alternative designs?

Comment. DOE questioned the regulatory basis of § 63.21(c)(7) that requires DOE to evaluate alternative designs. DOE believes evaluation of alternative designs goes beyond typical licensing practice by implying a need for DOE to justify selection of one design over another. DOE suggested they should be allowed to select the design that best suits their purposes consistent with the approach given other NRC-regulated activities at § 50.109(a)(7). Another commenter suggested that the consideration of alternative designs be limited to present-day technology.

Response. The Commission agrees with the comments and has removed this requirement 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 HLW 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 **Federal Register** 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 the DOE 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.

3.2 Individual Dose Limit

Issue 1: How is the protection of future generations considered as part of setting the dose limit?

Comment. A number of commenters expressed concern that the dose limit specified in the proposed rule provided inadequate protection for future generations. Commenters suggested that (1) selection of the dose limit should consider the unpredictability of the future, particularly where and how an individual would be exposed, and (2) the dose limit should reflect impacts from either future energy development or past releases on the local community, such as ground-water releases from the NTS or the Beatty Low-Level Waste facility, in developing the standard.

Response. The purpose of the postclosure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission has incorporated, an individual dose limit of 0.15 mSv/year (15 mrem/year). The Commission is confident that this limit is fully protective and that it provides an added margin of safety beyond what is necessary to ensure public health and safety. The Commission has long held that an individual dose limit of 0.25 mSv/year (25 mrem/year) TEDE is (1) a reasonable and appropriate level of protection for future generations, (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources.

In judging the adequacy of a dose limit for waste management and other related activities, NRC considers recommendations from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), EPA, and International Atomic Energy Agency (IAEA). The ICRP's and NCRP's recommendations are developed by recognized experts in the fields of radiation protection and health effects. The NCRP is a nonprofit corporation chartered by the U.S. Congress to develop and disseminate information and recommendations about radiation protection and to cooperate with the ICRP and other national and international organizations with regard to these recommendations. The ICRP is an international panel of radiation experts from all fields that provides estimates of radiation risk and recommendations on radiation protection and has continued to update and revise its risk estimates and radiation protection recommendations since its inception in 1928. In its deliberations, ICRP maintains relationships with United Nations health and labor organizations.

The IAEA is a United Nations agency involved in assisting member states to establish consistent radiation protection standards. In 1995, the IAEA identified a number of principles with the express purpose of giving a common basis for the development of more detailed standards and a basis for national waste management programs (The Principles of Radioactive Waste Management, IAEA Safety Series No.111–F, International Atomic Energy Agency, Vienna (1995)). Two of the principles are:

1. Protection of Future Generations. Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than the relevant levels of impact that are acceptable today.

2. Burdens on Future Generations. Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

In support of the proposed part 63 dose limit, the NRC considered other current regulations for consistency and the potential effects of other sources of radiation to select a limit that would be acceptable today for releases of radiation. The EPA, ICRP, and NCRP have all supported the use of source-specific constraints (i.e., a margin of safety) below the 1 mSv/year (100 mrem/year) public dose limit to account for the potential effect of multiple sources of radiation exposure. In addition, use of the critical group concept or the RMEI provides an additional margin of safety because it is difficult for the same individual to be a member of the critical group or to be the RMEI for multiple diverse sources.[1] The final regulations, which specify use of the RMEI concept and limit individual dose to 0.15 mSv/year (15 mrem/year) (15% of the public dose limit), are sufficiently protective that potential exposures from other sources (e.g., past releases from operations at NTS and future hospitals or research centers) would not be expected to result in exposures above the 100 mrem/year public dose limit.

Issue 2: Why does NRC prefer an individual dose limit over a total release limit like part 60?

Comment. Some commenters, while noting that the EnPA specified a dose limit for Yucca Mountain, expressed their support for a total release limit like

[1] Although an individual might be exposed to more than one source of radiation, it would be a very rare circumstance for that individual to retain the lifestyle and other characteristics of the RMEI for more than one source.

part 60. The commenters believed that a total release limit is more understandable, easier to implement, and a simpler way to measure compliance of the repository's performance.

Response. The EPA has established a dose limit for individual protection, expressed in terms of a limit on dose to the RMEI. The NRC is incorporating this limit as required by law. A total release limit may appear to be more straightforward and understandable. In fact, however, nearly all of the same issues, such as dose or risk limit, human behavior, or volume of water mixed with the release, must be addressed to determine an appropriate release standard that is protective of the health and safety of the public and environment. Furthermore, a release standard is more difficult to relate directly to site-specific risk.

To set a release limit, the regulatory agency would first need to establish a risk or dose goal and calculate the risk or dose per unit release (e.g., per curie). The risk/dose goal would need to be the collective risk/dose over the entire compliance time for any release into the environment based on some assumed level of waste (e.g., for 40 CFR part 191, EPA used a risk goal of 1,000 premature cancer deaths in 10,000 years per 100,000 metric tons of heavy metal contained in spent fuel (High-Level and Transuranic Radioactive Wastes: Background Information Document for Final Rule, Office of Radiation Programs, EPA 520/1–85–023, August 1985, Page 7–13)). To calculate the risk per unit release, a model estimating the individual dose from a release will need to be used. To develop the model and data parameters, assumptions about the type of release (e.g., for 40 CFR part 191, a release to surface water was assumed (ibid, pg. 7–13)), which biosphere processes to include, resource usage by the local population (e.g., for 40 CFR part 191, 65 percent of drinking water is assumed to be from the contaminated surface water (ibid, pg. 7–7)), and individual habits and characteristics (e.g., for 40 CFR part 191, annual individual intake of drinking water is assumed to be 600 liters (ibid, pg. 7–7)) will need to be made. In its current form, part 63 requires all the same calculations to be done, but the defense of many of the assumptions is the responsibility of DOE and will be subject to review and approval by NRC.

Use of a release limit also provides less information than calculating the dose from a release. The dose calculation combines the intake and exposure from all radionuclides in the environment into one term. The dose from one scenario or calculation can be readily compared to another. When release limits are used, it is very difficult to compare results if more than one radionuclide is involved because each radionuclide provides a different dose/risk per unit activity. For example, consider a review of two alternate designs. For design number one, the total release results in radionuclide A being released at 60 percent of its limit and radionuclide B is at 30 percent of its limit. For design number two, radionuclide A is 20 percent of its limit and radionuclide B is 70 percent of its limit. Without knowing the relative risk from a release per unit activity for each radionuclide, it would be difficult, if not impossible, to state which design results in a lower risk to the public. Thus, the total release limit yields less information in its application than a dose limit.

Issue 3: How does the use of an individual dose limit protect the entire population?

Comment. A few commenters supported either the use of collective dose limits or requiring dose distributions over the population to be calculated based on a concern that a single dose limit requiring only calculation of dose to the critical group would not adequately protect the overall population. Commenters: (1) Suggested that the collective dose is more important than the individual dose, (2) disagreed with the use of a negligible individual dose value to screen possible release scenarios, and (3) viewed a dose distribution over the population as more informative to the regulators and public, allowing a more risk-informed decision to be made.

Response. The Commission agrees with NAS that "a health-based individual standard will provide a reasonable standard for protection of the general public" (p. 65 of the NAS report). The final regulations, which specify characteristics of an RMEI and an individual dose limit of 0.15 mSv/year (15 mrem/year), are protective of the RMEI. The general public includes the small number of individuals within the RMEI's community as well as all other individuals residing near the Yucca Mountain area. Because the community in which the RMEI resides will have a higher estimated dose than the highest exposed individual who does not live in that community, an individual dose limit for the RMEI is protective of all individuals.

Although a distribution of individual doses for the entire population arguably can provide more information to consider in making a decision, the speculation and uncertainty regarding a representative population dose distribution would generally make the results inadequate to use in decision making. The difficulty lies in developing the habits, characteristics, location, and exposure time for the entire population. For analyses of possible future releases, such as from degrading waste in Yucca Mountain, the assumptions about the location, habits, and characteristics for each individual (or group of individuals) would be speculative. The Commission believes that it is possible to develop and defend a reasonable exposure scenario for a small group of individuals that would likely receive the largest doses based on current practices in the region because analyzing doses received by the RMEI living in a community at the 18-km (11-mile) location with a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada, would bound any doses received by other individuals in the population. Because of the uncertainty in the distribution and range of activities, including location and number of individuals, for other less exposed groups, unbounded speculation could make any resulting population dose distribution unsupportable.

Although the Commission could require performance assessments of the potential dose distribution to hypothetical individuals, at the same locations and with the same habits as the current residents, the Commission believes that the uncertainty in the doses calculated for those not subject to the largest expected exposures would make the results difficult to interpret. In the end, the speculation would lead NRC, DOE, EPA, and other interested parties to expend resources without a commensurate increase in public health and safety or protection of the environment.

Collective dose is useful for comparing options but it does not provide adequate protection of the individual. Collective dose is the total dose received by all exposed people, regardless of distance or magnitude of exposure, over all time from a source. In general, most analyses tend to truncate the dose by calculating over a certain time frame and a given environmental area. Truncated collective dose can provide an overall measure of radiological impact on society or on parts of society but is only useful as an aid to compare options (e.g., DOE has considered individuals living within 84 km (52 miles) of the Yucca Mountain site for evaluating population doses in the DEIS). Because the calculation of collective dose results in a single value (in person-Sv (person-rem)), it gives no

indication of the range or variability of individual doses or the time when the doses could occur. Meanwhile, the use of an individual dose limit to the RMEI assures that the vast majority of the population receive lower doses. The Commission believes that using an individual all-pathway dose assessment provides to the regulator and the public a meaningful measure for making decisions regarding public health and safety.

Issue 4: How is the "As Low As Reasonably Achievable" (ALARA) principle incorporated in part 63?

Comment. A few commenters suggested that the ALARA principle be explicitly part of the long-term compliance dose limit in part 63. Others supported the proposed rule for not including the ALARA principle in the requirements for the long-term performance requirements because the cost-benefit analysis would be highly speculative.

Response. The Commission believes that, although it is appropriate to explicitly require the application of the ALARA principle to the operational and decommissioning phases of the repository, the application of ALARA to achievement of the long-term performance objective is not appropriate.

The ALARA principle deals with optimizing the reduction of potential doses from radiation to members of the general public and workers. It is a principal component of the radiation protection philosophy during operations and decommissioning activities and it helps to ensure that no individual will receive a dose in excess of the annual dose limit (i.e., 1 mSv/year (100 mrem/year) for the public and 50 mSv/year (5,000 mrem/year) for radiation workers). Application of ALARA during operations compels the consideration of the benefits of further reduction in potential doses to present-day populations and workers relative to impacts to present-day populations (e.g., increased cost to reduce potential doses further). The application of ALARA to the achievement of the postclosure performance objective would involve considerations far more complicated than those evaluated for operations. The reasonableness of further reduction of potential doses would need to evaluate benefits and impacts that span many generations (e.g., costs incurred today versus a reduction of potential doses thousands of years in the future; repository designs that reduce potential doses in the future but increase doses to present-day workers during fabrication of the design such as installing a special backfill). By adopting the EPA's dose limit for long-term performance, the Commission implements a constraint that is a small fraction (15 percent) of the public dose limit, and which provides a significant margin of safety to ensure that public health and safety and the environment are protected.

In its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's Yucca Mountain regulations. In summary, their reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted it would be problematic to evaluate compliance with the application of ALARA principles in the postclosure phase of the repository. The Commission agrees with NAS in this regard. Therefore, although the Commission will require ALARA considerations for the operational phase and decommissioning of the surface facilities, NRC will not explicitly require an ALARA analysis as part of the postclosure performance assessment.

Issue 5: Why did NRC select 0.25 mSv/year (25 mrem/year) as the proposed dose limit?

Comment. A large number of commenters addressed the 0.25 mSv/year (25 mrem/year) dose limit in proposed part 63. A large number either disagreed with the limit, saying it was too high, or supported a lower standard such as the EPA's 0.15 mSv/year (15 mrem/year) standard in 40 CFR part 191 and proposed 40 CFR part 197. Some commenters (1) expressed confusion on whether the dose limit was for workers or members of the public, (2) requested additional clarification on what "fully protect" meant as part of the dose limit, or (3) supported the 0.25 mSv/year (25 mrem/year) dose limit.

Response. The purpose of the postclosure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission has incorporated, a dose limit of 0.15 mSV/year (15 mrem/year). The Commission has long held that its proposed dose limit of 0.25 mSv/year (25 mrem/year) to an individual is (1) a reasonable and appropriate fraction of the annual public dose limit to protect future generations from receiving doses greater than 1 mSv/year (100 mrem/yr), (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources. However, the Commission has changed the dose limit in the final rule because it is required to be consistent with EPA's final standards, and not because the Commission is persuaded that its earlier proposal is unsafe, inadequate, or not appropriate in any way. The Commission is confident that the 0.15 mSv/yr (15 mrem/yr) limit is also amply protective. Both limits ensure that no member of the public would be exposed to more than 1 mSv/yr (100 mrem/yr) from all sources of radiation, except background radiation. Both protect future generations. During the operational phase, the repository will be required to comply with part 20 for worker and public health and safety, except that the permitted public dose will be limited to 0.15 mSv/yr (15 mrem/yr).

Issue 6: How is NRC's proposed limit different than the dose limits in older rules (i.e., part 61) and how do they compare?

Comment. Many commenters were concerned that the proposed part 63 would relax health and safety standards. They (1) disagreed with the comparisons with other waste-related safety standards discussed in the Statements of Consideration of the proposed rule, especially with rules using an older dose methodology and (2) expressed concern that the use of the single limit on the TEDE did not adequately protect the organs. They pointed to regulations requiring specific organ limits. While not a dose limit, some commenters disagreed with the use of the national value for background radiation for comparison for the Nevada area because of impacts from past practices.

Response. Part 63 does not change the 1 mSv/yr (100 mrem/yr) public dose limit from part 20, which is the health and safety standard for protection of members of the public. The Commission adopts, in part 63, a limit specifically for the repository that is well below the public dose limit, and that is similar to, but more stringent than a number of other waste management-related dose limits. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE to be the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr). The single limit does account for each organ's sensitivity to radiation, and each organ is limited to the same risk as the whole body.

Different sources of radiation can have different constraints placed on them. The 0.25 mSv/yr (25 mrem/yr) dose limit is in a similar range as a number of other constraints for waste management facilities or

decommissioning requirements (e.g., 40 CFR 191.03(a), 10 CFR 72.104, 10 CFR 61.41, and 10 CFR 20.1402). Furthermore, during the operational and surface facility decommissioning phases, the facility will need to meet the ALARA requirements in 10 CFR 20.1101(b). This includes an 0.1 mSv/yr (10 mrem/yr) additional constraint on air emissions (10 CFR 20.1101(d)).

A number of the current regulations were published before the early 1990s when the NRC (and other Federal agencies) began using current knowledge about radiation risks and internal dosimetry. These older regulations generally have two or three limits associated with them. They tend to have separate limits for the dose to the whole body, the organs, and possibly, a specific limit for the thyroid (e.g., 10 CFR 72.104 limit of 0.25 mSv/yr (25 mrem/yr) whole body, 0.75 mSv/yr (75 mrem/yr) thyroid dose, and 0.25 mSv/yr (25 mrem/yr) to any other critical organ). At the time these older regulations were published, the Federal government was using a dosimetry system (i.e., a model that calculates the dose if a person ingests or inhales radioactive material) that did not account for the sensitivity to radiation of the various organs (also known as radiosensitivity) nor how the dose to an organ compared to a whole body dose. Because one could not add the various organ doses together, each needed its own limit. With little information on the radiosensitivity of different organs, most organs were given the same limit.

In the early 1990s, the Federal government began using a newer dosimetry system that accounted for how radiosensitive the various organ systems are. In addition to being able to compare the doses between organs, one can calculate what whole body dose would result in the same cancer risk. This whole body dose is known as an effective dose equivalent. By summing each organ's dose, weighted by its relative radiosensitivity, and adding in any whole body exposure, one could calculate the total dose received, which is called the TEDE. Therefore, by using the TEDE dosimetry system, not only the whole body but each of the organs are protected from an increased chance of cancer. They are also all protected at the same level of risk, which was not true of the earlier system.

Because each of the organs had the same limit under the older system even though each had a different level of radiosensitivity, it is very difficult to directly compare the old standards with the new standards. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr). However, to conform to the EPA standard, the Commission has incorporated a dose limit of 0.15 mSv/yr (15 mrem/yr) in final part 63.

In the proposed rule, as a point of reference, it stated that the national average background radiation is approximately 3 mSv/yr (300 mrem/yr). Some commenters questioned whether this was valid for the Nevada area considering past practices in the area. The average background radiation stated in the proposed rule did not include variations due to the geology, relative altitude above sea level, or past practices in the region around Yucca Mountain. The Commission does not consider dose from the residual radioactivity left by past practices to be part of the background radiation.

3.3 Calculation of Expected Dose

Issue: Is the "expected annual dose" an appropriate quantitative measure for demonstrating compliance?

Comment. The public noted that while a specialist may know that the "expected dose" and the "mean dose" are equivalent, to many people "expected" implies the most likely outcome. The same commenter asserted that the mean value derived from the performance assessment is not the most likely, but rather a value that is unlikely to be exceeded. The commenter sought clarification on whether the "expected annual dose" is the mean or the median dose or some other statistical measure. Some members of the public approved of the use of the mean dose rather than the median or mode and noted that the mean should provide a reasonable degree of conservatism. Furthermore, some commenters asserted that use of the "expected annual dose" is completely consistent with NAS recommendations that the mean value of the calculations be used for comparison to the standard. Finally, one commenter supported the use of a 25 mrem performance objective, but suggested that it be bolstered with the addition of a 100 mrem limit on the 95th percentile of the probabilistic dose distribution.

Response. Final EPA standards at 40 CFR part 197 specify that NRC determine compliance based upon the mean of projected doses of DOE's performance assessments. The Commission has incorporated this requirement at § 63.303 in subpart L. The mean of the projected annual dose is therefore the appropriate quantitative measure for demonstrating compliance with the dose limit. NAS recommended a performance objective for Yucca Mountain based on risk to an individual. Proposed part 63 defined "risk" to an individual as being proportional to two factors: (1) The dose to the individual from exposure to ionizing radiation and (2) the probability of the individual receiving that dose. Analyses conducted by NRC staff demonstrate that the mean annual dose correctly expresses the risk from radioactive exposure to the individual.

The Commission expects that performance assessments conducted by the applicant in support of any potential license application will use probabilistic methods to simulate a wide range of possible future behaviors of the repository system. Each possible future behavior of the repository system is represented by a curve describing the annual dose to the RMEI as a function of time. Generally, but not necessarily, each of the possible curves is assumed to be equally likely. Because none of these possible futures can be demonstrated to describe the actual future behavior of the repository system, the Commission requires that the applicant calculate the mean of these dose versus time curves, properly weighted by their individual probabilities.

In addition, NRC performance assessment experience indicates that the mean already reflects a high degree of confidence that dose limits will not be exceeded. For example, preliminary analysis of the proposed repository at Yucca Mountain (Mohanty, S., R. Codell, R. Rice, J. Weldy, Y. Lu, R. Byrne, T. McCartin, M. Jarzemba, and G. Wittmeyer, "System-Level Repository Analyses using TPA Version 3.2 Code," Center for Nuclear Waste Regulatory Analyses, CNWRA 99–002, August 1999) indicates that the mean exceeds the 95th percentile at early times (i.e., less than 600 years), the 80th percentile prior to 6,000 years and greater than the 70th percentile at 10,000 years. For this reason, NRC does not believe that addition of a 100-mrem limit on the 95th percentile would provide significant additional protection to the public.

3.4 Infant and Children Dose Standard

Issue: Is the dose limit protective of children (and other sensitive populations) and the environment?

Comment. Many commenters were concerned that the dose limits in part 63 may not be sufficiently protective of sensitive populations such as children or infants that may be more susceptible to the effects of radiation. Others were

concerned that by focusing the dose limit on protecting humans, the environment was not adequately protected.

Response. The international community and the Federal agencies (including EPA) follow ICRP's current guidelines that the overall annual dose to members of the public from all sources should not exceed 1 mSv (100 mrem), in order to be protective of all individuals and the environment. These guidelines also hold that exposures from a single practice should be limited to a fraction of this overall dose. The purpose of the public dose limit is to limit the lifetime risk from radiation to a member of the general public. The conversion factor used to equate dose into risk is based on data from various populations exposed to very high doses of radiation such as the atomic bomb survivors, and these populations contained individuals of all ages. Therefore, variation of the sensitivity to radiation with age and gender is built into the standards which are based on a lifetime exposure. A lifetime exposure includes all stages of life, from birth to old age. For ease of implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive. For more information on the selection of the 0.15 mSv/yr (15 mrem/yr) limit, see the discussion under the Individual Dose Limit.

Experimental studies have shown that many flora and fauna tend to be much more resistant to radiation than humans (Casarett, Alison, P., "Radiation Biology," Prentice-Hall, 1968, pages 220 and 300–302 and Nias, A.H.W., "An Introduction to Radiobiology," John Wiley and Sons, 1990, page 231). Therefore, except in cases where large concentrations of radionuclides can enter the environment and no reasonable exposure scenarios exist for humans, one of the principles of radiation protection is that by protecting the public, the environment is protected. In the case of Yucca Mountain and long-term releases, the primary pathway will be through the ground water. Although the contaminated ground water may rise up to the surface environment around Ash Meadows (approximately 40 km (25 miles) from Yucca Mountain), the contaminants will be diluted to much lower concentrations than those used in calculating the dose to the RMEI. Therefore, if the RMEI is protected from doses in excess of the dose limit, the environment is also protected.

3.5 Location of the Critical Group or RMEI

Issue 1: Should the NRC staff consider alternative locations to the proposed 20-km location of the proposed critical group?

Comment. Some commenters recommended that the critical group be located closer than 20 km (up to and including the outline of the repository footprint). Some commenters recommended distances greater than 20 km. Commenters suggested that locations downwind from Yucca Mountain should be considered under critical group locations. Another commenter suggested that NRC's limitation on well depths, based on 1950's–1960's drilling practices, in defining a critical group, was outdated and needed to be revised based on modern drilling practices and pumping technology.

Response. As required by law, the Commission will adopt a compliance location consistent with that established by EPA in its standards for Yucca Mountain. The EPA standards limit the permissible dose to the RMEI, an individual who resides in the "accessible environment", above the highest concentration of radionuclides in the plume of contamination. EPA has also established ground-water protection limits for a representative volume of water which includes the highest concentration level in the plume of contamination in the accessible environment. EPA defines the accessible environment as any point outside of the "controlled area." As defined by EPA the controlled area is a 300 square-kilometer surface area that extends no further south than 36° 40′13.6661″ north latitude, or roughly 18 kilometers, in the predominant direction of ground-water flow, and not beyond 5 kilometers in any other direction.

In its 1995 findings and recommendations, NAS recommended that dose calculations be performed, for specific populations, to avoid unlimited speculation about the behavior of future human society. Specifically, in performing the requisite calculations, NAS recommended consideration of the local biosphere, using the "critical group approach" specified by the ICRP and employing "cautious but reasonable assumptions." The ICRP has generally defined the critical group to be a relatively homogenous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of radionuclide releases (International Commission on Radiological Protection, "Recommendations of the ICRP," Annals of the ICRP, Vol. 1, No. 3 (1977). (ICRP Publication 26) and International Commission on Radiological Protection, "Radiological Protection Principles for the Disposal of Solid Radioactive Waste," Pergamon Press, Oxford, 1985. (ICRP Publication 46))

Both EPA and NRC have identified the ground-water pathway as the most likely pathway for radiological exposures at Yucca Mountain. EPA's standards, which specify the location for the RMEI at 18 kilometers in the predominant direction of ground-water flow, is consistent with the most likely pathway for radiological exposure. This location is generally considered the nearest location to Yucca Mountain where farming activities can reasonably be expected to occur. At distances less than 18 km to the Yucca Mountain site, there is evidence of intermittent or temporary occupation in modern (historic) times in and around the site—for prospecting or ranching (see "Preliminary Performance-Based Analyses Relevant to Dose Based Performance Measures for a Proposed Geologic Repository at Yucca Mountain," T. McCartin and M. Lee (eds.), NUREG–1538, 2001 (in press)). There also are a number of Native American archeological sites reported throughout NTS closer to the site than the Lathrop Wells location. However, the literature indicates that these were never permanently occupied, and most were abandoned by the end of the 1800's. Overall, the literature suggests many reasons for the absence of permanent inhabitation at distances much closer than 18 km to the site—unfavorable agricultural conditions, inhospitable terrain, the scarcity of mineral resources, and limitations on water availability.

As discussed in the proposed regulation, farming activities are considered to be representative of those individuals expected to receive the highest dose because (1) farming activities involve more exposure pathways than other known human activities in the region (e.g., ingestion pathway through consumption of contaminated water, crops, and animal products) and (2) the relatively large water demand for ground water for irrigation increases the likelihood of drawing contaminated water to the surface where human exposures could occur (64 FR 8645; February 22, 1999).

Finally, with regard to the suggestion that the NRC staff's understanding of drilling and pumping practices in the area is outdated, the Commission does not share this view. Rotary drilling technology, first introduced into the

U.S. in the early 1900's, is still used to drill most wells in the U.S., including those in the Amargosa Desert area. The Commission also is aware that there are now more efficient submersible pumps capable of pumping ground water from greater depths. However, the costs of developing deep ground-water resources increase proportionally with depth, regardless of pump efficiencies.

Issue 2: Should alternatives to the proposed farming community critical group be considered?

Comment. A few commenters objected to the NRC staff's proposed farming community critical group type and noted that parameters used by the NRC staff to define it were themselves controversial and speculative. Overall, the commenters recommended that the NRC staff give more consideration to the criteria used to define the characteristics of the critical group and, in doing so, other critical groups could be identified and situated at locations closer than 20 km to the proposed repository. A question was also raised whether doses would be higher if a farming critical group were located closer than 20 km to Yucca Mountain.

Response. EPA's standards specify the RMEI as the appropriate basis for application of the individual protection standard and adopted certain characteristics for the RMEI representative of the Town of Amargosa Valley. The Commission has added an additional requirement that DOE should assume the RMEI uses contaminated water with average concentrations of radionuclides in a volume of water reflective of the water demand associated with the community in which the RMEI resides (*i.e.*, 3,000 acre-feet/yr). EPA selected a rural-residential RMEI that is assumed to drink two liters per day of contaminated water and consume some locally produced food (based on surveys) (66 FR 32092; June 13, 2001). As noted in the preamble to the EPA standards (66 FR 32093; June 13, 2001), commercial farming occurs today in the southwestern portion of the Town of Amargosa Valley. Thus any survey of consumption of locally produced food for this area will include a variety of lifestyles including some full-time farmers, however, the RMEI is not assumed to be a full-time farmer. NRC proposed an average member of a farming community, in part, to ensure locally produced food was accounted for as a potential exposure pathway. The Commission considers the RMEI, as specified in the EPA's standards, to be protective and consistent with the Commission's intent of including locally produced food as a potential exposure pathway. Also, as noted in the response to the previous issue, EPA limits the location of the RMEI to any point outside of the "controlled area," which EPA defines as 300 square kilometer surface area that extends no further south than 36° 40′13.6661″ north latitude, or roughly 18 kilometers, in the predominant direction of ground-water flow, and not beyond 5 kilometers in any other direction. It is possible, of course, to postulate some other RMEI, however, doing so would be difficult to defend based on the pattern of historic development in the area prior to the establishment of NTS, and would also be inconsistent with NAS' overall recommendations.

In order to avoid boundless speculation, the NAS recommended that the characteristics of the exposure scenario be specified by rule. Thus, the EPA standards specify certain characteristics of the biosphere and the RMEI. NRC's proposed regulation also specified many of these same characteristics in addition to specifying a farming community of approximately 100 individuals (residing on 15 to 25 farms). This specification of the farming community provided flexibility to DOE in determining an appropriate water demand consistent with the specified farming community. It is reasonable to assume, based on current activities and water usage in the area, that the annual water demand for a farming community of this size could range from a few thousand to as much as ten thousand acre-feet. The final regulations specify a water demand of 3,000 acre-feet as a conservative value for use in estimating the dose to the RMEI. Specification of this value is consistent with: (1) The NAS recommendations for specifying the exposure scenario by rule; (2) NRC's proposed critical group (*i.e.*, farming community of 100 individuals); and (3) the criteria for the RMEI specified in the EPA standards (*i.e.*, diet and lifestyle representative of the people who now reside in the Town of Amargosa Valley, Nevada). Finally, the specification of the use of an average concentration is both consistent with the proposed regulation, which specified the use of an average dose, and the EPA standards that specify the use of a mean (average) dose.

Regarding the consideration of other types of critical groups, examination of the literature suggests that the pattern and nature of development in Amargosa Valley has been influenced by two types of factors—natural and engineered. Foremost among the natural factors is the physical geography of the area—particularly the type of climate and the availability of water. Amargosa Valley is considered a mid-latitude desert; it receives on average 4 inches of rain per year. Moreover, there are few naturally-occurring sources of drinking water supply; surface water supplies are restricted to a few natural springs and, although ground water is available, one has to drill for it. Because of costs associated with drilling and pumping ground water, agricultural development has tended to favor areas where the ground water is shallow. Thus, despite almost 100 years of improvements in farming technology, practical limitations in soil fertility combined with the economics of irrigation-based agriculture continue to restrict farming activities to the same basic location within Amargosa Valley.

Man-made developments, such as the introduction of commercial electricity in Amargosa Valley in the early 1960s, have made the economics of irrigation-based agriculture somewhat more attractive and led to diversification of the local economic base which now includes a dairy, a turf farm, a hotel, a casino, and a golf course. The availability of commercial electricity has also led to a moderate increase in the permanent, non-farming resident population. Non-farming activities, as one commenter pointed out, are generally unaffected by ground-water depth, soil type, and other similar factors and could take place anywhere in the Yucca Mountain area, but have not, because the lands immediately surrounding Yucca Mountain are Federally-owned. It is likely that in addition to the existence of infrastructure (roads and commercial electricity) other factors as significant as the physical ones, also have contributed to diversification of the local economic base in Amargosa Valley. However, decisions to pursue diverse business ventures are typically made privately, by business persons or corporations, taking into account economic forces in the market place. In the Commission's view, it is impossible to predict the future behavior of the national or local economy and translate this behavior into specific human actions in the Yucca Mountain area.

In summary, the requirement that the RMEI use water of average contaminant concentration, in a volume of water (3,000 acre-feet) reflective of a farming community, is conservative. Because the RMEI is defined as that person reasonably likely to receive the highest doses, the selection of RMEI characteristics must take into consideration both the magnitude of the dose likely to be received and the likelihood that a dose will actually occur at that location. The Commission believes that EPA selected the characteristics of the RMEI based on

cautious and reasonable assumptions for the community of individuals likely to receive the highest doses. For these reasons, the Commission has adopted EPA's definition of the RMEI, as it appears at 40 CFR part 197 and added the additional requirement for water usage by the RMEI.

Issue 3: How will potential doses from the air-pathway be evaluated during the period of repository operations (preclosure period)?

Comment. A subject of continuing concern for any possible geologic repository at Yucca Mountain is the potential effects of unexpected (low probability) releases of gaseous/particulate radionuclides during the preclosure phase of operations (*i.e.*, DBEs). As a matter of background, it was noted that radioactive fallout from atmospheric tests of nuclear weapons conducted at the NTS during the 1950's was transported by prevailing westerly winds to communities east of the NTS, such as Caliente (Nevada). Because prevailing wind patterns are unlikely to change, concerns were expressed that health effects similar to those assumed to have resulted from atmospheric testing may arise from potential repository operations. Accordingly, it was suggested that a critical group based on exposure to an air-pathway should be evaluated.

Response. The Commission is aware of the effects of local atmospheric conditions on past nuclear testing activities (which were not subject to NRC regulation). During operations, DOE is required to control releases from all potential pathways, including atmospheric, such that no member of the public is exposed to more than 0.15 mSv/year (15 mrem/year). To comply with this requirement (at § 63.111) DOE will need to account for potential gaseous and particulate releases to existing members of the public (including current down-wind communities, such as Caliente). This requirement also directs DOE to conduct a preclosure safety assessment (§ 63.112) that shows (1) that the GROA design and normal operations at the site will limit the release of gaseous and particulate radionuclides so that the public dose will remain below 0.15 mSv/yr (15 mrem/yr) dose and (2) that in the event of an unlikely, but credible emergency situation, the design is robust enough to constrain potential doses to within acceptable public health and safety standards.

3.6 Critical Group Characteristics and Reference Biosphere

Issue 1: Is the average member (of a critical group) an appropriate measure to protect public health and safety?

Comment. A number of commenters focused on the proposed approach of calculating doses to an average member of a critical group. Commenters noted: (1) Use of the average member results in some people (aside from those with extreme habits) receiving less protection than others (*i.e.*, individuals protected by assuming current conditions may not be protected under potentially different future conditions); (2) the proposed rule does not provide a definition of the average member of the critical group; (3) the appropriate measure is the average of calculated doses to members of the critical group rather than a single dose calculated for a single member with average characteristics; and (4) a subset of the farming group that would be more likely to experience health effects (*e.g.*, children) should be used.

A few commenters suggested use of a subsistence farmer. One commenter added that sensitivity studies should be done for a subsistence farmer (*i.e.*, all food locally grown) located closer than 20 km from the proposed repository site to gain insights into risk, even though such a scenario would be unlikely.

Response. Although the Commission finds that limiting the dose received by the average member of the critical group is protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use 40 CFR part 197's mean dose to the RMEI as the measure to compare with the dose limit. The RMEI approach has been characterized as providing a similar level of protection to that achieved by protecting the average member of the critical group, as was proposed for part 63. In its comments to EPA on the proposed 40 CFR part 197, the NAS noted that the reasonably maximally exposed individual is very similar to the internationally used critical group approach. Additionally, in the proposed rule, NRC quoted the International Commission on Radiological Protection, which stated that it may be convenient to define the critical group in terms of a single hypothetical individual. The International Atomic Energy Agency's (IAEA's) Biosphere Modeling and Assessment working group has taken it further and calls such a hypothetical individual a reasonably maximally exposed individual (BIOMASS, 1999). Although there are slight differences between the EPA's reasonably maximally exposed individual and NRC's proposed average member of the critical group, they are virtually the same (especially in view of the IAEA's guidance). As noted earlier, the Commission has adopted the RMEI approach to be consistent with 40 CFR part 197.

The issue of whether children are protected has been taken into consideration in developing the rule (see discussion under Infant and Children Dose Standard). In summary, the standards were developed with sufficient conservatism to protect all members of the public regardless of age or gender.

The Commission disagrees with the recommendation that the NRC should use the admittedly unlikely subsistence farmer approach as the basis to test sensitivities (for additional information on the subsistence farmer approach, see the response to Issue 2, below). The NRC expects that sensitivity studies based on unrealistic and unlikely exposure scenarios would provide results that would be difficult to interpret and relate to the actual anticipated conditions of exposure. The NRC, however, agrees with the commenters' recognition of the value of sensitivity analysis as a tool to gain insight into uncertainties and the importance of parameters and models. NRC conducted extensive sensitivity analyses with an independently developed total performance assessment code (Nuclear Regulatory Commission, "Sensitivity and Uncertainty Analysis for a Proposed Repository at Yucca Mountain, Nevada, Using TPA 3.1, Volume 2: Results and Conclusions," NUREG 1668, Vol. 2, Washington DC: Nuclear Regulatory Commission) in the development of the proposed rule.

Issue 2: Has NRC made cautious and reasonable assumptions about the characteristics of the proposed critical group?

Comment. A variety of comments were received which are related to critical group assumptions specified in the proposed NRC rulemaking. A few commenters disagreed with specification of critical group characteristics based on current conditions, noting that over long time frames such conditions are likely to change. Another commenter asserted that the assumption that all locally grown food is contaminated is vague because the proposed rule does not state all food consumed by the critical group is locally grown (the commenter disagreed with the use of a subsistence farmer approach that would result from assuming all consumption was local). The commenter further stated that the expected plume dimensions and

number of farms make the assumption that all local food is contaminated excessively conservative (*i.e.*, tends to overestimate the dose). The commenter noted local surveys show that not all food consumed in Amargosa Valley is locally grown. Other commenters offered that the critical group should be a subsistence farmer because that approach is conservative and bounding (suggesting that no dose would be allowed higher than the critical group's and therefore it would be protective of all). Another commenter stated the reasonably maximally exposed individual for a subsistence farmer also provides broad protection of all people (excepting those with extreme habits), and its conservatism would lessen the effect of assuming constancy of future behaviors. Still another commenter tentatively approved the NRC choice for critical group noting the actual critical group is likely to involve commercial, light industrial activities and, therefore, assuming a farming community is conservative (*i.e.*, protective). One commenter questioned the accuracy of the reported population count for Amargosa Valley.

Some commenters suggested alternative critical groups as being more representative or protective of the local population. Representatives of the Western Shoshone people suggested their long existence in the region and lifestyle in close proximity to the land support selection of a Western Shoshone critical group. They noted a long history of a hunting and gathering "subsistence" lifestyle that is expected to remain into the future. Farming and livestock activities were also discussed as recent introductions to the Western Shoshone lifestyle.

Response. Although the Commission considers the proposed assumptions about the characteristics of the critical group to be protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use the mean dose to the RMEI, as defined at 40 CFR part 197, as the measure to compare with the dose limit. Although there are slight differences between the characteristics of EPA's reasonably maximally exposed individual and the proposed average member of the critical group, they are practically the same. However, as noted, the Commission has adopted the characteristics of the RMEI as specified in 40 CFR 197 and added two additional requirements.

Regarding the two additional requirements, the final regulations specify: (1) The water demand to be used in estimating exposure to the RMEI (see response to Issue 2 under Critical Group Location); and (2) that the RMEI is an adult with metabolic and physiological considerations consistent with present knowledge. Specification of the RMEI as an adult is: (1) Consistent with the NAS recommendations for specifying the exposure scenario by rule; (2) consistent with the proposed regulation characteristics for the exposure scenario; (3) consistent with the criteria for the RMEI specified in the EPA standards (*i.e.*, drinks 2 liters of water per day); and (4) consistent with the EPA's Draft Federal Radiation Protection Guidance for Exposures of the General Public (59 FR 66422; December 23, 1994). The Commission considers the RMEI approach and associated characteristics of the RMEI to be protective of the health and safety of the public and environment (see also responses under Infant and Children Dose Standard and Location of the Critical Group or RMEI).

The Commission disagrees with the suggestions that a subsistence farming critical group should be used in dose calculations or that the RMEI be a subsistence farmer. As noted above, the Commission considers the RMEI approach from 40 CFR part 197 to be fully protective. The RMEI approach requires DOE to use diets and lifestyles representative of the people who now reside in the Town of Amargosa Valley, Nevada. Therefore, a variety of diets and lifestyles, including farming as it occurs today, will be represented in the characteristics of the RMEI. The Commission considers the use of local, present day conditions to be the most realistic basis for RMEI behavior assumptions, and present evidence indicates that there are no subsistence farmers in the vicinity of Yucca Mountain. NRC disagrees with the suggestion that the excessive conservatism of the subsistence approach is needed to offset any presumed lack of conservatism from the assumption of current conditions.

The Commission also disagrees with the suggestion that a Shoshone critical group should be used in dose calculations or that the RMEI be a Western Shoshone. In defining the critical group for the proposed rule, the Commission considered the possibility of a Native American based critical group. To date, based on all the information including the information provided by public comments, NRC has not been able to identify a suite of common characteristics of Native American groups in the region that is both different from the proposed farming critical group and likely to lead to greater exposures than the proposed farming critical group or the RMEI. Thus, the NRC believes the use of a RMEI for postclosure exposures protects Native Americans as well as other members of the public.

Issue 3: Should NRC include potential future climate changes in the specification of a reference biosphere?

Comment. One commenter asked that the NRC clarify whether it has determined with certainty that a future ice age will occur and, if so, provide the supporting documentation. If such a determination has not been made, NRC should revise the proposed rule to reflect greater uncertainty with regard to climate change. DOE recommended that NRC move proposed § 63.115(a)(3) and (4) to proposed § 63.114 to remove the implication that climate change needs to be considered for biosphere assumptions. Both DOE and another commenter claimed that because NRC expects that climate change (from arid to semi-arid) will not alter the biosphere sufficiently to cause major changes in potential exposure pathways, climate change should be removed from the biosphere requirements. DOE noted that climate change and changes in the geologic setting affect the performance assessment and, thus, should be moved to § 63.114. Another commenter recommended deleting proposed § 63.115(a)(3) and revising proposed § 63.115(a)(2) to reflect current climate conditions. Yet another commenter stated that evolution of the geologic setting should not be part of the reference biosphere, and thus the requirements should be moved under performance assessment (proposed § 63.114).

A commenter stressed the need to emphasize present-day conditions for defining the biosphere and provided a number of supporting points for NRC consideration. The commenter agreed with NRC that use of future human behavior is speculative and, thus, it is appropriate to limit assumptions to present-day behavior. The commenter noted risks to future generations should be based on levels deemed tolerable by present day society. The commenter claimed such analyses of future risk can only be done by assuming present-day behavior. The commenter also noted that using present-day characteristics provides confidence to the local community.

Another commenter believed that the emphasis on present-day conditions, while adequate for the time of site characterization, does not take into consideration processes and events currently taking place in Southern Nevada which could lead to different futures. Cited examples include the rapid growth that has occurred (and

continues) in Southern Nevada over the past 30 years and the increase in urban growth of southern Nye County (*e.g.*, Pahrump). Such growth was noted as important because it increases demand for, and pumping rates of, ground water, which could lead to changes in gradients that would accelerate contamination. It was further mentioned that ground-water sources north of Clark county have long been considered options to meet future water demands. For these reasons, the NRC should consider such future possibilities as alternatives to present-day biosphere conditions.

Response. Because some commenters questioned the Commission's basis for including climate change in the performance assessment requirements of the proposed rule, the Commission responds by providing additional information supporting the theory that climate change is possible during the proposed period of performance. The inclusion of climate change in biosphere requirements is consistent with the EPA standards and is also further justified based on a reasonable likelihood that climate change will occur in the future and the fact that such changes have the potential to impact the biosphere. However, comments suggesting that NRC consider future economic growth trends ignore inherently large uncertainties in predictions of such futures over both short and long time frames. The Commission finds that the inclusion of such future predictions would add inappropriate speculation into the requirements, would not enhance public safety, and is likely inconsistent with the EPA standards. Therefore, the language of the proposed rule, which requires DOE to consider climate change and precludes consideration of changes to assumptions of lifestyle and land use, that could be subject to speculation about future economic growth, is retained in the final rule, with the exception that the critical group has been replaced with the RMEI for consistency with EPA's standards.

Although it is beyond the capabilities of present-day science to determine "with certainty" that a future ice age will occur, the present paleoclimatic data support that (1) ice ages have occurred in past history, (2) climate changes in the past have exhibited a cyclical pattern, and (3) the cycle is likely to lead back to another ice age. The NRC has extensively investigated relevant research on future climate change in the vicinity of Yucca Mountain and has summarized the available information in an Issue Resolution Status Report (Nuclear Regulatory Commission, "Issue Resolution Status Report Key Technical Issue: Unsaturated and Saturated Flow Under Isothermal Conditions," Revision 2, Vol 1, Washington DC: Nuclear Regulatory Commission, June 1999). (For more information about obtaining reports from the NRC PDR, mail a request to U.S. Nuclear Regulatory Commission, Public Document Room, Mail Stop O1F13, Washington DC 20555, or e-mail pdr@nrc.gov.) The NAS committee also was familiar with the science behind future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is unlikely but not impossible, in the next 10,000 years is probable but not assured; however, over a million-year time frame, the climate is virtually certain to pass through several glacial-interglacial cycles (*i.e.*, ice ages). The Commission believes there is sufficient information in the paleoclimate record to justify including climate change in the final regulations regarding effects on repository performance.

Climate change was included in the proposed regulations for the reference biosphere in § 63.115 because the NRC believed there was sufficient scientific evidence supporting the potential for climate change over the long time frames considered by the performance assessment calculations. Although NRC analyses suggest that inclusion of climate change in the biosphere is not likely to significantly change the assumed local climate conditions and assumed exposure conditions, the Commission believes it is important to include the consideration of climate change in both the geosphere and the biosphere performance assessment calculations to ensure that the conceptual model of the environment is consistent with our scientific understanding of reasonably anticipated natural events. The NRC also believes it is important for DOE to include these processes in its performance assessment calculations and do the necessary technical analyses to ensure the processes have been adequately considered and addressed.

The NRC agrees there is a need to emphasize current conditions when applied to behavioral characteristics of the RMEI. The natural systems of the biosphere are allowed to vary (*e.g.*, climate change) because the geologic record provides evidence of past climate over a long time frame, which provides a strong basis for predicting future changes. Because human behavior cannot be similarly predicted, a similar approach cannot be used for the RMEI and the influence the local population has on the biosphere. Thus, it is necessary to emphasize current conditions for the RMEI (see response to Issue 1 for more information). The suggestion that NRC consider alternative futures related to human behavior is speculative and leads to problems deciding which alternative futures are credible and which are unrealistic. Such questions have no scientific or technical answer. It is DOE's responsibility to demonstrate that the RMEI and biosphere assumptions in performance assessment calculations are consistent with local conditions. During the review of the license application, the NRC will evaluate DOE's assumptions to ensure they are consistent with current information. Given the uncertainties associated with local economics, NRC believes it is unreasonable to expect DOE to predict future growth conditions in local areas and the consequences of growth trends.

3.7 Absence of Separate Ground-Water Protection Criteria

Issue: Why are there no separate requirements for the protection of ground water given the importance of ground water in the arid environment of Yucca Mountain and the fact that the most likely pathway for radionuclides to escape from the repository is via the ground-water pathway?

Comment. Commenters were divided on whether separate requirements for protection of ground water are necessary. Commenters supporting separate requirements for protection of ground water provided various rationales for instituting separate requirements, such as: (1) Ground water represents a valuable resource deserving separate protection; (2) ground water is the most likely source of contamination to Yucca Mountain residents; and (3) ground water at Yucca Mountain should be provided the same level of protection afforded other sites around the country that are subject to separate ground-water protection requirements under the Safe Drinking Water Act (SDWA). Generally, these commenters recommended protecting ground water by either limiting individual exposure from drinking water to 4 mrem per year or using EPA's maximum contaminant levels (MCLs). However, some commenters opposed the imposition of separate requirements for protecting ground water. One commenter opposed to separate requirements for protection of ground water stated: (1) An overall system approach for safety is appropriate, and separate requirements for protection of ground water represent unnecessary subsystem requirements and (2) such requirements would not be consistent with the recommendations of

NAS and go beyond the health-based standards mandated in section 801 of the EnPA.

Response. 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 EPA standards for Yucca Mountain at 40 CFR part 197, including separate ground-water protection requirements. These requirements, §§ 197.30 and 197.31, appear in the final 10 CFR part 63 regulations as §§ 63.331 and 63.332, respectively.

3.8 Multiple Barriers and Defense in Depth

Issue 1: Should NRC set quantitative limits (that is, subsystem requirements) for specific barriers that make up the repository system?

Comments. The NRC received comments both supporting and opposing the approach proposed in part 63, which would provide a single overall, health-based, performance objective and avoid setting arbitrary, quantitative limits on individual barriers. Commenters in favor of a single system performance goal stated that risk-informed and performance-based regulations allow the applicant and the regulator to place greatest emphasis on issues important to health and safety. Commenters supporting quantitative limits for specific subsystems expressed concern that reliance on quantitative performance assessments to show compliance with a single measure of performance is less protective than setting specific numerical criteria for the performance of individual barriers. They argued that quantitative limits for individual barriers are needed to provide greater assurance for overall repository performance and, in general, supported keeping the quantitative limits at part 60.

Response. The Commission believes that it presented a sound basis for the proposed approach to multiple barriers and defense in depth in the Supplementary Information accompanying the proposed part 63. The final rule adopts a single quantitative performance goal for individual protection and separate limits for ground-water protection as specified by the EPA standards. Beyond these, the final rule does not place quantitative limits on individual barriers. After considering the comments received, however, the Commission recognizes a need to clarify the multiple barrier requirements in the proposed rule. The response to the next issue discusses the specific clarifications adopted.

The Commission based its proposed treatment of multiple barriers on the following:

1. Consistent with the Commission's risk-informed and performance-based regulatory philosophy, DOE is provided flexibility for deciding the extent and focus of site characterization. As the repository designer, DOE may place greater or lesser reliance on individual components of the repository system when deciding how best to achieve the overall safety objective.

2. Estimates of subsystem performance are subject to many, if not all, of the same sources of uncertainty as are estimates of overall system performance. It is questionable, therefore, whether the subsystem criteria in part 60, or any other criteria, could provide truly independent assurance of total system performance.

3. The Commission recognizes that techniques of performance assessment have improved a great deal because of significant advances in knowledge and experience achieved since part 60 was developed. These advances in performance assessment technology support the use of performance assessment results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in a system's overall performance.

The Commission's goal is to protect public health and safety and to ensure compliance with EPA's standards. NRC's evaluation of DOE's compliance demonstration will examine how all components of the repository system work together to achieve this goal. Therefore, the emphasis should not be on the isolated performance of individual barriers but rather on ensuring the repository system is robust, and is not wholly dependent on a single barrier. Further, the Commission supports an approach that would allow DOE to use its available resources effectively to achieve the safest repository without unnecessary constraints imposed by separate, additional subsystem performance requirements. It is also important to remember that part 63 requires DOE to carry out a performance confirmation program to provide further confidence that barriers important to waste isolation will continue to perform as expected (see Section 2.4 on Performance Confirmation).

Issue 2: How does the multiple barrier provision fulfill NRC's philosophy of defense in depth in evaluating repository performance?

Comments. Some commenters asked the NRC to explain how we apply defense in depth to the repository without specific calculations or numerical limits for meeting this requirement. They stated that the proposed part 63 is not clear about how DOE must demonstrate defense in depth for repository performance.

Response. In general, the Commission believes that a repository system should reflect the philosophy of defense in depth. The Commission expects that if a repository system is made up of multiple barriers, then it will be more tolerant of unanticipated failures and external challenges. The final regulations specify criteria for quantitatively evaluating postclosure performance (*e.g.*, individual protection, ground-water protection, and evaluation of human intrusion). These criteria help ensure defense in depth by requiring calculations that provide risk insights into the impact on performance of specific system attributes and external conditions. DOE must evaluate the performance of the repository system, as it performs as a result of compliance with general design criteria (*e.g.*, required use of multiple barriers and identification of the repository by markers). DOE must also evaluate the system's response to various external challenges (*e.g.*, disruptive events treated in the performance assessment, as well as a specified human intrusion scenario).

Commenters on the proposed rule pointed out that neither the intent of the multiple barrier provision, mandated by the Nuclear Waste Policy Act, nor how NRC would determine compliance with this provision, were clear. To clarify this intent, the final rule explains the concepts associated with the multiple barrier provision in § 63.102, and provides the criteria in § 63.115.

The proposed rule would have required and the final rule requires DOE to: (1) Identify barriers; (2) describe quantitatively each barrier's ability to contribute to waste isolation; and (3)

provide technical bases for the barriers' capabilities as part of the overall demonstration of compliance with the individual protection standard (see § 63.114 (h)–(j) of the proposed rule). Although not necessarily required as a separate demonstration, this required information on the capability of barriers, integral to the performance assessment, illustrates the resilience or lack of resilience of the repository to unanticipated failures or external challenges. Also, quantitative insights about the defense in depth of the proposed repository emerge directly from the quantitative evaluations in the performance assessment. The performance assessment must include analyses of the effects of unlikely, but credible, external challenges on overall performance. (In its analyses, DOE must consider disruptive events that have an annual probability of occurrence greater than 10^{-8}.) Disruptive events may degrade performance of the engineered barriers or reduce the effectiveness of natural barriers or both. Also, DOE must evaluate uncertainty about the performance of both engineered and natural barriers in the performance assessment. For example, uncertainty about the corrosion rate of the waste package will necessarily affect the estimated lifetime of the package. Likewise, uncertainty about geochemical sorption will affect estimates of the time it takes specific radionuclides to travel in the geosphere. As with the disruptive events, the proper consideration of uncertainty in the performance assessment should ensure an evaluation of the range of response of individual barriers to various challenges (*e.g.*, higher than normal corrosion rates, lower than normal geochemical sorption). Thus, a complete performance assessment (*i.e.*, one that complies with § 63.114) will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged.

The Commission has clarified how DOE is to develop the technical basis for each barrier's technical capability. The change makes clear that a description of relevant information about a given barrier's characteristics and performance, which DOE has used to support the overall performance assessment, is sufficient to show compliance with this requirement. The language of the proposed rule was not intended to imply that an acceptable technical basis for multiple barriers need be (or even could be) derived separately from the basis for the performance assessment itself. Rather, the technical basis for the barriers should be presented in a focused, clear description. This description should be derived from pertinent information contained in the technical basis for the performance assessment.

Quantitative or Qualitative Assessment?

Consistent with the proposed rule, the final rule allows DOE to select from various methods to describe the capabilities of the barriers. Regardless of the method selected, DOE must describe 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. The Commission has considered the comment that an evaluation of each barrier's capability should be quantitative. The Commission continues to believe a qualitative approach, as proposed, is appropriate for the following reasons:

1. It provides the Commission with information to be considered in its decisions without constraining its considerations to a specific limit for a particular barrier, which could result in less favorable overall system performance.

2. It gives the Commission the flexibility to consider the nature and extent of conservatism in the evaluations used for compliance demonstration, and to decide whether there is a need to require DOE to reduce uncertainties in its assessment (*e.g.*, collecting more site data) or to include further mitigative measures.

3. Quantitative evidence of the capability of individual barriers to contribute to waste isolation is an integral part of the performance assessment. Therefore, an additional quantitative limit is not necessary to show that overall performance reflects a system of multiple barriers.

The Commission understands that establishment of explicit, quantitative limits for individual barriers might be considered a desirable and more easily explained approach. That being said, however, the Commission knows of no scientific basis for setting such limits for particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

Finally, the required description of barrier capability provides information that will aid in the interpretation of the performance assessment results, while at the same time providing information that is independent from the condition of the other barriers. For example, the unsaturated and saturated zones could provide significant retardation to many radionuclides such that radionuclides will not reach the RMEI within 10,000 years regardless of when the waste package fails. This capability of geologic systems to "retard" or slow the movement of contaminants exists whether or not the waste package is breached. Thus a geologic barrier can provide defense in depth irrespective of releases from the waste package. Describing the capabilities of the system's component barriers (*e.g.*, retardation of specific radionuclides in specific geologic media) can be accomplished by describing the applicable conceptual models and parameters used in the performance assessment. It does not require quantitative calculations beyond those performed to demonstrate compliance with the postclosure performance objectives. The Commission believes that understanding the capability of the system's component barriers provides an understanding of the repository system that can increase confidence that the postclosure performance objectives are met. The Commission is satisfied that the clarifying additions discussed above, along with other requirements at §§ 63.114 and 63.115, if met, will provide sufficient basis to determine whether a proposed repository system acceptably provides a system of multiple barriers.

3.9 Compliance Period

Issue 1: Is a 10,000-year compliance period reasonable in light of the NAS recommendations?

Comment. Several commenters stated that a 10,000-year compliance period conflicts with the NAS recommendation that the time over which compliance should be assessed should include the time when greatest risk occurs, within the limits imposed by the stability of the geologic system, and that rejecting the NAS recommendation is arbitrary.

Response. The EPA standards for Yucca Mountain provide for a demonstration of compliance over a 10,000-year time frame. Moreover, the

Commission agrees that a 10,000-year compliance period is reasonable for the reasons identified in the supplementary information provided with the proposed criteria at part 63 (64 FR 8647; February 22, 1999). The fact that it is feasible to calculate performance of the engineered and geologic barriers making up the repository system for periods much longer than 10,000 years does not mean that it is possible to make realistic or meaningful projections of human exposure and risk, attributable to releases from the repository, over comparable time frames. NAS acknowledged that projecting the behavior of human society over long periods is beyond the limits of scientific analysis and recommended that "cautious, but reasonable" assumptions, based upon current knowledge, be made with regard to the selection of biosphere and critical group parameters for Yucca Mountain. Determining just how far into the future current knowledge can no longer support "reasonable" assumptions about pathways affecting human exposure is clearly a subjective, policy judgment. NRC believes that, for periods approaching 1,000,000 years, as suggested by NAS, during which significant climatic and even human evolution would almost certainly occur, it is all but impossible to make useful and informed assumptions about human behaviors and exposure pathways. NAS explicitly acknowledged that selection of a time period over which compliance should be evaluated necessarily involves both technical and policy considerations (see p. 56, "Technical Bases for Yucca Mountain Standard," National Research Council, 1995).

Issue 2: Should NRC require DOE to provide supplemental analyses of repository performance at times other than 10,000 years?

Comment. One commenter stated that although a 10,000-year compliance period is well justified, it would be beneficial to require, either by rule or guidance, a supplemental analysis for performance at 1,000 years. This analysis would help to identify vulnerabilities such as juvenile failures of waste packages, so that DOE can reduce the likelihood and consequences of such vulnerabilities. The same commenter also stated that a supplemental analysis at 100,000 years, or even later, can provide a useful projection of the final transport of waste from the repository, particularly for the very long-lived isotopes.

Response. The Commission will not require DOE to provide supplemental analyses of repository performance at times other than 10,000 years. To demonstrate compliance with the individual dose limit, the expected annual dose needs to be below the regulatory limit at all times within the 10,000-year compliance period. This requires a time history of repository performance throughout the 10,000-year compliance period. Therefore, repository performance at 1,000 years can be derived from the performance assessment provided by DOE in the license application. A separate, supplemental analysis at 1,000 years is not necessary. It may be useful to note that NRC pre-licensing activities include providing guidance that DOE (and other stakeholders) can use to develop a transparent performance assessment that will reveal an understanding of the relationship between the performance of individual components or subsystems of the geologic repository and the performance of the total system at all times over the 10,000-year compliance period.

In response to Issue 1 (Is a 10,000-year compliance period reasonable in light of NAS recommendations?), the Commission questions the realism and meaningfulness of projections of human exposure and risk, attributable to releases from the repository, over time frames much longer than 10,000 years. Requiring DOE to provide a separate analysis of repository performance over very long times in the license application would be inconsistent with our position on the utility of this information, as well as with EPA's standards for Yucca Mountain. The EPA standards require that DOE include an analysis of repository performance up through peak dose in the EIS which would accompany any potential license application. This provision is included in the final part 63 regulations at § 63.341. The Commission notes that there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

3.10 Human Intrusion Scenario

Issue 1: Is the Commission's proposal for the human intrusion calculation appropriate for evaluating the ability of the repository to withstand an intrusion event?

Comment. Some commenters noted that, because of the uniqueness of the repository, it is likely that institutions involved with the development, construction, and operation of a repository, and knowledge of its existence, are likely to persist longer than 100 years after the repository is permanently closed. Because some form of institutional, corporate, or anecdotal knowledge about the proposed repository, would exist well beyond closure, any drilling into the repository would be advertent, not inadvertent, contrary to the NAS" recommendation. Thus, given the likelihood of multi-generational knowledge about any proposed repository that could persist well beyond permanent closure, there is no reason to believe that unintended human intrusion would occur shortly after the loss of institutional controls. Also, given the current waste package design, DOE asserted that current drilling techniques would likely not lead to waste package penetration without recognition by the drillers. Other commenters noted that any natural resource exploration campaign is likely to involve more than an exploratory borehole. Moreover, because of the potential for changing resource needs over the long period of regulatory concern, there is the possibility for multiple exploration campaigns and, thus, the potential for multiple boreholes breaching the repository. Consequently, the rule should be changed to require that effects of multiple boreholes on repository performance be evaluated.

One commenter questioned the rationale for not regulating the radioactive materials brought to the surface, in drill cuttings or captured in drill core, because these materials would enter the biosphere and have the potential for exposing members of the drilling crew and the public.

Response. The Commission supports and is implementing the approach for evaluation of human intrusion as specified in EPA's final standards. The Commission proposed at part 63 a stylized calculation that prescribed the timing of the intrusion (*i.e.*, 100 years after permanent closure), the repository barriers affected by the intrusion (*i.e.*, unsaturated zone and the waste package), and the relevant exposure pathway (*i.e.*, ground-water pathway). The comments received reflect the difficulties presented to EPA and to the Commission in selecting an appropriate approach for evaluating human intrusion. As noted by NAS, selecting an approach for evaluating human intrusion requires consideration of unknowns (*i.e.*, how and when intrusion into the repository will occur), ability to estimate the effect of a postulated intrusion into the repository, and policy considerations for setting an appropriate standard. In the proposed rule, the Commission specified a "stylized" calculation to test resilience of the repository and preclude

speculation on the form of the intrusion and when it may occur. However, the Commission also believes it is necessary to provide flexibility to DOE to support an alternative calculation such as the approach provided in EPA's final standards. The final EPA standards provide DOE the flexibility to identify the time of the intrusion as the earliest time that human intrusion into the waste package could occur without recognition by the drillers. The Commission has implemented this approach in the final regulations.

Responses to specific comments on the timing and frequency of the intrusion, details of the intrusion scenario regarding effects on the contents of the waste package, and exposure pathways for the intrusion are provided below:

Timing and Frequency of Intrusion

DOE commented that the proposed calculation was unrealistic because it is unlikely that a borehole would intersect a waste package because the cross-sectional area of the waste packages is small relative to the overall area of the repository footprint. DOE also noted that, at 100 years, it is unlikely the waste package could be penetrated, using current drilling techniques, without recognition by the drillers (DOE does not expect the waste packages to degrade significantly during the 10,000-year regulatory period). The final regulation, which implements the approach contained in the EPA standard, provides DOE with the flexibility to determine and to justify (subject to NRC review) its selection of the time of the intrusion event based on the condition of the waste package.

Another related issue is whether the stylized calculation should consider multiple intrusions. The final EPA standards resolve this issue in favor of a single intrusion. Moreover, in its findings and recommendations, NAS argued against analyses of whether and how often exploratory drilling would occur at Yucca Mountain because of the complexities associated in such assessments. Simply stated, the NAS felt that no one can accurately predict the characteristics of future human society and their technology. In the context of human intrusion, estimating the probability of exploratory drilling for a given resource relies on an ability to predict certain economic and technical factors that influence supply of, and demand for, that resource. In fact, NAS noted that the continued advances in noninvasive geophysical techniques may, in fact, reduce the number and frequency of exploratory boreholes. However, some evaluations of the resource potential of the site suggest that Yucca Mountain (and the area immediately around it) does not represent an attractive candidate for either random or systematic exploratory drilling at this time ((1) Raines, G.L., *et al.* (eds.), "Geology and Ore Deposits of the Great Basin," Geological Society of Nevada/U.S. Geological Survey, Symposium Proceedings, April 1–5, 1990, Reno/Sparks, Nevada, 2 vols., 1991; (2) Schalla, R.A., and E.H. Johnson (eds.), Oil Fields of the Great Basin, Reno, Nevada, Geological Society of Nevada, 1994; (3) Sherlock, M.G., D.P. Cox, and D.F. Huber, "Known Mineral Deposits and Occurrences in Nevada (Chapter 2)," in D.A. Singer (ed.), "An Analysis of Nevada's Metal-Bearing Mineral Resources," Reno, Nevada, Nevada Bureau of Mines and Geology, Open File Report 96–2, 1996; and (4) Singer, D.A. (ed.), "An Analysis of Nevada's Metal-Bearing Mineral Resources," Reno, Nevada, Nevada Bureau of Mines and Geology, Open File Report 96–2, 1996; and (5) U.S. Department of Energy, "Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area, Nevada," Office of Civilian Radioactive Waste Management, Nevada, DOE/RW–0199, 9 vols., December 1988, pp. 1–256–1–313). Consequently, any consideration for the drilling of multiple exploratory boreholes or later drilling of more boreholes further increases the speculative nature of the intrusion scenario with potentially little increase in understanding repository resilience.

The EPA standards provide for consideration of a single borehole at the earliest time that human intrusion into the waste package can occur without recognition by the drillers. The Commission believes this is an appropriate test for evaluating repository resilience. Moreover, the suggested alternative to evaluate multiple intrusions for the human intrusion calculation fails to reflect the purpose of the human intrusion calculation, that is to test the resilience of the repository, not to evaluate the speculative issue of frequency of the intrusion.

Intrusion Scenario

The public comments on part 63 point out the need to clarify certain aspects of the prescribed human intrusion event at proposed § 63.113(d) with respect to the effects of human intrusion on the contents of the waste package. Consistent with current drilling practices, it can be reasonably assumed that material inside the waste package that is intercepted by the borehole would be taken to the surface. Proposed part 63 stated the borehole "extends to the saturated zone, and is not adequately sealed." Some commenters suggested that particulate HLW inside the waste package would be free to fall to the saturated zone inside the inadequately sealed borehole. The Commission did not intend to imply that, contrary to current drilling practices, an inadequately sealed borehole would allow particulate waste to fall directly to the saturated zone. However, an inadequately sealed borehole would likely allow water to readily enter the waste package; release of radionuclides from the waste package by and in water, and transport of these radionuclides to the saturated zone by way of the borehole rather than through geologic units that could potentially retard the transport of radionuclides. NRC has clarified this point at § 63.322(e) and (f) in the final rule.

Exposure Pathways

Human intrusion has the potential for releasing particulate HLW to the surface with drill cuttings or providing a fast pathway for radionuclides to be transported to the saturated zone by water (*e.g.*, water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone). NAS concluded, and the Commission agrees, that analysis of the risk to the public or the intruders (*i.e.*, drilling crew) from radioactive drill cuttings left unattended at the surface for subsequent dispersal into the biosphere would not fulfill the purpose of the human intrusion calculation because it would not show how well a particular repository site and design would protect the public at large. Rather, an analysis of the hazard of particulate HLW left on the surface would be dominated by assumptions subject to significant speculation and uncertainty regardless of the particular site or design under evaluation. Additionally, the release to the surface represents a one-time release with no long-term effect on the repository barriers. Alternatively, releases to the ground-water pathway can be adversely influenced over a long period of time by an intrusion event that affects barriers of the repository (see the discussion on barriers). Therefore, an appropriate test of the resilience of the repository is an evaluation of the effects of intrusion on releases in the ground-water pathway.

Issue 2: Is a quantitative comparison between the individual dose limit and the results of the stylized human intrusion calculation appropriate for evaluating the impact of human intrusion?

Comment. Commenters questioned the value of comparing the results of what is essentially a deterministic "bounding" calculation for human intrusion with that of the probabilistic (risk) analysis of overall repository performance. Because risk is a function of both probability and consequence, evaluation of human intrusion, without accounting for the probability of the event taking place, must also apply judgment as to what constitutes an acceptable consequence. NEI suggested that selection of an acceptable consequence limit should be guided by the same logic that was used in establishing the proposed preclosure licensing requirements for DBEs found at § 63.111. This logic sets higher dose limits for those events that are unlikely to occur (*i.e.*, Category 2 DBEs) compared with the dose limit for those events expected to occur (*i.e.*, normal operations or Category 1 DBEs).

DOE suggested that the use of a highly speculative human intrusion scenario to evaluate the robustness of the repository is inappropriate and makes a poor criterion for potentially disqualifying the Yucca Mountain site. In particular, DOE noted that designing a repository to meet a restrictive human intrusion performance criterion may lead to suboptimization of the overall repository design. Therefore, DOE recommended that the results of the intrusion calculation be used as a qualitative indicator of repository "resilience."

Response. The objective of the human intrusion assessment is to inform any Commission decision regarding the need for DOE to reduce uncertainties in its estimates of performance or to provide more measures to mitigate consequences and protect public health and safety. As discussed in the previous response, the Commission is implementing the approach for evaluation of human intrusion as specified in EPA's final standards. This approach provides DOE flexibility in determining the timing of intrusion and sets an annual individual dose limit of 0.15 mSv/yr (15 mrem/yr).

3.11 Postclosure Aspects of Repository Design

Issue 1: Should the NRC limit the thermal energy output per unit area of the repository?

Comment. High-level waste (principally spent nuclear fuel) will continue to produce thermal energy following its disposal in a geologic repository. Host rock temperatures would be affected by the burn-up history of the waste, its age, and the density of waste package canisters within the repository. The resulting thermal load may result in a thermal-mechanical-hydrologic-chemical (T–M–H–C) response in the host rock and surrounding geologic setting, and thus may have a deleterious effect on repository performance. Given this concern, some commenters noted the proposed rule did not adequately account for the thermal output of the waste. In particular, some commenters suggested that the regulations should place a limit on the thermal output that would better ensure safe operation and long-term stability of the repository. One commenter even suggested that the waste be allowed to cool for 100 years prior to emplacement as a means of addressing this potential design issue.

Response. The Commission believes that it is inappropriate to specify a limit on the thermal energy output per unit area of the repository in the rule. This proposed regulation is performance-based and allows DOE wide latitude in how it designs any potential Yucca Mountain repository by requiring DOE to take into account likely site conditions, processes, and events expected during the time period of regulatory concern. Consequently, as a result of site characterization, DOE can be expected to come to some conclusion regarding the significance of T–M–H–C coupling to repository performance and account for it in both its preclosure design as well as in its postclosure performance assessment. The Commission recognizes that DOE is evaluating different thermal loading regimes in the context of its Supplemental Draft EIS. For its part, the Commission believes that it is inappropriate to specify a limit on the thermal energy output per unit area in advance of DOE's scientific decision making about the role and significance of T–M–H–C coupling at the Yucca Mountain site.

Issue 2: The repository design should be as robust as reasonably achievable.

Comment. A commenter suggested that although the ALARA principle should not be used in calculating doses, it should be used to design critical repository structures, systems, and components. By incorporating ALARA into the rule, the commenter proposed that the performance of certain design features, particularly barriers, would be optimized and made as robust as reasonably achievable.

Another commenter suggested that NRC should require that engineered barriers be designed to account for an oxidizing environment. The commenter stated that a ceramic waste package may function more effectively than a metal waste package in an oxidizing environment. One commenter was concerned that exceeding the Nelson limits could result in catastrophic failure of the waste package.

Finally, a commenter suggested that a repository with a natural-ventilation system may be safer and more sound. The commenter suggested that this design approach may be safer than complete closure of the repository.

Response. The Commission considers that part 63, as written, will ensure an adequate design and has not revised the proposed rule on this matter.

With regard to the public comment on the use of ALARA, in its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's postclosure requirements. In summary, its reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted that it would be problematic to evaluate compliance with the application of ALARA principles in the postclosure phase of the repository. The Commission agrees with NAS in this regard.

With regard to the comment concerning the potential oxidizing waste package environment, the Commission is aware of this concern and notes that, as the repository developer, the responsibility for designing an adequate engineered barrier system rests with DOE. As part of its responsibilities, DOE is required by the regulations to take into account applicable engineering limits, as well as likely site conditions, processes, and events, including those driven by thermal loads, when designing the waste package. As a result of its investigations, DOE is expected to reach some conclusion regarding the significance of the thermal pulse and its coupled effects on waste package lifetime. Thus, because DOE has some flexibility in how to design the repository and how it will allocate performance among the various natural and engineered barriers, DOE will have some flexibility in the choice of materials used to fabricate the waste package.

Lastly, with respect to the issue of repository ventilation, inasmuch as proposed part 63 is nonprescriptive, DOE has the responsibility to determine how to best design the geologic repository so that it complies with performance objectives. As noted above, DOE will be required by the regulations to take into account likely site conditions, processes, and events expected, including those driven by a thermal pulse. As a result of its

investigations, DOE would come to some conclusion regarding the significance of the thermal pulse to repository performance and account for such significance in both its preclosure design as well as in its postclosure performance assessment. For its part, the Commission will independently review this information in any potential license application, including the significance of thermal loading on the repository and how it has been accounted for in its design and in the context of overall performance of the repository, to ensure that the performance objectives are met.

Issue 3: Will NRC have sufficient information to evaluate DOE's repository design?

Comment. One commenter expressed the view that the amount of information being requested at § 63.21(c)(4)(i) in the proposed rule [moved to § 63.21(c)(3)(ii) in the final rule], the description and discussion of the engineered barrier system, is insufficient and inadequate for the NRC staff's requisite review. It was recommended that this section of the rule be expanded to include the requirements that DOE include detailed design drawings, including specifications and flow sheets for all manufacturing processes, etc., as part of any potential license application. One commenter asked whether the NRC will have access to classified information from other governmental agencies.

Response. The Commission believes that part 63 requires DOE to submit sufficient information to allow NRC to perform the necessary review but has revised the proposed rule to specify the level of detail required.

The rule requires that the general information of the license application shall include "* * * a description and discussion of the engineered barrier system. * * *" The types of information to be included in that "description and discussion" are currently being identified by the NRC staff as part of the development of the NRC's YMRP. Consistent with the rule, this review plan will identify the expected content of any potential license application. The guidance ensures that any potential license application submitted by DOE contains the information necessary for docketing and review by the NRC staff. However, to better assure that the information submitted by DOE is consistent with the level of detail being sought for the GROA design description for preclosure, the proposed rule has been revised to require that the design description include dimensions, material properties, specifications, and analytical and design methods used, along with any applicable codes and standards.

With regard to the comment on NRC access to classified information, all information (including classified information) used by DOE to support its license application is subject to NRC review. The Commission is capable of receiving, handling, and storing classified information.

4 General Requirements

4.1 Quality Assurance

Issue 1: Would the NRC rule weaken or undo the requirement that DOE systematically record its decisions that significantly concern safety, how those decisions were made, and what factors influenced them?

Comment. A number of comments expressed a concern that the NRC rule would weaken or undo the requirement that DOE systematically record its decisions that significantly concern safety, how those decisions were made, and what factors influenced them. The commenters further stated that systematic accountability on scientific and engineering decisions related to safety must be upheld.

Response. The regulations, while risk-informed and performance-based, contain provisions that require DOE to monitor and report on the types of potential concerns raised in this comment. These include reports on site characterization activities (§ 63.16); construction records (§ 63.72); potential site, design, and construction deficiencies (§ 63.73); the implementation of a program of continuing performance confirmation (§§ 63.131–63.134); and the application of a rigorous QA program to site characterization, design, construction, and operations (§§ 63.141–63.144).

Issue 2: Should the quality assurance program requirements contained in part 60 remain intact for part 63?

Comment. A number of comments identified a need for the QA requirements contained in part 60 to be applicable for part 63.

Response. The QA requirements initially proposed in Subpart G, "Quality Assurance," to part 63 required that the licensee implement a QA program that meets the applicable requirements of Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants") to part 50. However, rather than referencing Appendix B to 10 CFR part 50, as was done in the proposed rule, the final rule has incorporated quality assurance requirements from Appendix B that are specifically applicable to a geologic repository. Further, additional requirements are added in a new § 63.144 to address the controls that a licensee will have to meet for changing an NRC-approved QA program description.

Issue 3: Should there be requirements for qualification of data that existed prior to the implementation of QA programs?

Comment. One commenter expressed a concern that there are no requirements in the proposed rule to provide for the qualification of data that existed prior to the implementation of the QA program used by DOE.

Response. The Commission believes that the controls in §§ 63.141, 63.142, 63.143, and 63.144 are adequate. Based on these requirements, data related to structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto are subject to the applicable requirements of Appendix B to 10 CFR part 50 as incorporated into 10 CFR part 63. These provisions require DOE to evaluate data required to support its license application. If data related to structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto have not been collected in accordance with a QA program that meets these requirements, DOE would be required to show that such data have been qualified for its intended use.

The NRC recognized that some data supporting a license application for a high-level waste repository may not have been initially collected under a part 60, subpart G, QA program. In February 1987, the NRC published NUREG–1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories." NUREG–1298 provides guidance on the use and qualification of data not initially collected under a Subpart G QA program.

Issue 4: Should the NRC conduct an inspection to verify proper execution of QA programs? What additional steps will the NRC take to ensure that problems which occurred during site characterization will not occur after a license is granted (will there be requirements for NRC inspections)?

Comment. Commenters suggested that the regulations should include a requirement for NRC to conduct inspections to verify proper execution of the DOE QA program and that there should not be a strict reliance upon DOE to implement the program properly. Commenters also expressed a concern that the problems occurring during site characterization would continue after NRC granted a license to DOE. The

question was asked, "What additional steps will the NRC take to ensure that these same problems do not occur after a license is granted?'

Response. DOE is presently undertaking a comprehensive program that includes the proper steps to correct its QA program deficiencies, although some implementation issues remain to be resolved. Section 63.75, "Inspection," requires, in part, that DOE allow the NRC to inspect the premises of the GROA at the Yucca Mountain site and adjacent areas to which DOE has right of access. Further, § 63.75 requires that DOE afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors assigned to inspect the Yucca Mountain facility immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety. If NRC were to issue a license to DOE, NRC would periodically perform inspections of selected DOE activities at the Yucca Mountain site, at DOE support facilities, and at DOE subcontractor facilities to ensure that DOE's QA program is being effectively implemented. The number and depth of the inspections would be based on: the risk significance of the structures, systems, or components; activities related to these structures, systems or components; and DOE's past performance.

Issue 5: Should the NRC require the use of Part 2.7 of NQA–1 or a similar standard for software QA?

Comment. A comment stated that it was proper to use Appendix B for QA requirements applicable for part 63. However, the commenter noted that Appendix B is weak regarding computer QA software and that the NRC should use Part 2.7 of NQA–1 or a similar standard for software QA.

Response. The proposed rule has been revised to emphasize that the QA program description needs to include how the requirements of Appendix B will be satisfied. In the final rule, § 63.143, "Implementation," states: "DOE shall implement a quality assurance program based on the criteria required by § 63.142." As discussed in § 63.142, DOE's QA program would be applicable to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. Further, these activities include site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. Sections 63.142 and 63.21(c)(17) (§ 63.21(c)(11) in the proposed rule) have been changed to specifically require that the DOE QA program describe how the QA criteria contained in § 63.142 will be satisfied.

Presently, the DOE QA program for the Yucca Mountain site characterization (DOE Document No. DOE/RW–033P, Revision 8, dated June 5, 1998) includes a discussion of how the applicable requirements of Appendix B will be satisfied. Supplement 1, "Software," to DOE/RW–033P describes the QA controls for software and addresses controls such as: (1) Software life cycles, baselines, and controls; (2) software verification and validation; (3) software configuration management; (4) defect reporting and resolution; (5) control of the use of software; and (6) software documentation. The software controls described in DOE's QA program were reviewed by the NRC and found acceptable. Although § 63.142 in the final rule does not specifically address software QA, it does require that the QA controls be applied to certain design and analysis activities. By inference, software used for such activities would be subjected to the applicable requirements of § 63.142. The NRC will provide, as necessary, additional guidance for software QA in the YMRP that may include elements similar to those in existing standards such as Part 2.7 of NQA–1. The level of detail for software QA in Part 2.7 of NQA–1 is considered inappropriate for inclusion in the rule.

Also, as a result of this and other comments, the final rule does not reference Appendix B, but incorporates Appendix B, with appropriate modifications, to address its applicability to the high-level waste repository.

Issue 6: The applicability of the QA program is not clear. What does safety include?

Comment. One comment identified a concern that the applicability of the QA program was unclear and that he believed the QA program was applicable to all items and activities important to the isolation of radioactive waste at Yucca Mountain and suggested adding text to Part 63 to better define the applicability of the QA program.

Response. The QA program applies to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. These activities include site characterization, acquisition and analysis of samples and data, scientific studies, performance of tests and experiments, controlling geological and engineering materials samples, facility design and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. These terms are defined in § 63.2.

Based on this discussion, the NRC considers the applicability of the QA program to be adequately described in subpart G to part 63. Because proposed part 63 referred to Appendix B for QA requirements and Appendix B does not use the terms important to safety and important to waste isolation, requirements from Appendix B have been incorporated into final part 63 and modified accordingly to address their applicability to the high-level waste repository.

Issue 7: Should Part 63 contain QA program change controls similar to those found in § 50.54(a), and should the proposed § 63.44 change control process be applicable for QA program changes?

Comment. DOE identified a problem with proposed part 63 requirements for controlling changes to the QA program and recommended that requirements similar to those contained in § 50.54(a) be used. DOE correctly pointed out that the NRC stated, in the discussion accompanying the final rule for Part 50 concerning changes to QA programs (64 FR 9030; February 23, 1999), that "use of 10 CFR 50.59 criteria for QA program changes is not appropriate." DOE pointed out that, as written, proposed part 63 would permit QA program changes to be controlled in accordance with requirements similar to § 50.59 (as permitted by § 63.44). DOE suggested text changes to implement its comments. DOE also expressed a concern that as proposed, the location of § 63.21(c)(11) would cause the QA program description contained in the Safety Analysis Report to be subject to the change controls required by § 63.44.

Response. The Commission agrees that the use of the criteria specified at § 63.44 is not appropriate for changes to the QA program description included in the Safety Analysis Report. We also agree that the rule should identify change control requirements applicable to the licensee's QA Program and that those requirements should be similar to those contained in § 50.54(a)(3). The proposed rule has been revised to specifically address change control requirements for QA program descriptions.

We disagree that § 63.21(c)(11) should be relocated to § 63.21(b) because the QA program description is required to

specifically describe how the requirements of § 63.142 will be satisfied. By adding specific requirements in §§ 63.44 and 63.144 for the control of changes to the QA program description, the Commission believes it has resolved the expressed concern for relocating § 63.21(c)(11).

Note: The text at § 63.21(c)(11) in the proposed rule is specified at § 63.21(c)(17) in the final rule due to reordering of § 63.21 to achieve a more consistent order with the required analyses.

Issue 8: How will NRC ensure DOE properly implements its QA program and assures the quality of data it will use to support a license application?

Comment. A number of comments related to what actions the NRC would take to ensure that DOE is properly implementing its QA program and qualifying data.

Response. In early 1999, the NRC staff established a QA Task Force to review and evaluate the DOE QA program. The Task Force was created to address acknowledged concerns regarding the effective implementation of the DOE QA program. This task force includes a Senior QA Engineer, the NRC Onsite Representatives, and the CNWRA QA Director, under the direction of the Division of Waste Management (DWM) Division Director. The Task Force has been active in reviewing DOE's progress and issues.

With respect to data qualification, DOE has initiated corrective actions for the data qualification problems documented in 1998 and 1999. In September 1999, DOE committed to have 100 percent of all data fully qualified by the time of license application, should DOE submit a license application. DOE has made significant progress in confirming the adequacy of data collected before June 1999. In January 2001, DOE had qualified 80 percent of these data. As of June 13, 2001, DOE had qualified 86 percent of the data supporting the potential license application. Further, during the June 13, 2001 NRC/DOE Quarterly QA Breakout Session Meeting, DOE reported that its goal was to have all data fully qualified by site recommendation.

In late spring of this year, NRC and DOE identified further QA problems, this time affecting the processes controlling software verification and model validation. DOE acknowledged a need to revise and enhance some of its procedures, such as those controlling software development and model validation, and to provide needed training to its personnel. Further, DOE is evaluating traceability and transparency problems in its technical reports. The QA staff of DOE and their contractors have been successful in identifying the QA program deficiencies in the various participants' programs and, in many cases, highlighting the repetition of similar deficiencies. In the past, inadequate corrective action was taken, and the DOE organizations responsible for correcting the deficiencies were not held accountable. NRC has impressed upon DOE that correction of the QA program deficiencies is essential to any potential licensing of the Yucca Mountain repository and we are taking steps to ensure that NRC is able to evaluate the effectiveness of DOE action to correct the problem.

During fiscal year 2000 and through June 2001, the NRC staff evaluated the implementation of DOE's QA program by: (1) Continuing observation of DOE performance-based audits; (2) daily overviews by NRC Onsite Representatives assigned to the Yucca Mountain Project office in Las Vegas, Nevada; (3) enhanced participation of NRC's technical staff in activities at the various DOE facilities; and (4) interfacing with DOE during technical exchanges and management meetings. Through these activities, we are encouraged that many of the deficiencies are being corrected by DOE. Further, we have observed that DOE is continuing to adequately identify, process, and correct new problems. NRC believes its aggressive overview activities provide the ability to adequately evaluate whether the DOE QA program will continue to be effectively implemented.

4.2 Changes, Tests, and Experiments

Issue 1: Should the Commission adopt alternative criteria for changes, tests, and experiments?

Comments. Commenters who addressed the change process issue were generally supportive of applying alternative criteria, noting that the alternative criteria offered at § 63.44 were useful in clarifying the issues involved in evaluating the effects of changes, tests, and experiments on license conditions. Nonetheless, several commenters noted that the alternative criteria retained some terms that are ambiguous and that could be interpreted subjectively, and recommended that these terms be avoided or defined in the final rule.

Response. For nuclear reactors, ISFSIs, and holders of a certificate of compliance for a spent fuel storage cask, the Commission recently amended its regulations concerning the authority of these licensees and certificate holders to make changes to the facility or operating procedures, or to conduct tests or experiments, without prior NRC approval (64 FR 53582; October 4, 1999). The final rule clarified the specific types of changes, tests, and experiments conducted at a licensed facility and revised the criteria that must be used to determine when NRC approval is needed before such changes, tests, or experiments are made. The final rule also added certain definitions for terms that have been subject to differing interpretations. Requirements comparable to those recently amended were proposed at § 63.44 for a geologic repository at Yucca Mountain. In the Supplementary Information accompanying the proposed criteria, the Commission expressed its desire to establish a uniform policy approach for addressing the change process issue. To that end, the Commission sought comment on the suitability, for a repository at Yucca Mountain, of an approach substantially equivalent to that proposed for nuclear reactors and ISFSIs (63 FR 56098; October 21, 1998). Having taken into account the comments received on this approach for other NRC-licensed facilities and as applied to a potential repository at Yucca Mountain, the Commission is adopting final criteria for § 63.44 that are comparable, but not identical, to those recently applied to reactors and spent fuel storage facilities. Departures from the criteria applied to reactors and spent fuel storage facilities were made to reflect differences between the repository and such facilities (*e.g.*, replacement of "facility or cask design" with "geologic repository operations area and design," and of "importance to safety" to "importance to safety and important to waste isolation"). Other departures were necessary to reflect different administrative requirements of part 63 (*e.g.*, requirement that the Safety Analysis Report be updated rather than replaced with a Final Safety Analysis Report). Less obvious changes were needed to reflect the risk-informed, performance-based nature of the part 63 criteria, and the fact that part 63 contains fewer prescriptive requirements (*e.g.*, design basis limits).

Issue 2: Should the proposed, or alternate, requirements for changes, tests, and experiments at § 63.44 apply to the contents of the entire license application?

Comment. Some commenters felt that the requirements at § 63.44 should apply to the contents of the entire license application to ensure that the license application is maintained as a current reference document for describing activities at the geologic repository. Not all commenters agreed,

however, as some asserted that the proposed requirements should not apply to certain types of information that were unlikely to change (*e.g.*, General Information) or that which is already subject to control under separate NRC requirements incorporated by reference in part 63 (*e.g.*, parts 72, 73, and 74).

Response. The Commission intends to apply these criteria to the contents of the Safety Analysis Report (as updated). As the Commission noted in the Supplementary Information provided with the proposed regulations, the purpose of the criteria for changes, tests, and experiments is to ensure that the level of safety documented in the original licensing basis (*i.e.*, the Safety Analysis Report) is not eroded by subsequent modifications to the facility or operating procedures. Changes to other portions of the license application, provided under § 63.21(b), that have the potential to affect safety, *i.e.* the physical protection plan, the safeguards contingency plan, the security organization personnel training and qualification plan, along with the material control and accounting plan, are already subject to update and change control requirements elsewhere in NRC regulation (at parts 72, 73, and 74). Furthermore, as discussed earlier (under Quality Assurance), the Commission is adding additional requirements so that changes to DOE's QA program will be subject to explicit requirements at § 63.144.

Issue 3: Should specific modifications be made to the rule to exclude from reconsideration issues that have no bearing on public health and safety and to constrain NRC backfitting of the repository design after construction is authorized or imposition of additional tests under § 63.74?

Comment. One commenter recommended that once an issue is considered resolved for the purposes of the issuance of a license to commence with waste emplacement operations, license to amend for permanent closure, or license termination, it should not be subject to reevaluation by the Commission (and the ASLB) unless it can be demonstrated that the issue has a bearing on public health and safety, common defense and security, or the environment. To implement this proposal, alternative regulatory language was recommended to §§ 63.41, 63.51, and 63.52.

Consistent with other NRC regulations, the Commission should include provisions for backfitting of the repository design as well as any additional tests required under § 63.74. Specific regulatory language was recommended, and it was suggested that these new additional requirements would apply only following the issuance of a construction authorization. The commenter asserted that backfits should only be allowed under two conditions: (1) Where there would be a substantial increase in public health and safety; and (2) where the direct and indirect costs of the backfit are justified in view of this increased protection. In proposing backfits, the commenter recommended that the Commission first perform analyses that are systematic and documented.

DOE commented that regulatory changes may be needed to ensure that issues closed at the construction authorization stage would not be reopened at the receipt and possession stage absent significant new safety related information. DOE felt that such a change would allow NRC and DOE to keep their focus on the unresolved issues important to public health and safety. DOE understands that this change would need to be addressed in a subsequent rulemaking on the licensing process.

Response. The Commission agrees that the focus of a risk-informed, performance-based regulatory approach should be on those issues bearing on public health and safety, common defense and security, and protection of the environment. Clearly, the recently-adopted, generic approach (adapted in this rule for the repository) for defining a threshold of safety significance for changes, tests, and experiments, illustrates NRC's desire to confine its regulatory attention and resources to issues bearing on its regulatory responsibilities. That being said, however, the issue of imposing backfitting constraints on the Commission itself, as it proceeds to evaluate the license application for a proposed repository at Yucca Mountain, was not evaluated in developing the proposed part 63 criteria, and is therefore beyond the scope of this rulemaking.

Issue 4: How will DOE document its decision making as new information is obtained for the site?

Comment. No specifics are given regarding how the rule could be modified to address this concern. However, commenters suggested that in light of a proposed regulation that is performance-based, there is the potential for DOE's decision making related to safety issues to become less than transparent. The view expressed in this comment is that there needs to be transparency in safety-related decision making in order to have accountability for engineering and scientific decisions.

Response. The Commission agrees with the comment with regard to the importance of transparency and accountability of all safety significant decisions made in developing and licensing a geologic repository. It is for this very reason that part 63 includes extensive provisions for documenting new information and updating the SAR, in order to ensure that the technical bases for the Commission's licensing decisions are not eroded (§§ 63.22, 63.24, 63.32, 63.44, 63.46, and 63.51). In addition, part 63 also provides for the implementation of performance confirmation and quality assurance programs (subparts F and G), that help ensure the soundness of the data, assumptions, and modeling upon which DOE bases its safety case, and upon which the Commission bases its licensing judgments.

4.3 Land Ownership and Control

Issue 1: Must the U. S. Department of Energy (DOE) establish its ownership, title, or control of the Yucca Mountain site?

Comment. A number of commenters stated that under the Treaty of Ruby Valley of 1863, the Western Shoshone Nation never ceded the Yucca Mountain site to the United States and that title to the land therefore remains with the Western Shoshone Nation. These commenters further argue that all activities conducted by the United States at the Yucca Mountain site that are not within the specific privileges granted the United States under the Treaty of Ruby Valley constitute an illegal occupation of Western Shoshone territory and a violation of Western Shoshone sovereignty.

Response. 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 GROA 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.

Issue 2: Does siting a waste repository at Yucca Mountain unfairly impose undue risks on the Western Shoshone People or adversely affect their culture?

Comment. Commenters believed that the Western Shoshone People were being unfairly asked to accept the risks of a waste repository while the benefits

went to the waste generators. One commenter believed that the Western Shoshone culture was being transformed from one of protecting the environment to one of being a steward of HLW.

Response. The Nuclear Waste Policy Amendments Act of 1987 (NWPAA), authorizes only Yucca Mountain, Nevada, as a location to be characterized as a potential repository site. Part 63 does not site the repository at Yucca Mountain. Rather, it provides criteria and regulations to provide reasonable assurance that public health and safety will be protected if a repository is constructed at this site. DOE and the President of the United States are responsible for making a site recommendation. If the Yucca Mountain site is recommended and Congress allows the recommendation to take effect, DOE is to file a license application accompanied by an EIS. To the extent practicable, the NRC will adopt DOE's EIS in accordance with the NWPA. In its licensing proceeding, the NRC will consider the costs and benefits of authorizing construction of a repository.

Issue 3: Should proposed § 63.121 be revised to require that DOE conform to State water law and to acknowledge the responsibilities of the Federal Government for compensation when initiating takings?

Comment. Commenters were concerned about whether DOE must conform to State water law to obtain water rights (one commenter indicated DOE is required, under State water law, to show beneficial use in order to obtain water). A commenter viewed § 63.121 as giving DOE the right to take water rights in order to achieve waste isolation and stated that the rule must acknowledge the responsibilities of the Federal Government for compensation when initiating takings.

Response. Section 63.121(c)(1) requires DOE to obtain such water rights as may be needed to accomplish the purpose of the GROA. The "purpose of the geologic repository operations area" is intended to be construed broadly to include the isolation of radioactive wastes after permanent closure as well as any water rights needed during the period of operations. Whether DOE is subject to State law in obtaining any water rights that may be needed for this purpose is a matter to be determined by DOE and the State. The NRC does not have the authority to require that DOE conform to State law.

Comment. One commenter suggested that § 63.121(b) directly state that additional controls include water rights, instead of specifying in § 63.121(c)(2) that water rights are included in the additional controls to be established under § 63.121(b).

Response. The Commission prefers to retain the present format for clarity because water rights would be dealt with explicitly in one paragraph of § 63.121. "Controls" referred to in § 63.121(b) would, of course, include water rights.

Comment. One commenter viewed § 63.121 as giving DOE the right to take water rights in order to achieve waste isolation and stated that the rule must acknowledge the responsibilities of the Federal Government for compensation when initiating takings. This commenter was also concerned that the rule permits the spread of radionuclides to areas far outside the boundaries of the repository and believes that the repository should be designed so that it is not necessary to take water rights to achieve waste isolation. Another commenter believed that this regulation would allow Yucca Mountain to operate as a delayed radioactive waste release facility and not a permanent disposal site.

Response. Section 63.121 does not give DOE the right to take water rights; rather, it requires DOE to have obtained any water rights needed to achieve waste isolation. DOE will need to comply with whatever laws apply with respect to obtaining any needed water rights. The purpose of the regulation is to make sure that DOE is in a position to establish appropriate controls outside of the site necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve waste isolation. The NRC will not license the facility unless there is reasonable expectation that releases of radioactivity will remain within regulatory limits.

Issue 4: Do requirements for land ownership and control of the site apply equally to repository operations (preclosure) and long-term safety (postclosure) activities?

Comment. DOE commented that requirements for land ownership and control (§ 63.121) are not sufficiently clear regarding their applicability to preclosure and postclosure activities. The lack of a clear distinction between preclosure and postclosure activities could imply that DOE must designate the same area for the evaluation of design basis events and for postclosure considerations for preventing adverse human actions. Part 60 provided flexibility in designating areas under preclosure and postclosure activities that should be retained in Part 63.

Response. The Commission agrees with DOE that land ownership and control requirements are not sufficiently clear regarding their application to preclosure and postclosure activities. The requirements have been clarified to indicate that: (1) The GROA shall 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; (2) DOE has the flexibility to identify and establish additional controls for lands outside the GROA necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation (postclosure); and (3) DOE has the flexibility to identify and establish additional controls for lands outside the GROA to ensure the requirements at § 63.111(a) and (b) are met. These clarifications have been made in revisions to § 63.121 of the final rule.

5 *Selected Topics*

5.1 *Public Out-Reach*

Issue 1: What role do the public meetings serve in the rulemaking process?

Comment. Commenters questioned the use of the public meetings and were concerned about how the meeting record would be used in NRC's rulemaking process. Many commenters appreciated the efforts the NRC made to include the public in the promulgation of part 63. Based on listening to NRC staff presentations made at a public meeting, it appeared to some commenters that the objective was to convince the local populations about the safety of the Yucca Mountain Project and that NRC regulations will protect public health. Some commenters requested that sufficient time be given for the public to provide comments. One commenter asked if the dose limits would be lowered if public opinion favored a lower value.

Response. The purpose of the public meetings was to enhance the opportunity for the public to participate in NRC's rulemaking process. The public had an opportunity to question the NRC staff about the proposed rule and its decision making leading to it, as well as having the opportunity to express their views on the rule itself. To facilitate public interactions in this process, additional time was afforded to the public to comment on the proposed rule. Transcripts of the various public meetings were made as a way of accurately recording the public's views. These transcripts were later studied by the NRC staff so that the public's comments could be identified and responded to in this document. The Commission carefully considered the

issues raised by members of the public at the transcribed meetings, as well as the NRC staff's summary of written comments received, as part of its deliberations on the final form and content of part 63.

With regard to whether NRC would consider lowering the dose limits if public opinion favored it, the Commission has given serious consideration to the views of the public on this matter, and, consistent with its obligations under law, has adopted the dose limits published by EPA in its standards for Yucca Mountain.

Issue 2: Will there be more public meetings?

Comment. Commenters stated that it would be helpful for NRC to consider increasing its efforts in the area of public outreach and commit to holding more public meetings in the future. Another commenter suggested that the NRC program focus should be on public health and safety and not on political issues associated with the HLW program.

Response. The Commission agrees with the recommendation to increase its efforts in the area of public outreach. The NRC staff will continue to hold public meetings in Nevada. We continue to seek a better understanding of the views and concerns of the public on how we can best fulfill our independent regulatory responsibility to protect public health and safety.

As far as avoiding political issues associated with the Yucca Mountain site, the Commission notes that it has taken no position on the suitability of Yucca Mountain to host a potential geologic repository. That decision rests with DOE, with the subsequent approval of the President and Congress.

Issue 3: What is the role of NRC's local office in Nevada?

Comment. Some commenters asked if NRC had a local office in Nevada and if there was one, how could the public contact the staff there. One commenter suggested that the role of the local office be expanded to represent NRC in a manner more visible to the public.

Response. 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 subject to reexamination. Meanwhile, the public is encouraged to contact our staff at the onsite representative's office at: 1551 Hillshire Drive, Suite A, Las Vegas, Nevada 89137–1048, Telephone 702/794-[illegible]046.

Issue 4: Should AULGs and EPA be included in the regulations at part 63, subpart C, §§ 63.61–63.65, providing for participation in certain NRC regulatory activities?

Comment. One local government commenter noted that, under the NWPAA, there is a legal basis for the participation of affected units of local government (AULGs) in activities concerning a potential repository at the Yucca Mountain site and asked why AULGs have not been included in § 63.61 and subsequent sections dealing with participation in regulatory activities. Another local government commenter explicitly requested that AULGs be included in the requirement for provision of "timely and complete information" in § 63.61. EPA also requested that it be included in § 63.61(a) given its interest in the proper implementation of the standards.

Response. Section 116(c) of the NWPAA directs DOE to provide funding to AULGs so that they may participate in activities required or authorized under sections 116 and 117 of the NWPAA. Although these activities primarily involve DOE's interactions with the State, affected Indian tribes, and AULGs, the Commission believes that it would not be inconsistent with the intent of the statute to include AULGs at appropriate points in the regulations under part 63, subpart C, and has revised the regulations accordingly. The Commission is not adding EPA to § 63.61(a) because this provision is consistent with section 117(a)(1) of the NWPAA which does not include EPA. However, the information provided under § 63.61(a) is available to EPA.

Issue 5: Should the "unquestionable legal right to participate as a party" in a repository licensing hearing afforded to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a) also include affected units of local government (AULGs)?

Comment. A local government commenter stated that AULGs should have the same "unquestionable legal right to participate as a party" in a repository licensing hearing as is provided to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a).

Response. The Commission agrees. The hearing procedures in the current 10 CFR part 2, subpart J, have replaced the hearing procedures in 10 CFR part 2, subpart G (except for sections of subpart G specifically referenced in § 2.1000) with respect to a repository licensing proceeding. Under the subpart J rules for intervention in the licensing proceeding, AULGs are permitted to intervene as a matter of right (*see* 54 FR 14938; April 14,1989) in the same way as the State and an affected Indian Tribe. Thus, the Commission, in the final rule, has corrected the reference to "Subpart G" in the first sentence of § 63.63(a) to read "Subpart J" and has clarified the reference to local governments by changing it to "affected units of local government." The Commission deleted the final sentence because it does not add any right not provided by the first sentence.

The proposed § 63.63(a) states: "State and local governments and affected Indian Tribes may participate in license reviews as provided in subpart G of part 2 of this chapter. The State of Nevada and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings." This provision is modeled on, and virtually identical to, § 60.63(a). Section 60.63(a) was incorporated into NRC regulations prior to the Commission's adoption of 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" (subpart J) (54 FR 14925; April 14, 1989). Section 2.1014(c) of subpart J permits intervention of AULGs in a repository licensing proceeding without the need to establish "party" status:

> "Subject to paragraph (a)(3) of this section, the Commission, or the Presiding Officer designated to rule on petitions to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by an affected unit of local government as defined in section 2(31) of the Nuclear Waste Policy Act of 1982, as amended, 42 U.S. 10101." [§ 2.1014(c) (1999)]

See also the definition of "party" in § 2.1001 which, as amended in 1998 (63 FR 71729; December 30, 1998), defines a "party" to mean the DOE, the NRC staff, the host State, any AULG as defined in section 2 of the NWPA, any affected Indian Tribe as defined in section 2 of the NWPA, and a person admitted under the criteria in § 2.1014. These regulations relieve the State, affected Indian Tribes, and AULGs from the need to meet the standing requirements in order to be admitted as a party in the proceeding. The State, an affected Indian Tribe, and an AULG

must still submit contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii), and at least one contention must satisfy these requirements, or the State, affected Indian Tribe, or AULG shall not be permitted to participate as a party (§ 2.1014(a)(3) (1999)).

All the above is in the context of the existing hearing procedures in part 2. The Commission recently proposed revisions to part 2 (66 FR 19610; April 16, 2001). Even under the proposed revisions, however, a "party" in a subpart J proceeding continues to be defined as including the host State, any affected unit of local government and any affected Indian Tribe, provided that these entities file an acceptable contention. Thus, the Commission has not proposed any change to the ability of an affected unit of local government to participate as a party without the need to meet standing requirements.

Issue 6: What is the NRC's current approach to explaining the risks associated with the Yucca Mountain Project?

Comment. A commenter was concerned with how the NRC explains the risks associated with the Yucca Mountain Repository. The commenter stated that NRC bases its explanation of risk-informed regulation on comparison to other types of risks, such as exposure from other types of hazards or background levels of radiation. This commenter suggested that this relative risk explanation is not helpful or persuasive, and that the NRC should design a project that does not result in radioactive exposures. Other commenters complained that many of NRC's public documents, and the proposed rule in particular, are not written in language understandable to the public. For example, one commenter was confused about the intended meaning of "individuals with unusual habits and sensitivities."

Response. The Commission has the responsibility to establish disposal criteria that DOE must meet, consistent with the applicable environmental standards promulgated by EPA. As part of this responsibility, the Commission must explain the level of protection its regulations and regulatory programs provide. For its part, DOE, as the repository developer, is obliged to site and design the repository such that DOE can demonstrate, consistent with NRC regulations, that the proposed repository will perform as intended. In reaching any licensing decision, the Commission will need to perform an independent audit of DOE's analyses that show how DOE has complied with the established levels of protection, based on its independent review of DOE's license application and other confirmatory information and activities.

The NRC staff will continue to provide information to explain the risks that would be associated with a repository licensed in accord with its regulations by using a variety of comparisons. The potential health effects arising from any radiation exposure is a very complex subject. To provide a context for NRC's proposed criterion of 0.25 mSv/yr (25 mrem/yr) or EPA's final limit of 0.15 mSv/yr (15 mrem/yr) individual dose limit for Yucca Mountain, NRC staff members frequently draw comparisons with other dose limits applied in NRC's regulation for low-level waste disposal (part 61) as well as with national and international recommendations for radiation standards (see discussion under Individual dose limit). To provide some context for understanding what a radiation exposure at these levels represents, comparisons have been made to the values for more "routine" radiation exposures (*e.g.*, dental x-rays, increased radiation exposure from traveling in a plane). These comparisons are used to inform the public, not to persuade them.

With respect to the meaning of the term "individuals with unusual habits and sensitivities," the Commission believes the commenter refers to the findings and recommendations of NAS. Both these recommendations and final EPA standards require that DOE base the characteristics of the representative group for postclosure dose calculations (the community in which the RMEI resides) on lifestyles and dietary habits (*i.e.*, reliance on well water, extent to which food is grown locally, types of foodstuffs eaten) of individuals currently living in the Yucca Mountain region. NAS explained that specification of the representative group should avoid extreme cases defined by unreasonable assumptions regarding the factors affecting dose. NAS also stated that a reasonable and practicable objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with "unusual habits or sensitivities" (pp. 51–52, "Technical Bases for Yucca Mountain Standard," National Research Council, 1995). Hence, the terms "unusual habits" and "sensitivities" were used to exclude unreasonable assumptions about the characteristics of a hypothetical, future population group or RMEI. The NAS did not use these words to imply any judgment with regard to the behaviors or mental state of individuals residing near the site today. The Commission will continue to strive to explain more clearly the risks associated with the potential repository at Yucca Mountain.

Issue 7: In the future, how is the NRC going to effectively communicate the risks of the Yucca Mountain Project to public health and safety?

Comment. One commenter requested one-on-one contact answering calls and letters and following through with questions and sending written responses. Another commenter was concerned that the people of Nevada are not suitably informed about the risks involved with the Yucca Mountain Project. Also, one commenter suggested that a bulletin be published quarterly or as an insert to a local paper about the Yucca Mountain Project. A few commenters were concerned that their fears are considered "irrational" regarding the safety of the Yucca Mountain Project and will not be taken seriously.

Commenters suggested that NRC use "local" sources (*e.g.*, local government and libraries) to provide information to the public regarding meetings and other information. Information should be written in plain English.

Response. The NRC understands the importance of a strong public outreach program. NRC held five public meetings in Nevada during the public comment period on proposed part 63. Comments made at those meetings were instrumental in NRC deciding to extend the public comment period for the proposed rule. However, these meetings also demonstrated to NRC that it can improve its public outreach efforts. The NRC has held seven additional public information workshops in Nevada since the public comment period closed on part 63. We will continue to meet with the people of Nevada and continue to seek the public's views on how we can carry out our responsibilities in a more effective manner. We also intend to keep the public better informed about our independent regulatory activities and oversight. The NRC will also continue to work on providing displays and fact sheets that use plain English.

The Commission notes also that DOE maintains three visitor centers that are intended to keep the public informed. They are located in Beatty, Pahrump, and Las Vegas. DOE also sponsors regular field trips to the Yucca Mountain site. DOE maintains an Internet web page with information that is regularly updated on activities at the site and developments in the program; it can be found at *http://www.ymp.gov*. With regard to the comments proposing that activities and future events be

published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. The State of Nevada, Nye County, Clark County, Eureka County, Inyo County, California, and others also maintain web sites with information about the Yucca Mountain program. They are located, respectively, at *http://www.state.nv.us/nucwaste, http://www.nyecounty.com, http://www.co.clark.nv/us/complan/Nucwaste.htm, http://Yuccamountain.org* and *http://sdsc.edu/Inyo/yucca-pg.htm.*

Finally, the Commission notes that the NRC staff has maintained a schedule of meetings with DOE on its Web page (*http://www.nrc.gov/nmss/dwm/hlw/htm*) for several years. Important NRC documents related to the HLW program also are distributed to DOE, the State, Affected Units of Local Government, and other stakeholders. Since November 1, 1999, NRC has made HLW program documents generated and received available on its Public Electronic Reading Room located at *http://www.nrc.gov/NRC/ADAMS/index.html.* Documents generated prior to November 1, 1999, can currently be found at the two designated library reading rooms (in Nevada): James R. Dickinson Library, Government Publications Department, University of Nevada at Las Vegas, 4505 Maryland Parkway, Las Vegas, NV 89154, (702) 895–1572 and Business and Government Information Center, University of Nevada Library, University of Nevada, Reno, Reno, NV 89557–0044, (702) 784–6500 ext. 257.

Issue 8: How do the NRC and DOE, both as government agencies, maintain a proper relationship, respectively, as the regulator and a potential licensee?

Comment. One commenter was concerned that constant care needs to be taken by both NRC and DOE to maintain a relationship that clearly delineates between the regulator and the licensee.

Response. The interactions of the NRC staff and the DOE staff with respect to all activities preparatory to DOE's submission of a license application are governed by the "Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions," which was initially signed in 1983 and was revised in 1998, and by the NRC Staff's Policy Statement on Staff Meetings Open to the Public (65 FR 56964; September 20, 2000). These documents provide that meetings between the two staffs will be open to the public as specified in the Policy Statement and that management commitments will be documented in correspondence subsequent to the interactions. Thus, procedures are in place to ensure an appropriate open relationship between the potential regulator and the potential licensee.

Issue 9: Should different DOE organizations active in Nevada be required to better coordinate their activities and responses to questions from the public?

Comment. One commenter noted that the different DOE organizations operating within Yucca Mountain and the NTS need better coordination because the different organizations sometimes provide different answers to the same questions.

Response. The Commission is sensitive to the concern raised here, but this comment is beyond the scope of this particular rulemaking. This issue falls within DOE's purview as the overall operator of NTS and thus should be directed to it.

The Commission needs reliable information from DOE on its activities at Yucca Mountain in order to perform its independent regulatory role in the HLW program. DOE will be required to provide complete and accurate information for NRC's licensing decision. The Commission believes that the NRC licensing process for the repository will provide an adequate means to test the accuracy and reliability of the information submitted for licensing.

Issue 10: Where will the DOE license application be available for inspection by the public?

Comment. One commenter noted that the proposed rule (§ 63.22) stated that copies of the DOE license application will be made available for inspection by the public at "appropriate locations" near Yucca Mountain and inquired as to where these locations would be and how they would be determined.

Response. The determination as to what is an "appropriate location" has not been made at this time. In all likelihood, such a determination will be made in consultation with the State of Nevada and AULGs. Moreover, for those individuals who have access to the Internet, any potential DOE license application will also be available electronically for inspection on the NRC and DOE web pages.

Issue 11: Who is responsible for oversight and review of DOE's QA program?

Comment. The Western Shoshone Nation objected to DOE undertaking a QA program without strict oversight and review by the Western Shoshone Nation.

Response. NRC has the statutory responsibility for oversight and review of DOE's QA program for the proposed repository at Yucca Mountain. NRC cannot relinquish this authority to other groups or individuals. However, the Commission is interested in keeping the stakeholders informed of the results of the inspection process, including NRC's inspection of DOE's QA program. The Commission is interested in approaches for keeping the stakeholders informed and is interested in hearing from the stakeholders regarding their ideas for potential approaches.

5.2 Other Comments

Issue 1: Can the NWPA-mandated limit of 70,000 metric ton equivalent of uranium (MTU) for the proposed geologic repository at Yucca Mountain be exceeded?

Comment. Several comments were received in this area. Some commenters raised the possibility of the mass loading at the repository increasing from 70,000 MTU to 105,000 MTU. One commenter is concerned that such an increase may be approved by a Congressional action, without a scientifically-based recharacterization of the site. It appears that this comment was prompted as a result of published interviews with DOE officials quoted in June 1999 (in the Las Vegas Sun) that up to 105,000 MTU of waste may be destined for the repository. The comment concerns the effect of heat on the local geosphere given this alternative (higher) volume of waste.

Similarly, other commenters noted that a DOE report was published, which stated that there would likely be two repositories, and that the amount of waste emplaced in both would be a total of 126,000 metric tons plus 14,000 metric tons of defense waste.

Recognizing the potential need for additional repository disposal capacity, NEI suggested that the reference in § 63.42(d) (Conditions of License), to the NWPAA-mandated limit of 70,000 MTU for the proposed geologic repository at Yucca Mountain, should be deleted, and just refer to NWPA, as amended. This design limit is currently specified in legislation for the HLW program. If the legislation were to change, it would precipitate a need for an additional Yucca Mountain-specific rulemaking. By simply referring to NWPA, as amended, the need for a future rulemaking would be obviated if the legislation ever changes.

Response. The 70,000 MTU limit for the proposed geologic repository at Yucca Mountain is mandated by NWPAA. Specifically, NWPAA provides that no more than 70,000 MTU

can be placed in the first geologic repository. Whether the statutorily-imposed limit should be changed is an issue for Congress and the President to decide. Regardless of the limit, DOE must demonstrate in its license application that the types, kinds, and amounts of HLW to be disposed in any potential geologic repository at Yucca Mountain can be disposed in a way that ensures public health and safety. The Commission does agree that referencing the NWPA, as amended, is more appropriate than NRC providing the specific value of 70,000 MTU. The proposed rule has been revised accordingly.

Issue 2: Should there be specific requirements for postclosure monitoring of ground water?

Comment. Local ground water supplies the domestic and agricultural water needs for area residents and, therefore, needs to be part of a DOE postclosure monitoring program. The most likely exposure scenario to radionuclides released from a potential geologic repository at Yucca Mountain would be in the ground water, down-gradient from the site. Because of this potential hazard, some commenters expressed the view that there is a need for the NRC to require that DOE implement a postclosure ground-water monitoring system. It was noted that such a system would protect citizens living near the repository by providing early warning of the presence of radionuclides in the ground water.

Response. Consistent with the EnPA, § 63.51(a)(3)(iii) requires a program for continued oversight of the repository site after permanent closure. One objective of the oversight program is to ensure that exposure to individual members of the public does not exceed allowable limits. Because the ground-water pathway is the most likely exposure pathway, it is expected that ground water would be monitored.

Issue 3: Would local residents be compensated if radioactive contamination, due to transport of HLW to Yucca Mountain or to leakage from the repository, damages their health or property?

Comment. Several commenters were concerned about whether local residents would be able to obtain compensation if their health should be adversely affected by leaking of radiation from the repository or from casks being transported to the repository. They were also concerned about whether damage to land or ground water due to radioactive contamination or to the lowering of property values would be compensated.

Response. 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.

Issue 4: Over what time period must physical security be maintained over the site and how would this be maintained?

Comment. Some comments were made regarding how security would be maintained over the site for very long time periods. One commenter asked if the site would be safeguarded against sabotage.

Response. NRC's regulation requires that DOE will have a system of active institutional controls and (passive) site markers, specified at § 63.21(c)(18) (§ 63.21(c)(15) in the proposed rule) and § 63.51(a)(3), that will prevent human intrusion into the repository by ensuring physical security indefinitely following permanent closure of any potential geologic repository at Yucca Mountain. That being said, by its very nature, geologic disposal is intended to provide a high degree of physical security by rendering the wastes difficult to access owing to their remote location deep underground (*i.e.*, about 300 meters/1000 feet). As a practical matter, once the repository is closed—*i.e.*, by sealing and possibly backfilling the underground drifts and access tunnels—the level of effort to reopen the repository and gain access to the wastes while preserving radiological safety will entail a substantial technical effort and expertise given current technology, and any action to do so would likely be detected.

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 § 63.21(b)(3) require that licensees have in place adequate physical security plans and attendant procedures to protect against radiological sabotage, consistent with § 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.

Issue 5: Terminology in the rule is not always as clear as it should be.

Comment. DOE indicated instances where particular words or phrases in Part 63 lacked clarity. The following specific changes to the proposed rule were suggested by DOE:

1. The phrase "* * * could adversely affect safety * * *," found at § 63.32(b)(3), should be replaced with "* * * could constitute a substantial safety hazard * * *" as defined in part 21 of this chapter. (The phrase "substantial safety hazard" is well defined in NRC's part 21 regulations; there is no need to introduce a new, undefined term such as "adversely impact safety".)

2. DOE indicated that the location of the compliance point could be misinterpreted and recommended that the rule use "the junction of U.S. Route 95 and Nevada Route 373" and delete "near Lathrop Wells, Nevada."

Response. The Commission inadvertently used two different phrases ("could adversely affect safety" [§ 63.32(b)(3)] and "[b]e a substantial safety hazard" (§ 63.73(a)(1))) when describing requirements for reporting deficiencies in proposed part 63. The Commission's intent was to specify a general level of concern (*i.e.*, could adversely affect safety) for deficiencies that would require reporting to the NRC as specified at §§ 63.32(b)(3) and 63.73(a)(1). Although the proposed rule used the phrase "substantial safety hazard" (§ 63.73(a)(1)), it was not the Commission's intent to imply the reporting requirements under § 63.73 were to be construed as the same as the part 21 requirements for reporting of defects. Accordingly, the Commission will clarify its intent by replacing "[b]e a substantial safety hazard" with "adversely affect safety at any future time," and identify specific events and conditions that require reporting by reference to § 72.75 at § 63.73(c).

The location of the RMEI, for purposes demonstrating compliance with the postclosure performance objectives, is in the accessible environment above the highest concentration of radionuclides in the plume of contamination. EPA standards for Yucca Mountain define "accessible environment" as any point outside of the "controlled area." To be consistent with EPA's standards, the Commission has incorporated EPA's definitions of "accessible environment" and "controlled area", as specified at 40 CFR 197.12, into subpart L of part 63.

Issue 6: Address the technical skills of the NRC staff to regulate a potential geologic repository at Yucca Mountain Project.

Comment. During the June 15, 1999, public meeting in Amargosa Valley, Nevada, one individual questioned the NRC staff's understanding of the fundamentals of the Yucca Mountain Project. This individual questioned how the NRC can regulate such a highly technical process without having its own highly technical personnel on staff. Commenters asked if NRC had its own experts or if NRC had to rely solely on information collected and developed by DOE. Although this comment is beyond the scope of the rulemaking, it questions the core technical expertise of the NRC staff to promulgate and implement this rule.

Response. The NRC (and its predecessor agency, the Atomic Energy Commission) has been regulating civilian uses of radioactive materials for nearly five decades. With increased awareness in the area of radioactive waste management, beginning in the late 1970s, the Commission's regulatory purview was expanded to include the disposal of HLW. As a complement to the existing NRC staff expertise in regulating nuclear activities and facilities, the Commission recruited and maintained a core staff with scientific expertise in those areas generally recognized to be important to radioactive waste management—the earth sciences, applied mathematics, geotechnical and materials engineering, and health physics. In the late 1980s, the Commission created a federally-funded research and development center, the CNWRA, to provide dedicated, conflict-of-interest-free technical assistance as a further complement to its scientific expertise.

In order to maintain an independent technical capability of the highest order, the NRC staff and its technical assistance consultants have been engaged over the years in scientific investigations and research necessary to understand how to properly regulate the management of radioactive wastes. The results of these efforts are widely published in the technical literature. In addition to these efforts, when there is a common interest, the NRC staff and its technical assistance consultants monitor or engage in international activities related to the regulation of radioactive wastes or the advancement of technical capability in radioactive waste management. To oversee these activities, the Commission's ACNW makes recommendations, when appropriate, to adjust or expand the technical capabilities needed by its staff.

In summary, the Commission believes that the qualifications and knowledge of the NRC staff and its technical assistance consultants with respect to the important technical aspects of the Yucca Mountain Project provide them with the credentials, skills, and state-of-the-art knowledge that are necessary and appropriate to ensure that NRC regulatory decisions with respect to public health and safety are made with the highest degree of scientific competence.

Issue 7: Does Yucca Mountain fail to comply with one of the [technical] criteria in the existing (Part 60) rule?

Comment. A commenter noted that it appears from DOE analyses that the Yucca Mountain site does not comply with one of the specific criteria in the existing rule, not the proposed new rule.

Response. DOE has not submitted an analysis to NRC for review that would fit the description of this comment. In addition, this final rule amends 10 CFR 60.1 to clearly state that Part 63, not Part 60, applies to licensing a disposal facility at Yucca Mountain, Nevada.

Issue 8: How should the material control and accounting program balance the need for inspections with worker exposures?

Comment. One commenter suggested that the program for maintaining material control and accounting should balance the need for periodic inspections with the potential for increased exposures of the inspectors. It was recommended that DOE and NRC should agree on how and when to terminate material control and accounting surveillance.

Response. The Commission agrees with the comment that workers should be protected from unnecessary doses due to repository operations. Although the requirement for conducting a physical inventory of HLW (reference to § 72.72 at § 63.78) extends over the operational period of the repository, the regulations provide flexibility to the Commission in determining the frequency for conducting the physical inventories. Determination of an appropriate frequency for conducting the inventories will consider such things as DOE's proposal for the material control and accounting program, the requirements for material control and accounting, and safety of inspectors. It is anticipated that the frequency for conducting inventories could vary due to significant changes in operations (*i.e.*, emplacement versus post-emplacement activities) over the long operational period (*e.g.*, 100 years) for the repository. The Commission considers a decision on how and when to terminate material control and accounting to be unnecessary and premature. The regulations provide the necessary flexibility for the Commission to determine how and when to terminate the material control and accounting that would consider the important issue raised by the commenter.

Issue 9: All references to "* * * decontamination or dismantlement * * *" of geologic repository facilities in the proposed rule (*e.g.*, § 63.21) should be revised to refer to "* * * decontamination or decontamination and dismantlement * * *" to avoid confusion about the need for decontamination.

Comment. EPA suggested that the reference to decontamination and dismantlement in the proposed rule needed clarification because the current language implies that facilities that needed dismantlement did not need to be decontaminated.

Response. The Commission agrees with this comment and has revised the proposed rule as suggested.

Issue 10: Should there be additional requirements for the content of the application?

Comment. One commenter recommended that the contents of the license application at § 63.21(c)(1)(iv) should also include information on the hydrology, geology, and climate at and near the chosen location for the critical group.

Response. In general, the Commission agrees with this comment to the extent that the Commission anticipates that it will need such information because it has a bearing on understanding the lifestyles and habits of the RMEI. However, in the Commission's view, the type of information suggested by the commenter is already included in the regulations at § 63.21(c)(1). Nonetheless, the Commission expects that this subject will be addressed in the YMRP, which describes the required contents and methods for the NRC staff review of any potential DOE construction authorization application, as well as DOE's compliance demonstration with the rule. At the appropriate time, the YMRP will be shared with interested stakeholders and published for public comment. Based on the public comments received, the staff will determine if additional revisions to the YMRP or regulations are necessary (*e.g.*, additional information to be included in the content of the application and a requirement for DOE to address all the issues in the YMRP).

Issue 11: Does the requirement for collecting information during construction (§ 63.72) take precedence over preservation of the design integrity?

Comment. It should be recognized that there is the possibility that the collection of certain types of data could

have a negative effect on the waste isolation capabilities of the site. The proposed requirements found in § 63.72 should be modified to recognize that data should be collected only when it is determined that the activities will have no adverse effect on the long-term performance of the repository.

Response. The Commission shares the commenter's concern that the collection of data could (potentially) have an adverse effect on the long-term performance of the repository. In this regard, it should be noted that the Commission is not in favor of any particular data collection techniques nor would it encourage data collection that could potentially affect the long-term performance of the repository or the effectiveness of its barriers be they natural or engineered. Nonetheless, during repository construction, DOE will need to collect data to confirm certain design (and performance) parameters as well as to identify previously undetected geologic conditions so as to have confidence that the repository will function as intended. To ensure that these activities have no effect on long-term repository performance, consistent with section 113(b)(1)(A)(ii) of the NWPAA, DOE will need to describe its data collection plans during construction in the manner described in § 63.72 so that their effect, if any, on containment and waste isolation can be independently evaluated by the NRC staff.

Issue 12: The reference to § 63.51(a)(2) (postclosure monitoring program) in §§ 63.71(b) (records and reports) and 63.72(a) (construction records) should be changed to refer to § 63.51(a)(3) (measures to regulate or prevent activities that could impair repository long-term performance).

Comment. Section 63.51(a)(3) refers to the description of the program for the postclosure monitoring program for the repository and not to record retention. The proposed requirements in §§ 63.71(b) and 63.72(a) also bear some relation to postclosure design, and this should be clarified in the rule.

Response. The commenter is correct, and the final rule contains the correct reference.

Issue 13: It is not clear how liquid HLW fits into DOE's disposal scenario.

Comment. From the definition of HLW found at § 63.2, it would appear that liquid HLW could also be disposed of at Yucca Mountain.

Response. Because of processing in the nuclear fuel cycle, some HLW can occur in the liquid (aqueous) state. However, this waste type is not expected to be disposed of at Yucca Mountain. Rather, liquid HLW will be vitrified—mixed with molten glass and solidified—to reduce the actual volume of waste and make it easier to handle. The definition of HLW found at § 63.2 was intended only to provide a technically correct definition of HLW in its various states. To provide further clarification, the definition has been revised to better reflect the language in the Nuclear Waste Policy Act of 1982 and final 40 CFR part 197, and continues to include the reference to irradiated reactor fuel consistent with the definition in the proposed rule.

Issue 14: Should climatological data be included for the update of the application and EIS?

Comment. EPA suggested that climatological data should be included in the types of data to be updated in the application and EIS [§ 63.24(b)(1)].

Response. The list of information to be updated at § 63.24(b)(1) includes meteorological data. Meteorological data are used as a general term indicating weather related information that would include information necessary to make inferences regarding climate. The addition of the word climatological is not needed; therefore, the language in proposed part 63 will be retained in final part 63.

6 Beyond the Scope of This Rulemaking

The following comments addressed issues that are beyond the scope of this rulemaking. Many of the comments in this category were directed at the hearing process, transportation, the selection of Yucca Mountain as a potential site for a geologic repository, or objected to deep geologic disposal as a method of managing HLW. Part 63 does not affect these issues because they already have been determined by legislation, are pertinent to other regulations or rulemakings but not to part 63, or because the provisions of part 63 are limited to specific regulatory areas while these issues are much broader.

6.1 Hearing Process

Issue: Will the Commission amend the hearing process for repository licensing to provide for informal, legislative-style hearings?

Comment. Some commenters, including EPA, urged NRC to change its hearing process to provide for informal, legislative-style hearings for repository licensing. One commenter suggested that the Commission itself be the hearing board. NEI expressed the view that a legislative-style hearing process is more conducive to effective scientific inquiry than formal adjudicatory procedures. NRC's decision on whether to adopt an informal process for repository licensing, in NEI's view, should not be tied to the generic question whether to revise the overall hearing process but, instead, should be the subject of a separate rulemaking. However, another commenter strongly opposed any suggestion to depart from formal trial-type adjudicatory and evidentiary hearing rules in 10 CFR part 2 for this potentially complex and first-of-a-kind licensing proceeding.

Response. In the proposed rule, the Commission told commenters that it had a broad study of the NRC hearing process underway, including the process that would be used for repository licensing. The Commission stated that it was inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste. If the Commission were to conclude that changes to the hearing process are warranted, the Commission stated that it would propose them for adoption in a separate notice and comment rulemaking. For that reason, the Commission did not seek comments on potential changes to the hearing process in this rulemaking. Subsequently, the Commission finished its study of the NRC hearing process and directed the staff to prepare a proposed rule to provide changes to that process. The proposed rule was published on April 16, 2001 (66 FR 19610) and the comment period closes on September 14, 2001 (extension of comment period, 66 FR 27045; May 16, 2001). In this recent notice, the Commission proposes to use formal hearing procedures in proceedings for the initial authorization to construct a geologic repository operations area and proceedings for initial authorization to receive and possess high-level waste at the repository. However, amendments to the construction authorization and to the authorization to receive and possess high-level waste may be conducted under informal hearing procedures. *See* proposed § 2.310(e). The Commission will make its final determinations on these issues in a final rule after it has considered all public comments received in this separate rulemaking.

6.2 Transportation

Issue 1: What regulations or controls will be used to ensure nuclear waste is transported safely including operations at an intermodal transfer facility?

Comment. Commenters raised concern that the risks for transporting nuclear waste were not being addressed in proposed part 63. Many commenters interpreted the absence of transportation criteria in proposed part 63 as an indication that NRC has deemphasized

transportation issues. One commenter raised concern over the possibility of terrorism and theft of spent fuel shipments.

Response. Nuclear waste transportation safety is not specifically addressed by the proposed part 63 because it is beyond the scope of this rulemaking. Issues related to terrorism or theft of spent fuel shipments during transport are also beyond the scope of this part 63 rulemaking. Nothing in this rule changes the existing regulatory regime governing the transportation of 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.

Section 180 of the NWPA requires DOE to use packages that have been certified by NRC for transportation of spent nuclear fuel and HLW. The NRC regulations in 10 CFR part 71 specify the standards for certification. These standards provide that a package must prevent the loss or dispersion of radioactive contents, provide adequate shielding and heat dissipation, and prevent nuclear criticality under both normal and accident conditions of transportation.

Section 180 of the NWPA also requires that DOE abide by NRC regulations regarding advance notification of State and local governments prior to transportation of spent nuclear fuel or high-level radioactive waste. These advance notification requirements are set forth in 10 CFR 73.37. The NWPA also requires DOE to provide funds and technical assistance for training of local public safety officials (*e.g.*, emergency responders) along the routes.

In Volume II of the Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High Level Radioactive Waste at Yucca Mountain, Nye County, Nevada, dated July 1999 (DEIS) (at J–23), DOE states that its proposed procedures for implementing Section 180 of the NWPA provide that routing for shipments to Yucca Mountain would comply with applicable regulations of the U.S. Department of Transportation (DOT) in effect at the time of such shipments. DOT regulations on route approval for transporting radioactive material by highway and State or Tribal designation of preferred routing [as an alternative to Interstate System highways] are contained in 49 CFR 397.101, 397.103, and 397.201.

A DOT–NRC Memorandum of Understanding (44 FR 38690; July 2, 1979) specifies that, in general, the DOT is responsible for regulating safety in transportation of all hazardous materials, including radioactive material. The NRC is responsible for regulating safety in receipt, possession, use, and transfer of radioactive materials. The NRC also reviews and approves package designs for transporting fissile material and other radioactive material in quantities exceeding Type A limits. Facilities which temporarily handle and store radioactive material during and incidental to their transport (*i.e.*, movement), such as operations at an intermodal transfer facility, are subject to DOT requirements.

Issue 2: How will transportation routes be selected and will local governments and communities be informed and consulted about the routes?

Comment. Commenters raised a number of questions regarding the selection of transportation routes for nuclear waste, such as: (1) Will DOE analyze the impacts of transportation routes; (2) Can rural roads be used to safely transport large nuclear waste shipments; (3) Will transportation route selection be addressed in DOE's license application; (4) Will local governments and communities be able to participate in route selection; and (5) Does NRC require DOE contractors to be responsible for transporting waste or are third-party contractors responsible for transporting waste.

Response. The routing requirements and practices largely depend upon whether a particular shipment is made by highway or railway. DOE is evaluating its options regarding the mix of road and rail shipments to the potential repository and will decide the appropriate level of analysis needed for transportation routes.

As noted, DOE has stated that routing of shipments of spent nuclear fuel and high-level waste will comply with applicable DOT regulations (DEIS, Vol. II, at J–23). The DEIS (Vol. I and Vol. II, Appendix J) also contains a discussion of the impacts associated with shipments to the proposed repository. The DOT regulations (49 CFR part 397) provide that shipments are to be on preferred routes (Interstate System highways and city bypasses) or State-or Tribal-designated preferred routes (i.e., alternate routes). These routing requirements were developed by the DOT considering the risks of transportation. Further, DOT has published guidelines (DOT/RSPA/HMS/92-[illegible]) for State or Tribal agencies to use [illegible] performing route analyses to ensure that the overall risk of the shipments to the public is considered in designating preferred routes. The degree of local participation in the State or Tribal routing agency's process may vary from State to State or from Tribe to Tribe.

NRC licensees, contractors of NRC licensees, DOE, and DOE contractors who are transporting spent fuel by highway must abide by the DOT's routing rules when they transport spent fuel by highway. There are no Federal regulations for selecting railway routing. Once a highway or railway route is selected, the route is reviewed by the NRC for physical protection purposes. NRC annually publishes a report, "Public Information Circular for Shipments of Irradiated Reactor Fuel" (NUREG–0725, Rev. 13, 1998), that describes the routes taken by commercial spent fuel shipments. For physical protection reasons, certain information on shipments is protected from general release until after the shipment (or series of shipments) is completed.

Issue 3: What criteria will be used to ensure the shipping cask can survive a variety of challenges during transportation?

Comment. Commenters inquired into how shipping casks were designed and who was responsible for manufacturing the casks. Additionally, one commenter asked whether the shipping cask design and testing consider specific accident scenarios, including sabotage.

Response. An application for a cask design is submitted to NRC by the cask vendor, and an approval certificate must be issued by NRC before a cask can be used to transport spent fuel. Typically, private firms manufacture a cask under contract to the cask's vendor. NRC requires that casks be designed, fabricated, used, and maintained under an NRC-approved QA plan. Activities under these plans are subject to NRC's inspection and enforcement programs. Safety standards, design criteria, and design test requirements for spent fuel casks are set forth in NRC regulations at 10 CFR part 71. Casks must be designed to withstand a series of impact, puncture, and fire environments, thereby providing reasonable assurance that packages will withstand serious transportation accidents. NRC regulations require that casks protect against the loss or dispersion of radioactive contents, provide adequate shielding and heat dissipation, and prevent nuclear criticality, under both incident-free and accident conditions of

transportation. NRC conducts an independent design review prior to issuing a cask certificate.

In the 1980's, NRC sponsored experiments and studies of the effects of sabotage on casks that meet NRC's safety standards. In addition, DOE has sponsored similar studies, most recently in 1999. The estimated performance of spent fuel casks during historically severe, actual accidents (viz., these severe accidents did not actually involve radioactive materials) was investigated as part of the NRC-sponsored study (*e.g.*, Fischer, L.E., *et. al.*, "Shipping Container Response to Severe Highway and Railway Accident Conditions," NUREG/CR–4829, 1987). NRC's studies show that risks are low, from both incident-free shipments of radioactive material and possible accidents during transport. Therefore, the Commission has found that approved cask designs provide an adequate level of protection of public health and safety.

Issue 4: Will dose estimates be calculated for exposures from transportation and operations at an intermodal transfer facility?

Comment. A commenter asked that dose estimates be calculated for exposures from transportation and operations at an intermodal transfer facility.

Response. NRC has estimated the radiation doses to the population as a result of transportation of radioactive material. These estimates are performed as part of environmental impact studies such as NUREG–0170 (1977), "Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes."

The specific operations that would occur at an intermodal transfer facility related to the repository have not been identified. Consequently, NRC is not aware of radiation dose estimates that have been performed for that facility. Furthermore, the NRC notes that DOT requirements govern radiation safety for facilities which temporarily handle and store radioactive material during and incidental to their transport (*i.e.*, movement), such as operations at an intermodal transfer facility.

6.3 Other Comments

Issue 1: Should nuclear waste be sent somewhere else/out of Nevada?

Comment. A number of commenters believed that nuclear waste should be sent somewhere else (other than Yucca Mountain), or out of Nevada. Yucca Mountain was viewed as unsafe. Commenters did not want a nuclear waste repository constructed there and strongly objected to disposal of radioactive waste there. An opposing view was expressed by other commenters who stated that Yucca Mountain was the best place for disposal of radioactive waste. One commenter just wanted the waste kept safe.

Response. The NWPAA authorizes characterization of only Yucca Mountain, Nevada, as a potential repository site. Part 63 does not select Yucca Mountain as a site for a potential repository. Part 63 is being promulgated to provide reasonable assurance that, if a repository is built and operated at Yucca Mountain, public health and safety will be protected.

Issue 2: Is there a better solution for managing nuclear waste than geologic disposal?

Comment. There were a number of comments focused on whether an alternative should be used for management of radioactive waste. Some commenters stated that the use of onsite storage (*i.e.*, at nuclear reactors) of nuclear waste should be pursued. This would avoid transportation risks and be a suitable interim method of managing nuclear waste until a safe long-term disposal method was found. However, one commenter stated that it was appropriate and safe to place the waste in one location. Newly emerging technologies, such as transmutation, were cited by some commenters as methods that could reduce the hazard of the waste. A commenter noted that the materials making up the waste could be used in the future; there were numerous applications. Comments were received opposing underground disposal of spent fuel rods as unsafe, and not the best answer for disposal, and that only cooled spent fuel rods, but no plutonium, should be stored at Yucca Mountain or the NTS.

Response. The decision about how to manage HLW and spent fuel does not result from part 63. Deep geologic disposal of HLW was authorized by the NWPA. The NWPAA and the EnPA continue the U.S. government policy of disposal of HLW in a geologic repository. Nothing in part 63 changes this method of managing HLW authorized by existing law. The regulations in part 63 are designed to provide reasonable assurance of protection of public health and safety from any radioactive material disposed of, including surplus weapons plutonium.

Issue 3: Who should manage the Yucca Mountain project?

Comment. Commenters suggested that the University of Nevada at Las Vegas should manage the Yucca Mountain project.

Response. The NWPA gives DOE the responsibility for management of the Yucca Mountain project. DOE must address how to carry out its responsibility for management of the Yucca Mountain project.

Issue 4: Should nuclear power be used?

Comment. A commenter opposed the use of nuclear power as wasteful and the source of dangerous long-lived radioactive products. Another commenter said that sources of energy other than fission should be investigated.

Response. Part 63 establishes requirements for disposal of HLW at a potential repository at Yucca Mountain. It does not encourage or restrict the use of nuclear power. The NRC is establishing part 63 in accordance with its statutory responsibilities under the Atomic Energy Act (AEA), the NWPAA, and the EnPA.

Issue 5: How much money has been spent on Yucca Mountain?

Comment. A commenter wanted to know how much money had been spent on the Yucca Mountain project.

Response. The DOE publishes reports that give details of its budget and spending on the Yucca Mountain project. Expenditures are the subject of appropriations by Congress and oversight by both Congress and the General Accounting Office. In May 2001, DOE published its most recent cost estimates [see "Analysis of the Total System Lifecycle Costs of the Civilian Radioactive Waste Management Program," DOE/RW–0533, May 2001; available on DOE's Web page at *http://www.rw.doe.gov*].

Issue 6: What happens if the Yucca Mountain project is developed and Congress cuts the budget for it? Or appoints a weaker agency to oversee the project?

Comment. A commenter noted that Congress had cut DOE's budget for Yucca Mountain in past years. What will NRC do, especially regarding monitoring, if construction of the project is underway, and a budget cut occurs?

Response. Responsibility for the Yucca Mountain project rests with DOE. Changes in budget levels for the Yucca Mountain project would have to be addressed by DOE in its planning for the project. If the Commission believes that it does not have sufficient funds to carry out its mission to protect public health and safety, it would ask Congress for additional funding.

Issue 7: Will the NRC staff seek input from local governments to assist it in providing comments to the DOE on the DEIS for Yucca Mountain?

Comment. One commenter asked the NRC to seek input from local governments to assist the NRC in providing comments on the DOE's DEIS.

Response. The NRC is expected, under the NWPA, to comment on the DEIS during the DEIS public comment period. The NRC provided comments for DOE to consider as part of the DEIS public comment process. In preparing these comments, the NRC staff observed DOE's DEIS public meetings to better understand what DEIS issues were of concern to the public. In addition, the NRC staff conducted its own meetings with AULG officials and conducted a public meeting in Caliente (Nevada) to discuss the NRC role with respect to the EIS, as it was formulating its comments. For its part, the Commission invited AULGs, stakeholders, and other interested parties to express their views on the DEIS during a public meeting on January 21, 2000. The Commission has considered these views before forwarding its comments to DOE.

Issue 8: Does the public have enough time to prepare comments on DOE's DEIS for Yucca Mountain and attend NRC meetings on part 63?

Comment. The NRC staff was asked at several public meetings to avoid scheduling future public workshops and meetings on part 63 during the DEIS public comment period.

Response. The Commission is sensitive to the issue being raised here and notes that the NRC is making every effort practical to schedule its public workshops and meetings in such a way so as to afford the public opportunity to participate in other agencies' activities. Accordingly, the Commission held only one meeting on part 63 during the public comment period on the DEIS.

Issue 9: What about the possibility that a waste repository at Yucca Mountain would be a target in the event of a nuclear war?

Comment. A commenter stated that the Air Force base and Hoover dam would be likely targets in the event of war. If a repository were developed at Yucca Mountain, that would also be a target.

Response. Consideration of the effects of wars and military actions is beyond the scope of NRC's responsibility. The NRC has not taken into account the effects of war in developing part 63.

Issue 10: Decisions regarding the licensing of a potential geologic repository at Yucca Mountain should be left to the voters to decide.

Comment. A commenter stated that important decisions, such as the potential geologic repository, should be placed on a nationwide ballot for the voters to decide.

Response. The NWPA and the EnPA establish the framework for licensing a potential geologic repository at Yucca Mountain. This legislation gives the NRC the responsibility for making a licensing decision on such a potential repository. Under this framework for licensing, there are opportunities for public input in the licensing process. The requirements promulgated here as part 63 do not make any change in public input opportunities already established.

Issue 11: How much radiation is being released from nuclear facilities?

Comment. Commenters wanted to know how much radiation was being released from nuclear facilities around the U.S. and what is being done to control those releases.

Response. The NRC's Annual Report—Reactors, NUREG–1272, Vol. 11, No.1, November 1998, gives annual exposures to the average person in the U.S. of less than 1 mrem (0.01 mSv) TEDE from the entire nuclear fuel cycle, including operation of reactors. All NRC licensees are required to limit radiation exposures from licensed activities in accordance with NRC regulations in 10 CFR part 20, 10 CFR part 50, Appendix I, and 10 CFR part 72.

Issue 12: Is radioactive material recycled into consumer products?

Comment. One commenter was concerned about potential exposure from radioactive material that has been recycled into consumer products.

Response. Part 63 is concerned only with disposal of HLW in a potential geologic repository at Yucca Mountain, Nevada. There are no provisions in this final rule that affect recycling of radioactive material into consumer products.

NRC is in the preliminary stages of examining its approach for controlling solid material. A paper that discusses issues associated with alternative courses of action was published in the **Federal Register** on June 30, 1999 (64 FR 35090). This issues paper is also available at NRC's web site.

Issue 13: Does NRC regulate the transportation of nuclear weapons?

Comment. One commenter inquired as to NRC's role in the transportation of nuclear weapons.

Response. The NRC does not have authority to regulate the transportation of nuclear weapons. The NRC's regulations for packaging and transportation of radioactive materials, 10 CFR part 71, do not apply to transportation of nuclear weapons.

IV. Changes from the Proposed Rule

Subpart A—General Provisions

Section 63.2 Definitions

Several terms have been deleted and definitions revised either to conform with the final EPA standard (40 CFR part 197) or to provide needed clarification. The terms annual dose and expected annual dose have been replaced by a single definition for TEDE (total effective dose equivalent) that provides for the use of organ weighting factors for assessing potential doses to members of the public. The term critical group has been deleted, and the term reasonably maximally exposed individual added and defined. The term design basis event has been deleted, and replaced with the terms event sequence and initiating event (the term design basis event has been replaced throughout the rule with event sequence). The term integrated safety analysis has been deleted, and replaced with the term preclosure safety analysis (the term integrated safety analysis has been replaced throughout the rule with preclosure safety analysis). The definition of performance confirmation has been revised to more clearly reflect the intent of the general requirements for performance confirmation at § 63.131(a). The definition of the engineered barrier system has been revised to include engineered components and systems other than the waste package (*e.g.*, drip shields). The definition of retrieval has been revised to clarify that retrieval means the act of "permanently" removing radioactive waste. The clarification to the definition of retrieval was done to differentiate it from operational activities (*e.g.*, DOE might intentionally remove one or several waste packages from its emplacement location and re-emplace them either at the same or a different location in the underground facility during the operational life of the repository as part of testing, demonstration, repair, maintenance or performance confirmation) that would not be considered as permanent retrieval. The definition for high-level waste has been modified to more closely reflect the definition provided in the Nuclear Waste Policy Act of 1982 and final 40 CFR part 197. The definition for the saturated zone has been revised to more accurately describe the intent of the definition. Other definitions have been modified in whole or in part to conform with the final 40 CFR part 197, including barriers, important to waste isolation, isolation, performance assessment, and reference biosphere. The definition for ground water has

been removed from this section because the definition for the same term provided in 40 CFR part 197 has been adopted into the regulations at § 63.302.

Section 63.4 Communications and Records

The section was revised to reflect the current address of the Commission.

Section 63.8 Information collection requirements: OMB approval

This section has been revised according to the current standard wording.

Section 63.10 Completeness and Accuracy of Information

The recipient of notification of information was changed from the Administrator of the appropriate Regional Office to the Director of the Office of Nuclear Material Safety and Safeguards.

Subpart B—Licenses

Section 63.16 Review of site Characterization Activities

Section 63.16(d) was clarified to specify that public comments would be sought on comments made by the Director of the Office of Nuclear Material Safety and Safeguards to DOE after the Director's comments had been sent to DOE. Section 63.16(d) essentially adopts 10 CFR 60.18(i) with the addition of performance assessment as a subject area for potential public comments. The Commission explained at the time it adopted § 60.18(i) that "(j)ust as the Commission will solicit comments on its comments on DOE's initial S(ite) C(haracterization) P(lan), it wants to allow for public comment on any Commission comments on DOE's semi-annual reports (or on any other comments which the Director makes to DOE on site characterization)" (51 FR 27161; July 30, 1986). Under § 60.18(f), the Director must publish in the **Federal Register** a notice of the availability of comments on DOE's Site Characterization Plan for public comment after the comments have been sent to DOE. Section 63.16(d) was clarified to reflect the Commission's intent that the timing of any public comment period remain the same as under § 60.18.

Section 63.21 Content of Application

Requirements associated with the description of the engineered barrier system, quality assurance program, physical protection, design criteria, and decontamination of surface facilities have been clarified. The requirements in this section have been regrouped in an order more consistent with the required analyses. The requirement for DOE to provide a comparative evaluation of alternatives to major design features has been removed. The level of information necessary to support each licensing stage has been clarified by stating the application must be as complete as possible in the light of information that is reasonably available at the time of docketing. The words "principal design criteria" have been replaced with "design criteria" to avoid any confusion with the meaning of the word "principal;" this was not intended as a substantive change. The design criteria to be described are those that relate to the preclosure and postclosure performance objectives. This provides DOE sufficient guidance as to which design criteria are to be provided. The reference to "ground water" at § 63.21(c)(10) was changed to "water" to maintain the intent of the proposed rule, which included both saturated and unsaturated zone water in the definition of ground water, and avoid conflict with the new definition for "ground water" in subpart L. Additional changes have been made to conform to the final 40 CFR part 197.

Section 63.31 Construction Authorization

This section was modified to reflect a finding of reasonable expectation for demonstration of compliance with the quantitative standards now specified in new Subpart L.

Section 63.41 Standards for Issuance of a License

Clarification has been made regarding decontamination of surface facilities.

Section 63.42 Conditions of License

Section 63.42(d) was modified to eliminate the specific reference to the NWPA limit of 70,000 MTU. Although this limit still applies, by simply referring to "* * * NWPA, as amended * * *," the need for a future rulemaking would be obviated if the legislation ever changes this disposal volume restriction.

Section 63.44 Changes, Tests, and Experiments

This section has been extensively revised in accordance with NRC-wide programmatic changes in this area.

Section 63.51 License Amendment for Permanent Closure

This section has been revised to specifically require that performance confirmation data pertinent to compliance with § 63.113 be included in the update of the performance assessment in the application for a license amendment for permanent closure.

Section 63.52 Termination of License

Clarification has been made regarding decontamination of surface facilities.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

Section 63.61 Provision for Information

This section has been changed to include the affected units of local government.

Section 63.62 Site Review

This section has been changed to include the affected units of local government.

Section 63.63 Participation in License Reviews

This section has been changed to correct the reference to "Subpart G" to read "Subpart J," and the reference to local governments has been clarified by changing it to "affected units of local government." The final sentence in proposed § 63.63(a) has been deleted.

Section 63.65 Representation

This section has been changed to include the affected units of local government.

Subpart D—Records, Reports, Tests, and Inspections

Section 63.71 Records and Reports

The record retention requirements referenced at § 63.71(b) were incorrect in the proposed rule and have been modified to refer correctly to § 63.51(a)(3).

Section 63.72 Construction Records

The record retention requirements referenced at § 63.72(a) were incorrect in the proposed rule and have been modified to refer correctly to § 63.51(a)(3). Additionally, the design specifications and "as built" drawings have been added to the list of required records.

Section 63.73 Reports of Deficiencies

The phrase "(b)e a substantial safety hazard," found at § 63.73(a)(1), was replaced with the phrase "(a)dversely affect safety at any future time," to be consistent with terminology used at § 63.32(b)(3) and to avoid confusion with reporting requirements under 10 CFR part 21, which includes a very precise definition for what constitutes a "substantial safety hazard." Specific requirements regarding DOE's implementation of a program for

evaluating and reporting deficiencies have been included to clarify the reporting requirements.

Subpart E—Technical Criteria

Section 63.101 Purpose and nature of findings

This section has been revised to address how the Commission intends to implement a finding of reasonable expectation. The discussion of postclosure performance objectives has been revised to conform with the public health and environmental radiation standards for geologic disposal now specified in Subpart L, which are referenced in § 63.113.

Section 63.102 Concepts

This section has been changed to clarify NRC's expectations for the demonstration of compliance with the requirements for multiple barriers, performance confirmation, and preclosure safety analysis. The discussion of multiple barriers has been modified to clarify the intent of the multiple barrier requirement. The discussion of preclosure safety analysis has been revised to clarify requirements for the dose calculations due to the event sequences and the selection of specific event sequences to be included in the analysis. The discussion of performance confirmation has been revised to more clearly reflect the intent of the general requirements for performance confirmation at § 63.131(a). Additional changes have been made to conform with the final 40 CFR part 197, including among others the discussion of the reference biosphere, reasonably maximally exposed individual, and human intrusion; and addition of a discussion on ground-water protection.

Section 63.111 Performance Objectives for the Geologic Repository Operations Area Through Permanent Closure

The performance objectives at § 63.111(b)(1) and (2) have been changed to clarify that (1) the doses from consequence analyses for Category 1 event sequences are to be aggregated to a single estimate and (2) the dose from the consequence analysis for each Category 2 event sequence is to be estimated for that specific event sequence only. Section 63.111(a)(2) has been modified to conform with the individual protection standard now specified in subpart K.

Section 63.112 Requirements for Preclosure Safety Analysis of the Geologic Repository Operations Area

This section has been revised to clarify that the objective of the analysis is to evaluate event sequences; as such, the phrase "accidents that would result in unacceptable consequences" has been replaced with "event sequences." The consideration of criticality has been clarified by requiring analysis of the means to prevent and control criticality. The words "principal design criteria" have been replaced with "design criteria" to be consistent with the changes made at § 63.21 (as noted in the discussion under § 63.21, this change was not intended as a substantive change).

Section 63.113 Performance Objectives for the Geologic Repository After Permanent Closure

This section has been modified to conform with the public health and environmental radiation standards for geologic disposal now specified in subpart L.

Section 63.114 Requirements for Performance Assessment

The reference to features, events, and processes in this section has been changed by removing the words "of the geologic setting." In addition, the requirements for multiple barriers have been moved to the revised § 63.115.

Section 63.115 Required Characteristics of the Reference Biosphere and Critical Group

Requirements related to characteristics of the reference biosphere and critical group have been deleted from this section in light of the definitions and concepts necessary to estimate dose to the reasonably maximally exposed individual, now specified in subpart L. This section now contains the requirements related to multiple barriers formerly at § 63.114. This section is now titled "Requirements for multiple barriers'.

Section 63.121 Requirements for Ownership and Control of Interests in Land

This section has been revised to clarify the extent and manner of control over lands that DOE must exercise during the preclosure period.

Subpart F—Performance Confirmation Program

Section 63.131 General Requirements

This section has been revised to replace the word "geologic" with "natural" at § 63.131(a) to be consistent with terms used in the definition of important to isolation.

Section 63.132 Confirmation of Geotechnical and Design Parameters

This section has been revised to require DOE to identify parameters and interactions to be measured or observed rather than specifically prescribing such parameters and interactions.

Section 63.133 Design Testing

This section has been revised to clarify testing requirements such that testing is not limited to in situ testing only; to require specific testing of the effectiveness of backfill placement and compaction only if backfill is included in the repository design; to require "tests", rather than "test sections," so as to be more general; and to generally reference "engineered systems and components," with examples, so as not to limit tests to specific features that may or may not be included in the final design of the repository. The reference to "ground water" was changed to "unsaturated zone and saturated zone water" to maintain the intent of the proposed rule, which included both saturated and unsaturated zone water in the definition of ground water, and avoid conflict with the new definition for "ground water" in subpart L.

Subpart G—Quality Assurance

Section 63.141 Scope

This section was revised to clarify the extent of the geologic repository system by adding "structures" and "systems" and deleting the word "subsystems."

Section 63.142 Quality Assurance Criteria

This section has been revised to include previously referenced quality assurance requirements. Provisions of Appendix B to 10 CFR part 50, as applicable, have been brought into this section rather than merely referencing appendix B in the rule. The introduction of the language from Appendix B into the final part 63 has not changed any requirements in the proposed part 63. This approach specifies the quality assurance requirements and removes any ambiguity regarding which portions of Appendix B are applicable to Yucca Mountain.

Section 63.143 Implementation

This section has been revised to reference the criteria at § 63.142 rather than the criteria in Appendix B of 10 CFR part 50, as applicable.

Section 63.144 Quality Assurance Program Change

This section has been added to provide requirements for how changes to the quality assurance program description are to be processed.

Subpart K—Preclosure Public Health and Environmental Standards

Section 63.201 Purpose and Scope

New section that states the requirements in this subpart apply to the storage of radioactive material in the Yucca Mountain repository and on the Yucca Mountain site.

Section 63.202 Definitions for Subpart K

New section adopted from the final 40 CFR part 197 that contains definitions of terms as used in subpart K.

Section 63.203 Implementation of Subpart K

New section adopted from the final 40 CFR part 197 that states DOE must demonstrate that normal repository operations will meet the requirements of this subpart.

Section 63.204 Preclosure Standard

New section adopted from the final 40 CFR part 197 that establishes a 0.15 mSv (15 mrem) dose limit during the preclosure period.

Subpart L—Postclosure Public Health and Environmental Standards

Section 63.301 Purpose and Scope

New section that states the requirements in this subpart apply to the disposal of radioactive material in the Yucca Mountain repository.

Section 63.302 Definitions for Subpart L

New section adopted from the final 40 CFR part 197 that contains definitions of terms as used in subparts L and K.

Section 63.303 Implementation of Subpart L

New section adopted from the final 40 CFR part 197 that states DOE must demonstrate there is a reasonable expectation that the projected performance of any geologic repository at Yucca Mountain will meet the requirements of this subpart for 10,000 years after disposal.

Section 63.304 Reasonable Expectation

New section adopted from the final 40 CFR part 197 that defines what is meant by the reasonable expectation concept used in relation to projecting the long-term performance of any geologic repository at Yucca Mountain.

Section 63.305 Required Characteristics of the Reference Biosphere

New section adopted from the final 40 CFR part 197 that describes the characteristics of the reference biosphere DOE is to assume for the purpose of projecting the long-term performance of the geologic repository.

Postclosure Individual Protection Standard

Section 63.311 Individual Protection Standard After Permanent Closure

New section adopted from the final 40 CFR part 197 that establishes an annual, all pathway, individual protection standard of 0.15 mSv (15 mrem) for the reasonably maximally exposed individual from potential releases of radioactivity from any geologic repository at the Yucca Mountain site for 10,000 years following disposal.

Section 63.312 Required Characteristics of the Reasonably Maximally Exposed Individual

New section adopted from the final 40 CFR part 197 that defines the required characteristics of the reasonably maximally exposed individual to be used by DOE in the dose calculations necessary to assess the long-term performance of any geologic repository at the Yucca Mountain site.

Human Intrusion Standard

Section 63.321 Individual Protection Standard for Human Intrusion

New section adopted from the final 40 CFR part 197 that describes the stylized human intrusion calculation to be used by DOE to evaluate the resilience of any geologic repository at the Yucca Mountain site. Establishes an annual, all pathway, individual protection standard of 0.15 mSv (15 mrem) for the reasonably maximally exposed individual, from potential releases of radioactivity from the geologic repository for 10,000 years after disposal, as a result of the stylized human intrusion.

Section 63.322 Human Intrusion Scenario

New section adopted from the final 40 CFR part 197 that describes the assumptions related to a stylized human intrusion scenario DOE will use to estimate the dose to any reasonably maximally exposed individual from a human intrusion. Additionally, NRC has clarified that the human intrusion scenario is to include only those radionuclides transported to the saturated zone by water (*e.g.*, water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone); and not consider particulate waste material falling into the borehole.

Ground-Water Protection Standards

Section 63.331 Separate Standards for Protection of Ground Water

New section adopted from the final 40 CFR part 197 that establishes limits on the level of radioactivity that would be acceptable in a representative volume of ground water 10,000 years following repository closure.

Section 63.332 Representative Volume

New section adopted from the final 40 CFR part 197 that describes the assumptions DOE will use in the calculation to estimate the level of radioactivity in a representative volume of ground water, at a specified point, down-gradient from any geologic repository at Yucca Mountain.

Additional Provisions

Section 63.341 Projections of Peak Dose

New section adopted from the final 40 CFR part 197 that requires DOE to estimate peak dose and include the results in its Environmental Impact Statement. However, there is no standard that must be met with respect to these peak dose calculations, and there is no finding that the NRC must make with respect to these peak dose calculations, nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

Section 63.342 Limits on Performance Assessments

New section adopted from the final 40 CFR part 197 that describes how DOE will determine which features, events, and processes need to be considered in the dose assessments described in subpart L.

Section 63.343 Severability of Individual Protection and Ground-Water Protection Standards

New section adopted from the final 40 CFR part 197 that indicates the individual protection and ground-water protection standards are wholly severable.

Parts 2, 19, 20, 51, 70, 72, 73, and 75

The following changes are being made to other parts to add references to part 63 where appropriate. These changes are needed to reflect changes in NRC regulations that have occurred since development of the proposed rule and to correct omissions.

Section 2.714 Interventions

A reference to part 63 is added in the section on interventions in any hearing on a license application for a repository.

Section 2.1013 Use of the electronic docket during the proceeding

A reference to part 63 is added in the section on use of the electronic docket (Licensing Support Network) for a license application for a repository.

Section 2.1014 Intervention

A reference to part 63 is added in the section on procedures for intervention and for filing an amendment to a contention.

Section 2.1021 First Prehearing Conference

A reference to part 63 is added in the section on procedures for conducting the first prehearing conference.

Section 2.1023 Immediate Effectiveness

A reference to part 63 is added in the section containing criteria for immediate effectiveness of a decision on issuance or amendment of a construction authorization for a repository.

Section 19.20 Employee Protection

A reference to part 63 is added in the section on employee protection to make employee protection provisions applicable to employees engaged in protected activities under part 63.

Section 20.1003 Definitions

A reference to part 63 is added to the definition of "License" in the definitions section.

Section 20.1401 General Provisions and Scope

A reference to part 63 is added to the section on general provisions and scope of radiological criteria for license termination to make these provisions applicable to decommissioning facilities licensed under part 63.

Section 20.2001 General Requirements

A reference to part 63 is added to the section on general requirements for waste disposal.

Section 20.2206 Reports of Individual Monitoring

A reference to part 63 is added to the section on reports of individual monitoring to make requirements for individual monitoring applicable to a part 63 licensee.

Section 51.22 Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or otherwise Not Requiring Environmental Review

A reference to part 63 is added to the section on categorical exclusions to allow for technical requirements and criteria promulgated under part 63 to be included along with technical requirements and criteria promulgated under part 60 as actions eligible for categorical exclusions.

Section 70.17 Specific Exemptions

A reference to part 63 is added to the section on specific exemptions to include DOE activities that are subject to part 63 or part 60 to be exempt from the requirements of part 70.

Section 72.44 License Conditions

A reference to part 63 is added to the section on license conditions. Part 72 already contains a provision limiting the quantity of spent fuel at the site of a monitored retrievable storage facility until a repository authorized under NWPA and part 60 begins operations. This change allows for a repository authorized under part 63 as well.

Section 73.1 Purpose and Scope

A reference to part 63 is added to the section on purpose and scope. This makes certain requirements for the establishment and maintenance of a physical protection system applicable to a repository licensed under part 63 in addition to part 60.

Section 73.51 Requirements for the Physical Protection of Stored Spent Nuclear Fuel and High-Level Radioactive Waste

A reference to part 63 is added to the section on requirements for physical protection of spent fuel and HLW. Applicability of these requirements is extended to the GROA licensed under part 63.

Section 75.4 Definitions

A reference to part 63 is added to the definition of "Installation" in the definitions section. This identifies locations where possession of more than 1 effective kilogram of nuclear material requires certain safeguards requirements.

V. Section-by-Section Analysis of Part 63

Subpart A—General Provisions

This subpart, except for § 63.2, "Definitions," contains general provisions that are similar to the provisions of part 60 with minor wording changes for simplification, clarification, or to refer specifically to the Yucca Mountain site, where appropriate. Definitions have been revised to reflect their use in this part, as appropriate.

Section 63.1 Purpose and Scope

This section limits the purpose and scope of part 63 to the licensing of DOE to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada. It states that generic regulations at part 60 of this title do not apply and cannot be the subject of any litigation in any licensing proceeding for the Yucca Mountain site.

Section 63.2 Definitions

This section contains definitions of terms as used in this part.

Section 63.3 License Required

This section prohibits DOE from receiving or possessing source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site without having a license issued by the Commission. It also prohibits DOE from beginning construction of the geologic repository operations area without authorization from the Commission.

Section 63.4 Communications and Records

This section describes requirements for communications and reports submitted to the Commission, including appropriate addresses for communications to be forwarded to NRC.

Section 63.5 Interpretations

This section specifies when interpretations of the meaning of the regulations in this part by NRC officers or employees will be considered binding on the Commission.

Section 63.6 Exemptions

This section states the bases on which the Commission may grant exemptions from the requirements of this part.

Section 63.7 License Not Required for Certain Preliminary Activities

This section allows DOE to possess source, special nuclear, or byproduct material at Yucca Mountain for the purposes of site characterization, and for use in certain construction activities.

Section 63.8 Information Collection Requirements: OMB Approval

This section indicates that the information collection requirements contained in this part have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act.

Section 63.9 Employee Protection

This section specifies requirements for protection of licensee or contractor and subcontractor personnel from certain adverse actions by employers.

Section 63.10 Completeness and Accuracy of Information

This section requires information provided to the Commission be complete and accurate. It also requires NRC notification of information having significant public health and safety implications.

Section 63.11 Deliberate Misconduct

This section prohibits certain licensee activities and describes resulting enforcement action.

Subpart B—Licenses

This subpart, except for § 63.15, "Site characterization," § 63.16, "Review of site characterization activities," and § 63.21, "Content of application," contains provisions that are similar to the licensing provisions of part 60 with minor wording changes for simplification, clarification, or to refer to the Yucca Mountain site, where appropriate. Provisions related to the content of the license application have been developed to be consistent with the technical criteria of subpart E. Provisions related to site characterization have been simplified from similar sections of part 60 to reflect the maturity of site characterization at Yucca Mountain. For example, there are no provisions requiring DOE to prepare and submit a site characterization plan to NRC or any requirement for NRC to prepare a specific site characterization analysis inasmuch as both activities have been completed. However, provisions requiring DOE to undertake site characterization and submit semiannual progress reports to NRC and provisions allowing NRC to comment on any aspect of site characterization or performance assessment, at any time, are retained as indicated in the analysis of pertinent sections of subpart B that follows.

Section 63.15 Site Characterization

This section specifies that a program of site characterization is to be conducted prior to submittal of an application and that investigations are to be conducted in a manner that limits adverse effects on the performance of the geologic repository.

Section 63.16 Review of Site Characterization Activities

This section specifies that DOE must submit to the Commission semiannual reports on the progress of site characterization, that the NRC staff shall be permitted to visit, inspect, and observe site characterization activities at the Yucca Mountain site, and that the Director may, at any time, comment on any aspect of site characterization and performance assessment. This section further provides that the Director shall invite public comment on any comments made by the Director after the Director's comments have been sent to DOE. This section also specifies that the Commission will determine whether any proposed onsite testing with radioactive material during site characterization is necessary to provide data for the preparation of the environmental reports required by law and for the license application.

Section 63.21 Content of Application

This section specifies that the license application must include general information, a safety analysis report, and be accompanied by an environmental impact statement. This section also describes the detailed information to be included in the safety analysis report.

Section 63.22 Filing and Distribution of Application

This section describes requirements for filing and distribution of the license application, amendments to the license application, environmental reports, and related updates and supplements.

Section 63.23 Elimination of Repetition

This section allows DOE to incorporate by reference information in previous applications, statements, or reports filed with the Commission in its application or environmental statement.

Section 63.24 Updating of Application and Environmental Impact Statement

This section requires DOE to submit a complete application, to update or supplement the application or environmental impact statement in a timely manner, and certify that updated copies contain current information.

Section 63.31 Construction Authorization

This section states the bases on which the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site.

Section 63.32 Conditions of Construction Authorization

This section indicates that the Commission will include conditions in the construction authorization as necessary to protect the health and safety of the public, the common defense and security, and environmental values, and describes specific provisions and restrictions that will be included in the construction authorization. This section also indicates that a license will not be issued until DOE has updated its application as required at § 63.24 and the Commission has made the findings stated at § 63.41.

Section 63.33 Amendment of Construction Authorization

This section requires DOE to apply for an amendment of the construction authorization if changes are desired. This section also states the bases on which the Commission may approve an amendment of the construction authorization.

Section 63.41 Standards for Issuance of a License

This section states the bases on which the Commission may issue a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site.

Section 63.42 Conditions of License

This section indicates that the Commission will include conditions or specifications in the license as necessary to protect the health and safety of the public, the common defense and security, and environmental values. This section also identifies general conditions that will be considered conditions of the license, whether stated in the license or not.

Section 63.43 License Specification

This section indicates that the Commission will include conditions in the license that are derived from the analyses and evaluations included in the application and amendments made before a license is issued. This section also describes specific categories of restrictions, requirements, and controls that will be included as conditions of the license.

Section 63.44 Changes, Tests, and Experiments

This section states the bases on which DOE may change the geologic repository operations area or procedures as described in the application, and conduct tests or experiments not described in the application, without prior Commission approval. This section also requires DOE to maintain records of changes made and tests undertaken under this section.

Section 63.45 Amendment of License

This section requires DOE to apply for an amendment of the license if changes are desired. This section also states the bases on which the Commission may approve an amendment of the license.

Section 63.46 Particular Activities Requiring License Amendment

This section describes specific activities that require amending the license prior to being performed, unless expressly authorized in the license.

Section 63.51 License Amendment for Permanent Closure

This section requires DOE to apply for an amendment of the license to permanently close a geologic repository at the Yucca Mountain site. This section also requires DOE to submit an update of the license application and describes the detailed information to be included in the update.

Section 63.52 Termination of License

This section requires DOE to apply for an amendment to terminate the license following permanent closure of the geologic repository and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

This subpart contains provisions that are similar to the State and affected Indian Tribe participation provisions of 10 CFR part 60, with some wording changes to refer to the State of Nevada, the Yucca Mountain site, and to include the AULGs, where appropriate.

Section 63.61 Provision of Information

This section states that the NRC shall provide to the Governor, the Nevada State legislature, AULGs, and any affected Indian Tribe timely and complete information regarding determinations made by the Commission with respect to the Yucca Mountain site. The NRC shall also make this information available to the public and DOE.

Section 63.62 Site Review

This section states that the NRC shall consult with the State of Nevada, AULGs, and affected Indian Tribes regarding site characterization activities.

Section 63.63 Participation in License Reviews

This section sets forth procedures for the State, AULGs, and affected Indian Tribes to participate in license review activities.

Section 63.64 Notice to State

This section notes that, if the Governor and legislature of the State of Nevada have designated a joint person or entity to receive information from NRC, the NRC will send such information to the jointly designated addressee.

Section 63.65 Representation

This section allows the Commission to request that any person acting as a representative of the State, Governor, or legislature of Nevada, or any AULG, or any affected Indian Tribe provide the Commission with the authority basis for such a representation.

Subpart D—Records, Reports, Tests, and Inspections

This subpart contains provisions that are similar to the records, reports, tests, and inspection provisions of part 60 with minor wording changes for simplification, clarification, or to refer to the Yucca Mountain site, as appropriate.

Section 63.71 Records and Reports

This section requires DOE to make and maintain records and reports as required by conditions of the license or rules, regulations, and orders of the Commission.

Section 63.72 Construction Records

This section requires DOE to maintain records of the construction of the geologic repository operations area and describes the types of records to be maintained.

Section 63.73 Reports of Deficiencies

This section requires DOE to notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site and the design and construction of the geologic repository operations area, if the uncorrected deficiency could adversely affect safety, represent a deviation from the design criteria or design bases, or represent a deviation from conditions of the construction authorization or license.

Section 63.74 Tests

This section requires DOE to perform such tests, or to allow the Commission to perform such tests, as the Commission determines necessary for administration of the regulations in this part. This section also describes the types of tests that may be included under this section.

Section 63.75 Inspections

This section requires DOE to afford the Commission opportunity for inspection of the geologic repository operations area and adjacent areas. This section also requires DOE to provide office space for Commission inspection personnel.

Section 63.78 Material Control and Accounting Records and Reports

This section requires DOE to establish a material inventory system, whereby material and accounting procedures are developed, physical inventories are performed, loss of special nuclear material or accidental criticality is reported, and material status and nuclear material transfer reports are generated. This section notes that the material and accounting program is to be the same as that specified at §§ 72.72, 72.74, 72.76, and 72.78.

Subpart E—Technical Criteria

This subpart, except for § 63.101, "Purpose and nature of findings," § 63.102, "Concepts," and § 63.121, "Requirements for ownership and control of interests in land," contains performance objectives for the geologic repository operations area through permanent closure (preclosure) and the geologic repository after permanent closure (postclosure), separate requirements for protection of ground water (postclosure), and requirements for the analyses used to demonstrate compliance with the performance objectives. The preclosure performance objective is similar to the provisions in part 60. However, the postclosure performance objective and other requirements differ significantly from part 60. This subpart requires compliance to be demonstrated in the context of safety analyses of total system performance and does not prescribe general design or siting criteria, or specific quantitative subsystem performance objectives as was done in part 60. Performance requirements from the final 40 CFR part 197, incorporated into subparts K and L, are referenced in this subpart.

Section 63.101 Purpose and Nature of Findings

This section describes the Commission's expectations for demonstration that the geologic repository will be in conformance with the performance objectives.

Section 63.102 Concepts

This section provides a functional overview of this subpart.

Section 63.111 Performance Objectives for the Geologic Repository Operations Area Through Permanent Closure

This section requires DOE to design the geologic repository operations area

to comply with the exposure limits given in this section, conduct a preclosure safety analysis, permit implementation of a performance confirmation program, and preserve the option for waste retrieval.

Section 63.112 Requirements for Preclosure Safety Analysis of the Geologic Repository Operations Area

This section specifies the requirements for the preclosure safety analysis used to demonstrate compliance with the performance objective through permanent closure provided at § 63.111(a)(1) and (a)(2).

Section 63.113 Performance Objectives for the Geologic Repository After Permanent Closure

This section requires DOE to include a system of multiple barriers for the geologic repository, comply with the limits on radiological exposures to the reasonably maximally exposed individual, comply with limits on releases of radionuclides into the accessible environment, comply with the limits on radiological exposures to the reasonably maximally exposed individual as a result of a specified human intrusion event, and conduct related assessments.

Section 63.114 Requirements for Performance Assessment

This section specifies the requirements for the performance assessment used to demonstrate compliance with the requirements specified at § 63.113(b), (c), and (d).

Section 63.115 Requirements for Multiple Barriers

This section requires DOE to identify and describe the natural features of the geologic setting and design features of the engineered barrier system that are considered barriers important to waste isolation.

Section 63.121 Requirements for Ownership and Control of Interests in Land

This section requires DOE to have permanent control of the geologic repository operations area. It states that DOE shall set up controls necessary to prevent adverse human actions that could affect the repository. Appropriate controls shall be established outside the geologic repository operations area. DOE is required to obtain water rights needed for the repository.

Subpart F—Performance Confirmation Program

This subpart contains provisions that are similar to the performance confirmation provisions of 10 CFR part 60.

Section 63.131 General Requirements

This section states the objectives of the performance confirmation program and specifies that the program be started during site characterization and continue until permanent closure.

Section 63.132 Confirmation of Geotechnical and Design Parameters

This section requires DOE to monitor subsurface conditions during repository construction and operation to confirm original design assumptions and to ensure that performance of geologic and engineered features is within design limits. DOE is also required to inform the Commission of any design changes needed to accommodate actual field conditions encountered.

Section 63.133 Design Testing

This section requires DOE to undertake a program of testing of such features as borehole and shaft seals, backfill, drip shields, and the thermal interaction effects of waste packages, backfill, rock, and ground water.

Section 63.134 Monitoring and Testing Waste Packages

This section requires DOE to establish a program for monitoring and testing waste packages at the geologic repository operations area that is to continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

This subpart contains provisions that are similar to the quality assurance provisions of 10 CFR part 60. Rather than referencing Appendix B to 10 CFR part 50, as was done in 10 CFR part 60, 10 CFR part 63 has incorporated quality assurance requirements from Appendix B that are specifically applicable to a geologic repository.

Section 63.141 Scope

This section requires DOE to establish a quality assurance program to be applied at the geologic repository at the Yucca Mountain site.

Section 63.142 Quality Assurance Criteria

This section indicates that the quality assurance program applies to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto. This section specifies the applicability and criteria for DOE's quality assurance program description.

Section 63.143 Implementation

This section indicates that the quality assurance program is to be based on the criteria required by § 63.142.

Section 63.144 Quality Assurance Program Change

This section specifies when DOE is allowed to make a change to a previously accepted quality assurance program without prior NRC approval.

Subpart H—Training and Certification of Personnel

This subpart contains provisions that are similar to the training and certification provisions of 10 CFR part 60.

Section 63.151 General Requirements

This section specifies that operations of systems and components important to safety are to be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operations. This section also specifies that supervisory personnel who direct operations that are important to safety are to be certified in such operations.

Section 63.152 Training and Certification Program

This section specifies that a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel is to be established.

Section 63.153 Physical Requirements

This section specifies physical requirements for personnel certified for operations that are important to safety.

Subpart I—Emergency Planning Criteria

This subpart contains provisions for emergency planning.

Section 63.161 Emergency Plan for the Geologic Repository Operations Area Through Permanent Closure

This section requires DOE to develop and be prepared to implement a plan to cope with radiological emergencies. The section indicates that the emergency plan is to be based on criteria at § 72.32(b).

Subpart J—Violations

This subpart contains provisions that are similar to the violation provisions of 10 CFR part 60.

Section 63.171 Violations

This section specifies actions the Commission may take, including obtaining a court order to prevent a violation, and contains civil penalty provisions.

Section 63.172 Criminal Penalties

This section specifies criminal sanctions for violations. For purposes of section 223 of the Atomic Energy Act of 1954, as amended, that provides for criminal sanctions, all regulations in part 63 are issued under one or more of sections 161b, 161i, or 161o except for the sections listed in § 63.172(b).

Subpart K—Preclosure Public Health and Environmental Standards

This subpart contains provisions that are consistent with the public health and environmental standards for storage specified at 40 CFR part 197.

Section 63.201 Purpose and scope

This section stipulates that, to the extent that there may be a conflict, the requirements in this subpart take precedence over other requirements in subparts A through J.

Section 63.202 Definitions for Subpart K

This section contains definitions of terms as used in this subpart and subpart L.

Section 63.203 Implementation of Subpart K

This section provides a functional overview of this subpart.

Section 63.204 Preclosure Standard

This section specifies the dose limits that DOE must meet when storing waste at a geologic repository.

Subpart L—Postclosure Public Health and Environmental Standards

This subpart contains provisions that are consistent with the public health and environmental standards for disposal specified at 40 CFR part 197.

Section 63.301 Purpose and Scope

This section stipulates that, to the extent that there may be a conflict, the requirements in this subpart take precedence over other requirements in subparts A through J.

Section 63.302 Definitions for Subpart L

This section contains definitions of terms as used in this subpart.

Section 63.303 Implementation of Subpart L

This section provides a functional overview of this subpart.

Section 63.304 Reasonable Expectation

This section defines what is meant by the reasonable expectation concept.

Section 63.305 Required Characteristics of the Reference Biosphere

This section specifies characteristics of the reference biosphere to be used by DOE in its performance assessment to demonstrate compliance with the requirements specified at § 63.113(b) and (d).

Postclosure Individual Protection Standard

Section 63.311 Individual Protection Standard After Permanent Closure

This section specifies the dose limit for any geologic repository at the Yucca Mountain site.

Section 63.312 Required Characteristics of the Reasonably Maximally Exposed Individual

This section specifies characteristics of the reasonably maximally exposed individual to be used by DOE in the performance assessment used to demonstrate compliance with the requirements specified at § 63.113(b) and (d).

Human Intrusion Standard

Section 63.321 Individual Protection Standard for Human Intrusion

This section directs DOE to estimate the dose resulting from a stylized human intrusion drilling scenario and specifies the dose limit that any geologic repository at the Yucca Mountain site must meet as the result of any such hypothetical human intrusion.

Section 63.322 Human Intrusion Scenario

This section specifies the assumptions related to a stylized human intrusion scenario DOE will use to estimate the dose to any reasonably maximally exposed individual from a human intrusion.

Ground-Water Protection Standards

Section 63.331 Separate Standards for Protection of Ground Water

This section specifies limits on the levels of radioactivity that would be acceptable in a representative volume of ground water found in the accessible environment for up to 10,000 years following repository closure.

Section 63.332 Representative Volume

This section specifies the assumptions DOE will use to estimate the levels of radioactivity in a representative volume of ground water, at a specified point, down-gradient from any geologic repository at the Yucca Mountain site for up to 10,000 years following repository closure.

Additional Provisions

Section 63.341 Projections of Peak Dose

This section specifies that DOE will estimate peak dose and include the results in its Environmental Impact Statement. However, there is no standard that must be met with respect to these peak dose calculations, and there is no finding that the NRC must make with respect to these peak dose calculations, nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

Section 63.342 Limits on Performance Assessments

This section specifies how DOE will identify which features, events, and processes will be considered in the dose assessments described in Subpart L.

Section 63.343 Severability of Individual Protection and Ground-Water Protection Standards

This section stipulates that calculations required by §§ 63.311 and 63.331 can be performed independently of each other.

VI. Section-by-Section Analysis of Corresponding Changes to Other Parts

Section-by-section analysis of changes to parts 2, 19, 20, 21, 30, 40, 51, 61, 70, 72, 73, and 75.

10 CFR Part 2

Section 2.101, Filing of applications, is amended to add a reference to part 63 in the procedures for filing of applications.

Section 2.103, Action on applications for byproduct, source, special nuclear material, and operator licenses, is amended to add a reference to part 63 in the procedures for notification in this section.

Section 2.104, Notice of hearing, is amended to add a reference to part 63 in the procedures for notification of hearings.

Section 2.105, Notice of proposed action, is amended to add a reference to part 63 in the procedures for notification of proposed actions in this section.

Section 2.106(c), Notice of issuance, is amended to provide for public notification of any action with respect to a license application or license amendment under part 63.

Section 2.714—A reference to part 63 is added in the section on interventions in any hearing on a license application for a repository.

Section 2.1013—A reference to part 63 is added in the section on use of the

electronic docket (Licensing Support Network) for a license application for a repository.

Section 2.1014—A reference to part 63 is added in the section on procedures for intervention and for filing an amendment to a contention.

Section 2.1021—A reference to part 63 is added in the section on procedures for conducting the first prehearing conference.

Section 2.1023—A reference to part 63 is added in the section containing criteria for immediate effectiveness of a decision on issuance or amendment of a construction authorization for a repository.

10 CFR Part 19

Section 19.2, Scope, is amended to make part 63 subject to the regulations in part 19.

Section 19.3, Definitions, is amended to add part 63 to the definition of "license."

Section 19.20—A reference to part 63 is added in the section on employee protection to make employee protection provisions applicable to employees engaged in protected activities under part 63.

10 CFR Part 20

Section 20.1002, Scope, is amended to make part 63 subject to the regulations in part 20.

Section 20.1003—A reference to part 63 is added to the definition of "License" in the definitions section.

Section 20.1401—A reference to part 63 is added to the section on general provisions and scope of radiological criteria for license termination to make these provisions applicable to decommissioning facilities licensed under part 63.

Section 20.2001—A reference to part 63 is added to the section on general requirements for waste disposal.

Section 20.2206—A reference to part 63 is added to the section on reports of individual monitoring to make requirements for individual monitoring applicable to a part 63 licensee.

10 CFR Part 21

Section 21.2(a), Scope, is amended to make part 63 subject to the regulations in part 21.

Certain definitions in § 21.3 are amended to include part 63.

Section 21.21 is amended to make part 63 subject to the regulations for reporting defects and noncompliance.

10 CFR Part 30

Section 30.11, Specific exemptions, is amended to exempt DOE from part 30 regulations for activities subject to part 63.

10 CFR Part 40

Section 40.14, Specific exemptions, is amended to exempt DOE from part 40 regulations for activities subject to part 63.

10 CFR Part 51

Section 51.20, Criteria for and identification of licensing and regulatory actions requiring environmental impact statements, is amended to add a reference to part 63 under actions requiring environmental impact statements.

Section 51.22, Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review, is amended to add a reference to part 63 in requirements for categorical exclusion from environmental review.

Section 51.26, Requirement to publish notice of intent and conduct scoping process, is amended to add a reference to part 63 in procedures for receipt of an application and accompanying environmental impact statement from DOE.

Section 51.67, Environmental information concerning geologic repositories, is amended to add a reference to part 63 in requirements for submission of an environmental impact statement by DOE.

10 CFR Part 61

Section 61.1, Purpose and scope, is amended to state that the regulations of part 61 do not apply to disposal of HLW as provided for in part 63.

In § 61.2, Definitions, the definition of "land disposal facility" is amended to clarify that a geologic repository as defined in part 63 is not considered a land disposal facility.

Section 61.55, Waste classification, is amended to add a reference to part 63 in the definition of a geologic repository.

10 CFR Part 70

Section 70.17—A reference to part 63 is added to the section on specific exemptions to exempt DOE activities that are subject to part 63 or part 60 from the requirements of part 70.

10 CFR Part 72

Section 72.44—A reference to part 63 is added to the section on license conditions. Part 72 already contains a provision limiting the quantity of spent fuel at the site of a monitored retrievable storage facility until a repository authorized under NWPA and part 60 begins operations. This change allows for a repository authorized under part 63 as well.

10 CFR Part 73

Section 73.1—A reference to part 63 is added to the section on purpose and scope. This makes certain requirements for the establishment and maintenance of a physical protection system applicable to a repository licensed under part 63 in addition to part 60.

Section 73.51—A reference to part 63 is added to the section on requirements for physical protection of spent fuel and HLW. Applicability of these requirements is extended to the GROA licensed under part 63.

10 CFR Part 75

Section 75.4—A reference to part 63 is added to the definition of "Installation" in the definitions section. This identifies locations where possession of more than 1 effective kilogram of nuclear material requires certain safeguards requirements.

VII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is publishing licensing criteria for the disposal of spent nuclear fuel and high-level radioactive waste in the proposed geologic repository at Yucca Mountain, Nevada. This action does not constitute the establishment of a standard that contains generally applicable requirements.

VIII. Finding of No Significant Environmental Impact: Availability

Pursuant to section 121(c) of the Nuclear Waste Policy Act, this rule does not require the preparation of an environmental impact statement under section 102(2)(c) of the National Environmental Policy Act of 1969 or any environmental review under subparagraph (E) or (F) of section 102(2) of such act.

IX. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, approval number 3150–0199.

The public reporting burden for this information collection is estimated to average 121 hours per response, including the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0199), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

X. Regulatory Analysis

The NRC has prepared a regulatory analysis for this regulation. The analysis examines the alternatives considered by NRC. The analysis is available for inspection in the NRC's Public Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html*.

Single copies of the analysis may be obtained from Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6203, e-mail *CWP@nrc.gov*.

XI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this final rule does not have a significant economic impact on a substantial number of small entities. This final rule relates to the licensing of only one entity, the Department of Energy, which does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act.

XII. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and, therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

XIII. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 2

Administrative procedure and practice, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 60

Criminal penalties, High-level waste, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 61

Criminal penalties, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 63

Criminal penalties, High-level waste, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Waste treatment and disposal.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Administrative practice and procedure, Criminal Penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 2, 19, 20, 21, 30, 40, 51, 60, 61, 70, 72, 73, and 75, and adding the new 10 CFR part 63.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409

(42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183i, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948–951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Section 2.205(j) also issued under Pub. L. 101–410, 104 Stat. 90, as amended by section 3100(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Subpart M also issued under sec. 184 (42 U.S.C. 2234) and sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135).

2. Section 2.101 is amended by revising paragraphs (f)(1) and (f)(5) to read as follows:

§ 2.101 Filing of applications.

* * * * *

(f)(1) Each application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and any environmental impact statement required in connection therewith pursuant to subpart A of part 51 of this chapter, shall be processed in accordance with the provisions of this paragraph.

* * * * *

(5) If a tendered document is acceptable for docketing, the applicant will be requested to submit to the Director of Nuclear Material Safety and Safeguards such additional copies of the application and environmental impact statement as the regulations in part 60 or 63 and subpart A of part 51 of this chapter require; serve a copy of such application and environmental impact statement on the chief executive of the municipality in which the geologic repository operations area is to be located, or if the geologic repository operations area is not to be located within a municipality, on the chief executive of the county (or to the Tribal organization, if it is to be located within an Indian reservation); and make direct distribution of additional copies to Federal, State, Indian Tribe, and local officials in accordance with the requirements of this chapter, and written instructions from the Director of Nuclear Material Safety and Safeguards. All such copies shall be completely assembled documents, identified by docket number. Subsequently distributed amendments to the application, however, may include revised pages to previous submittals and, in such cases, the recipients are responsible for inserting the revised pages.

* * * * *

3. Section 2.103 is amended by revising paragraph (a) to read as follows:

§ 2.103 Action on applications for byproduct, source, special nuclear material, and operator licenses.

(a) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, finds that an application for a byproduct, source, special nuclear material, or operator license complies with the requirements of the Act, the Energy Reorganization Act, and this chapter, he will issue a license. If the license is for a facility, or for the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, or if it is to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State, Tribal, and local officials specified in § 2.104(e) of the issuance of the license. For notice of issuance requirements for licenses issued pursuant to part 61 of this chapter, see § 2.106(d).

* * * * *

4. Section 2.104 is amended by revising paragraph (e) to read as follows:

§ 2.104 Notice of hearing.

* * * * *

(e) The Secretary will give timely notice of the hearing to all parties and to other persons, if any, entitled by law to notice. The Secretary will transmit a notice of the hearing on an application for a license for a production or utilization facility, for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, for a license under part 61 of this chapter, for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and for a license under part 72 of this chapter to acquire, receive or possess spent fuel for the purpose of storage in an independent spent fuel storage installation (ISFSI) to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be so located or conducted within an Indian reservation). The Secretary will transmit a notice of hearing on an application for a license under part 72 of this chapter to acquire, receive or possess spent fuel, high-level radioactive waste or radioactive material associated with high-level radioactive waste for the purpose of storage in a monitored retrievable storage installation (MRS) to the same persons who received notice of docketing under § 72.16(e) of this chapter.

5. Section 2.105 is amended by revising paragraph (a)(5) to read as follows:

§ 2.105 Notice of proposed action.

(a) * * *

(5) A license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter.

* * * * *

6. Section 2.106 is amended by revising paragraph (c) to read as follows:

§ 2.106 Notice of issuance.

* * * * *

(c) The Director of Nuclear Material Safety and Safeguards will also cause to be published in the **Federal Register** notice of, and will inform the State, local, and Tribal officials specified in § 2.104(e) of any action with respect to, an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, or for the amendment to such license for which a notice of proposed action has been previously published.

* * * * *

7. Section 2.714 is amended by revising paragraph (d) to read as follows:

§ 2.714 Intervention.

* * * * *

(d) The Commission, the presiding officer, or the Atomic Safety and Licensing Board designated to rule on petitions to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by the State in which such area is located and by any affected Indian Tribe as defined in part 60 or 63 of this chapter.

* * * * *

8. In § 2.1001, the definitions of *Documentary material, Interested governmental participation, Licensing Support Network,* and *Party* are revised to read as follows:

§ 2.1001 Definitions.

* * * * *

Documentary material means any information upon which a party, potential party, or interested governmental participant intends to rely and/or to cite in support of its position in the proceeding for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; any information that is known to, and in the possession of, or developed by the party that is relevant to, but does not support, that information or that party's position; and all reports and studies, prepared by or on behalf of the potential party, interested governmental participant, or party, including all related "circulated drafts," relevant to both the license application and the issues set forth in the Topical Guidelines in Regulatory Guide 3.69, regardless of whether they will be relied upon and/or cited by a party. The scope of documentary material shall be guided by the topical guidelines in the applicable NRC Regulatory Guide.

* * * * *

Interested governmental participant means any person admitted under § 2.715(c) of this part to the proceeding on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter.

Licensing Support Network means the combined system that makes documentary material available electronically to parties, potential parties, and interested governmental participants to the proceeding for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, as part of the electronic docket or electronic access to documentary material, beginning in the pre-license application phase.

* * * * *

Party for the purpose of this subpart means the DOE, the NRC staff, the host State, any affected unit of local government as defined in section 2 of the Nuclear Waste Policy Act of 1982, as amended (42 U.S.C. 10101), any affected Indian Tribe as defined in section 2 of the Nuclear Waste Policy Act of 1982, as amended (42 U.S.C. 10101), and a person admitted under § 2.1014 to the proceeding on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area under part 60 or 63 of this chapter, provided that a host State, affected unit of local government, or affected Indian Tribe shall file a list of contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii).

* * * * *

9. Section 2.1013 is amended by revising paragraphs (a)(2) and (c)(1) to read as follows:

§ 2.1013 Use of the electronic docket during the proceeding.

(a) * * *

(2) Commencing with the docketing in an electronic form of the license application to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Secretary of the Commission, upon determining that the application can be properly accessed under the Commission's electronic docket rules, will establish an electronic docket to contain the official record materials of the high-level radioactive waste licensing proceeding in searchable full text, or, for material that is not suitable for entry in searchable full text, by header and image, as appropriate.

* * * * *

(c)(1) All filings in the adjudicatory proceeding on the license application to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter shall be transmitted electronically by the submitter to the Presiding Officer, parties, and the Secretary of the Commission, according to established format requirements. Parties and interested governmental participants will be required to use a password security code for the electronic transmission of these documents.

* * * *

10. Section 2.1014 is amended by revising the introductory text of paragraph (a)(1) and paragraph (a)(4) to read as follows:

§ 2.1014 Intervention.

(a)(1) Any person whose interest may be affected by a proceeding on the application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, and who desires to participate as a party, shall file a written petition for leave to intervene. In a proceeding noticed pursuant to § 2.105, any person whose interest may be affected may also request a hearing. The petition and/or request, and any request to participate under § 2.715(c), shall be filed within thirty days after the publication of the notice of hearing in the **Federal Register**. Nontimely filings will not be entertained absent a determination by the Commission, or the Presiding Officer designated to rule on the petition and/or request, that the petition and/or request should be granted based upon a balancing of the following factors, in addition to satisfying those set out in paragraphs (a)(2) and (c) of this section:

* * * * *

(4) Any party may amend its contentions specified in paragraph (a)(2)(ii) of this section. The Presiding Officer shall rule on any petition to amend such contentions based on the balancing of the factors specified in paragraph (a)(1) of this section and a showing that a significant safety or environmental issue is involved or that the amended contention raises a material issue related to the performance evaluation anticipated by §§ 60.112 and 60.113 or §§ 63.112 and 63.113 of this chapter.

* * * * *

11. Section 2.1021 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 2.1021 First prehearing conference.

(a) In any proceeding involving an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter, the Commission or the Presiding Officer will direct the parties, interested governmental participants, and any petitioners for intervention, or their counsel, to appear at a specified time and place, within seventy days after the notice of hearing is published, or such

other time as the Commission or the Presiding Officer may deem appropriate, for a conference to:

* * * * *

12. Section 2.1023 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 2.1023 Immediate effectiveness.

(a) Pending review and final decision by the Commission, an initial decision resolving all issues before the Presiding Officer in favor of issuance or amendment of a construction authorization pursuant to § 60.31 or 63.31 of this chapter or a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to § 60.41 or 63.41 of this chapter, will be immediately effective upon issuance except—

* * * * *

PART 19—NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS

13. The authority citation for part 19 continues to read as follows:

Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

14. Section 19.2 is revised to read as follows:

§ 19.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, including persons licensed to operate a production or utilization facility under part 50 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The regulations regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the Nuclear Regulatory Commission other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued pursuant to 10 CFR 2.720.

15. Section 19.3 is amended by revising the definition of *License* to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to part 50 of this chapter.

* * * * *

16. Section 19.20 is revised to read as follows:

§ 19.20 Employee protection.

Employment discrimination by a licensee (or a holder of a certificate of compliance issued pursuant to part 76) or a contractor or subcontractor of a licensee (or a holder of a certificate of compliance issued pursuant to part 76) against an employee for engaging in protected activities under this part or parts 30, 40, 50, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

17. The authority citation for part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2297f), secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

18. Section 20.1002 is revised to read as follows:

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material, or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with § 35.75, or to exposure from voluntary participation in medical research programs.

19. Section 20.1003 is amended by revising the definition of License to read as follows:

§ 20.1003 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

* * * * *

20. Section 20.1401 is amended by revising paragraph (a) to read as follows:

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 60, 61, 63, 70, and 72 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to Appendix A to 10 CFR part 40 or to uranium solution extraction facilities.

* * * * *

21. Section 20.2001 is amended by revising paragraphs (a)(1) and (b)(5) to read as follows:

§ 20.2001 General requirements.

(a) * * *

(1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter;

* * * * *

(b) * * *

(5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

22. Section 20.2206 is amended by revising paragraph (a)(4) to read as follows:

§ 20.2206 Reports of individual monitoring.

(a) * * *

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; or

* * * * *

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

23. The authority citation for part 21 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83, Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C.

2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

24. Section 21.2 is amended by revising paragraph (a) to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for the manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 63, 70, 71, or part 72 of this chapter.

* * * * *

§ 21.3 [Amended]

25. In § 21.3, the definitions of Basic component, Commercial grade item, and Dedication are amended by adding the number 63 after "10 CFR parts 30, 40, 50 (other than nuclear power plants), 60" and the definition of Substantial safety hazard is amended by adding the number 63 between "61" and "70."

26. Section 21.21 is amended by revising paragraphs (d)(1)(i) and (d)(1)(ii) to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

* * * * *

(d)(1) * * *

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

27. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 69 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

28. Section 30.11 is amended by revising paragraph (c) to read as follows:

§ 30.11 Specific exemptions.

* * * * *

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

29. The authority citation for part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

30. Section 40.14 is amended by revising paragraph (c) to read as follows:

§ 40.14 Specific exemptions.

* * * * *

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

* * * * *

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

31. The authority citation for part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953, (42 U.S.C. 2201, 2297f); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842). Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853–854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95–604, Title II, 92 Stat. 3033–3041; and sec. 193, Pub. L. 101–575, 104 Stat. 2835 (42 U.S.C. 2243). Sections 51.20, 51.30 51.60, 51.61, 51.80, and 51.97 also issued under secs 135, 141, Pub. L. 97–425, 96 Stat, 2232, 2241, and sec. 148, Pub. L. 100–203, 101 Stat. 1330–223 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036–3038 (42 U.S.C. 2021) and under Nuclear Waste Policy Act of 1982, sec. 121, 96 Stat. 2228 (42 U.S.C. 10141). Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act of 1982, sec 114(f), 96 Stat. 2216, as amended (42 U.S.C. 10134 (f)).

32. Section 51.20 is amended by revising paragraph (b)(13) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(13) Issuance of a construction authorization and license pursuant to part 60 or part 63 of this chapter.

* * * * *

33. Section 51.22 is amended by revising the introductory text of paragraph (c)(3) and paragraphs (c)(10), (c)(12), and (d) to read as follows:

§ 51.22 Criteria for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 39, 40, 50, 51, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * * * *

(10) Issuance of an amendment to a permit or license under parts 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 60, 61, 63, 70, or part 72 of this chapter which —

(i) Changes surety, insurance and/or indemnity requirements; or

(ii) Changes recordkeeping, reporting, or administrative procedures or requirements.

* * * * *

(12) Issuance of an amendment to a license pursuant to parts 50, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted pursuant to parts 50, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

(i) Organizational and procedural matters;

(ii) Modifications to systems used for security and/or materials accountability;

(iii) Administrative changes; and

(iv) Review and approval of transportation routes pursuant to 10 CFR 73.37.

* * * * *

(d) In accordance with section 121 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10141), the promulgation of technical requirements and criteria that the Commission will apply in approving or disapproving applications under part 60 or 63 of this chapter shall not require an environmental impact statement, an environmental assessment, or any environmental review under subparagraph (E) or (F) of section 102(2) of NEPA.

34. Section 51.26 is amended by revising paragraph (c) to read as follows:

§ 51.26 Requirement to publish notice of intent and conduct scoping process.

* * * * *

(c) Upon receipt of an application and accompanying environmental impact statement under § 60.22 or § 63.22 of this chapter (pertaining to geologic repositories for high-level radioactive waste), the appropriate NRC staff director will include in the notice of docketing required to be published by § 2.101(f)(8) of this chapter a statement of Commission intention to adopt the environmental impact statement to the extent practicable. However, if the appropriate NRC staff director determines, at the time of such publication or at any time thereafter, that NRC should prepare a supplemental environmental impact statement in connection with the Commission's action on the license application, the NRC shall follow the procedures set out in paragraph (a) of this section.

35. Section 51.67 is amended by revising paragraphs (a) and (b) to read as follows:

§ 51.67 Environmental information concerning geologic repositories.

(a) In lieu of an environmental report, the Department of Energy, as an applicant for a license or license amendment pursuant to part 60 or 63 of this chapter, shall submit to the Commission any final environmental impact statement which the Department prepares in connection with any geologic repository developed under Subtitle A of Title I, or under Title IV, of the Nuclear Waste Policy Act of 1982, as amended. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.) The statement shall include, among the alternatives under consideration, denial of a license or construction authorization by the Commission.

(b) Under applicable provisions of law, the Department of Energy may be required to supplement its final environmental impact statement if it makes a substantial change in its proposed action that is relevant to environmental concerns or determines that there are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. The Department shall submit any supplement to its final environmental impact statement to the Commission. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.)

* * * * *

PART 60—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

36. The authority citation for part 60 continues to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97–425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

37. Section 60.1 is revised to read as follows:

§ 60.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated in accordance with the Nuclear Waste Policy Act of 1982. This part does not apply to any activity licensed under another part of this chapter. This part does not apply to the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992, subject to part 63 of this chapter. This part also gives notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 60.11.

PART 61—LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

38. The authority citation for part 61 continues to read as follows:

Authority: Secs. 53, 57, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246, (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851) and Pub. L. 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851).

39. Section 61.1 is amended by revising paragraph (b) to read as follows:

§ 61.1 Purpose and scope.

* * * * *

(b) Except as provided in part 150 of this chapter, which addresses assumption of certain regulatory authority by Agreement States, and § 61.6 "Exemptions," the regulations in this part apply to all persons in the United States. The regulations in this part do not apply to—

(1) Disposal of high-level waste as provided for in part 60 or 63 of this chapter;

(2) Disposal of uranium or thorium tailings or wastes (byproduct material as defined in § 40.4 (a-1) as provided for in part 40 of this chapter in quantities greater than 10,000 kilograms and containing more than 5 millicuries of radium-226; or

(3) Disposal of licensed material as provided for in part 20 of this chapter.

* * * * *

40. In § 61.2, the definition of Land disposal facility is revised to read as follows:

§ 61.2 Definitions.

* * * * *

Land disposal facility means the land, building, and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this chapter, a "geologic repository" as defined in part 60 or 63 is not considered a land disposal facility.

* * * * *

41. Section 61.55 is amended by revising paragraph (a)(2)(iv) to read as follows:

§ 61.55 Waste classification.

(a) * * *

(2) * * *

(iv) Waste that is not generally acceptable for near-surface disposal is waste for which form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this part, such waste must be disposed of in a geologic repository as defined in part 60 or 63 of this chapter unless proposals for disposal of such waste in a disposal site licensed pursuant to this part are approved by the Commission.

* * * * *

42. Part 63 is added to read as follows:

PART 63—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

Subpart A—General Provisions

Sec.
63.1 Purpose and scope.
63.2 Definitions.
63.3 License required.
63.4 Communications and records.
63.5 Interpretations.
63.6 Exemptions.
63.7 License not required for certain preliminary activities.
63.8 Information collection requirements: OMB Approval.
63.9 Employee protection.
63.10 Completeness and accuracy of information.
63.11 Deliberate misconduct.

Subpart B—Licenses

Preapplication Review

63.15 Site characterization.

63.1 Review of site characterization activities.

License Application

63.21 Content of application.
63.22 Filing and distribution of application.
63.23 Elimination of repetition.
63.24 Updating of application and environmental impact statement.

Construction Authorization

63.31 Construction authorization.
63.32 Conditions of construction authorization.
63.33 Amendment of construction authorization.

License Issuance and Amendment

63.41 Standards for issuance of a license.
63.42 Conditions of license.
63.43 License specification.
63.44 Changes, tests, and experiments.
63.45 Amendment of license.
63.46 Particular activities requiring license amendment.

Permanent Closure

63.51 License amendment for permanent closure.
63.52 Termination of license.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

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Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2[illegible], 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95–601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97–425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141), and Pub. L. 102–486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

Subpart A—General Provisions

§ 63.1 Purpose and scope.

This part prescribes rules governing the licensing of the U.S. Department of Energy to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area sited, constructed, or operated at Yucca Mountain, Nevada, in accordance with the Nuclear Waste Policy Act of 1982, as amended, and the Energy Policy Act of 1992. As provided in 10 CFR 60.1, the regulations in part 60 of this chapter do not apply to any activity that is subject to licensing under this part. This part does not apply to any activity licensed under another part of this chapter. This part also gives notice to all persons who knowingly provide, to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 63.11.

§ 63.2 Definitions.

As used in this part:

Affected Indian Tribe means any Indian Tribe within whose reservation boundaries a repository for high-level radioactive waste or spent fuel is proposed to be located; or whose Federally-defined possessory or usage rights to other lands outside of the reservation's boundaries arising out of Congressionally-ratified treaties or other Federal law may be substantially and adversely affected by the location of the facility if the Secretary of the Interior finds, on the petition of the appropriate governmental officials of the Tribe, that the effects are both substantial and adverse to the Tribe.

Barrier means any material, structure, or feature that, for a period to be determined by NRC, 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. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

Commencement of construction means clearing of land, surface or subsurface excavation, or other substantial action that would adversely affect the environment of a site. It does not include changes desirable for the temporary use of the land for public recreational uses, site characterization activities, other preconstruction monitoring and investigation necessary to establish background information related to the suitability of the Yucca Mountain site or to the protection of environmental values, or procurement or manufacture of components of the geologic repository operations area.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Containment means the confinement of radioactive waste within a designated boundary.

Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be constraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include:

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

(2) Estimates of severe external human-induced events to be used for deriving design bases, that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Director means the Director of the Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Disposal means the emplacement of radioactive waste in a geologic repository with the intent of leaving it there permanently.

DOE means the U.S. Department of Energy or its duly authorized representatives.

Engineered barrier system means the waste packages, including engineered components and systems other than the waste package (e.g., drip shields), and the underground facility.

Event sequence means a series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least one chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences.

Geologic repository means a system that is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the engineered barrier system and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic repository operations area means 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.

Geologic setting means the geologic, hydrologic, and geochemical systems of the region in which a geologic repository is or may be located.

High-level radioactive waste or *HLW* means:

(1) 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;

(2) Irradiated reactor fuel; and

(3) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

HLW facility means a facility subject to the licensing and related regulatory authority of the Commission pursuant to sections 202(3) and 202(4) of the Energy

Reorganization Act of 1974 (88 Stat. 1244).[1]

Host rock means the geologic medium in which the waste is emplaced.

Important to safety, with reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in radiological exposures exceeding the values specified at § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide a reasonable expectation that high-level waste can be disposed of without exceeding the requirements of § 63.113(b) and (c).

Initiating event means a natural or human induced event that causes an event sequence.

Isolation means inhibiting the transport of radioactive material to:

(1) The location of the reasonably maximally exposed individual so that radiological exposures will not exceed the requirements of § 63.113(b); and

(2) The accessible environment so that releases of radionuclides into the accessible environment will not exceed the requirements of § 63.113(c).

Performance assessment means an analysis that:

(1) Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates the dose incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

Performance confirmation means the program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in subpart E of this part.

Permanent closure means final backfilling of the underground facility, if appropriate, and the sealing of shafts, ramps, and boreholes.

Preclosure safety analysis means a systematic examination of the site; the design; and the potential hazards, initiating events and event sequences and their consequences (e.g., radiological exposures to workers and the public). The analysis identifies structures, systems, and components important to safety.

Public Document Room means the place at One White Flint North, 11555 Rockville Pike, Room O–1F13, Rockville, MD, at which records of the Commission will ordinarily be made available for public inspection and any other place, the location of which has been published in the **Federal Register**, at which public records of the Commission pertaining to a geologic repository at the Yucca Mountain site are made available for public inspection.

Radioactive waste or *waste* means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reasonably maximally exposed individual means the hypothetical person meeting the criteria specified at § 63.312.

Reference biosphere means the description of the environment inhabited by the reasonably maximally exposed individual. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of permanently removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means the part of the earth's crust beneath the regional water table in which statistically all voids, large and small, are filled with water under pressure greater than atmospheric.

Site means that area surrounding the geologic repository operations area for which DOE exercises authority over its use in accordance with the provisions of this part.

Site characterization means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and the surrounding region to the extent necessary, relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at depth needed to determine the suitability of the site for a geologic repository.

Total effective dose equivalent (TEDE) means, for purposes of assessing doses to workers, the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). For purposes of assessing doses to members of the public (including the RMEI), TEDE means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Underground facility means the underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts, and boreholes, including their seals).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Unsaturated zone means the zone between the land surface and the regional water table. Generally, fluid pressure in this zone is less than atmospheric pressure, and some of the voids may contain air or other gases at atmospheric pressure. Beneath flooded areas or in perched water bodies, the fluid pressure locally may be greater than atmospheric.

Waste form means the radioactive waste materials and any encapsulating or stabilizing matrix.

Waste package means the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

[1] These are DOE "facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such Act (the Atomic Energy Act)" and "Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by (DOE), which are not used for, or are part of, research and development activities."

Water table means that surface in a ground-water body, separating the unsaturated zone from the saturated zone, at which the water pressure is atmospheric.

§ 63.3 License required.

(a) DOE may not receive nor possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site except as authorized by a license issued by the Commission under this part.

(b) DOE may not begin construction of a geologic repository operations area at the Yucca Mountain site unless it has filed an application with the Commission and has obtained construction authorization as provided in this part. Failure to comply with this requirement is grounds for denial of a license.

§ 63.4 Communications and records.

(a) Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Communications, reports, and applications may be delivered in person at the Commission's offices at 11555 Rockville Pike, Rockville, MD.

(b) Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 63.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel is binding on the Commission.

§ 63.6 Exemptions.

The Commission may, upon application by DOE, any interested person, or upon its own initiative, grant an exemption from the requirements of this part if it determines that the exemption is authorized by law, does not endanger life nor property nor the common defense and security, and is otherwise in the public interest.

§ 63.7 License not required for certain preliminary activities.

The requirement for a license set forth in § 63.3(a) is not applicable to the extent that DOE receives and possesses source, special nuclear, and byproduct material at a geologic repository at the Yucca Mountain site:

(a) For purposes of site characterization; or

(b) For use, during site characterization or construction, as components of radiographic, radiation monitoring, or similar equipment or instrumentation.

§ 63.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0199.

(b) The approved information collection requirements contained in this part appear in §§ 63.62, 63.63, and 63.65.

§ 63.9 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant, against an employee, for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission, or his or her employer, information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those aforementioned statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section, or under these requirements, if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section;

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section does not apply to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license;

(2) Imposition of a civil penalty on the licensee or applicant; or

(3) Other enforcement action.

(d) Actions taken by an employer, or others, that adversely affect an

employee, may be predicated on nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each licensee and each applicant for a license shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in § 19.11(c) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to part 20 of this chapter or by accessing the NRC Web site *www.nrc.gov/NRC/FORMS/forms3.html*.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision that would prohibit, restrict, or otherwise discourage an employee from participating in a protected activity as defined in paragraph (a)(1) of this section, including, but not limited to, providing information to NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

§ 63.10 Completeness and accuracy of information.

(a) Information provided to the Commission by an applicant for a license or by a licensee, or information required by statute, or required by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) The applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having, for the regulated activity, a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, within 2 working days of identifying the information. This requirement is not applicable to information that is already required to be provided to the Commission by other reporting or updating requirements.

§ 63.11 Deliberate misconduct.

(a) Any licensee, applicant for a license, employee of a licensee or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Subpart B—Licenses

Preapplication Review

§ 63.15 Site characterization.

(a) DOE shall conduct a program of site characterization with respect to the Yucca Mountain site before it submits an application for a license to be issued under this part.

(b) DOE shall conduct the investigations to obtain the required information in a manner that limits adverse effects on the long-term performance of the geologic repository at Yucca Mountain to the extent practical.

§ 63.16 Review of site characterization activities.[2]

(a) If DOE's planned site characterization activities include onsite testing with radioactive material, including radioactive tracers, the Commission shall determine whether the proposed use of such radioactive material is necessary to provide data for the preparation of the environmental reports required by law and for an application to be submitted under § 63.22.

(b) During the conduct of site characterization activities at the Yucca Mountain site, DOE shall report the nature and extent of the activities, the information that has been developed, and the progress of waste form and waste package research and development to the Commission not less than once every 6 months. The semiannual reports must include the results of site characterization studies, the identification of new issues, plans for additional studies to resolve new issues, elimination of planned studies no longer necessary, identification of decision points reached, and modifications to schedules, where appropriate. DOE shall also report its progress in developing the design of a geologic repository operations area appropriate for the area being characterized, noting when key design parameters or features that depend on the results of site characterization will be established. Other topics related to site characterization must also be covered if requested by the Director.

(c) During the conduct of site characterization activities at the Yucca Mountain site, NRC staff shall be permitted to visit and inspect the locations at which such activities are

[2] In addition to the review of site characterization activities specified in this section, the Commission contemplates an ongoing review of other information on site investigation and site characterization, to allow early identification of potential licensing issues for timely resolution at the staff level.

carried out and to observe excavations, borings, and in situ tests, as they are done.

(d) The Director may comment at any time in writing to DOE, expressing current views on any aspect of site characterization or performance assessment at the Yucca Mountain site. In particular, the Director shall comment whenever he or she determines that there are substantial grounds for making recommendations or stating objections to DOE's site characterization program. The Director shall invite public comment on any comments that the Director makes to DOE on review of the DOE semiannual reports or on any other comments that the Director makes to DOE on site characterization and performance assessment by placing the comments in a public forum to allow the public to comment on them after the Director's comments are sent to DOE.

(e) The Director shall transmit copies of all comments to DOE made by the Director under this section to the Governor and legislature of the State of Nevada and to the governing body of any affected Indian Tribe.

(f) All correspondence between DOE and NRC resulting from the requirements of this section, including the reports described in paragraph (b) of this section, must be placed in the Public Document Room.

(g) The activities described in paragraphs (a) through (f) of this section constitute informal conference between a prospective applicant and the NRC staff, as described in § 2.101(a)(1) of this chapter, and are not part of a proceeding under the Atomic Energy Act of 1954, as amended. Accordingly, the issuance of the Director's comments made under this section does not constitute a commitment to issue any authorization or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board, other presiding officers, or the Director, in any such proceeding.

License Application

§ 63.21 Content of application.

(a) An application consists of general information and a Safety Analysis Report. An environmental impact statement must be prepared in accordance with the Nuclear Waste Policy Act of 1982, as amended, and must accompany the application. Any Restricted Data or National Security Information must be separated from unclassified information. The application must be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) The general information must include:

(1) A general description of the proposed geologic repository at the Yucca Mountain site, identifying the location of the geologic repository operations area, the general character of the proposed activities, and the basis for the exercise of the Commission's licensing authority.

(2) Proposed schedules for construction, receipt of waste, and emplacement of wastes at the proposed geologic repository operations area.

(3) A description of the detailed security measures for physical protection of high-level radioactive waste in accordance with § 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.

(4) A description of the material control and accounting program to meet the requirements of § 63.78.

(5) A description of work conducted to characterize the Yucca Mountain site.

(c) The Safety Analysis Report must include:

(1) A description of the Yucca Mountain site, with appropriate attention to those features, events, and processes of the site that might affect design of the geologic repository operations area and performance of the geologic repository. The description of the site must include information regarding features, events, and processes outside of the site to the extent the information is relevant and material to safety or performance of the geologic repository. The information referred to in this paragraph must include:

(i) The location of the geologic repository operations area with respect to the boundary of the site;

(ii) Information regarding the geology, hydrology, and geochemistry of the site, including geomechanical properties and conditions of the host rock;

(iii) Information regarding surface water hydrology, climatology, and meteorology of the site; and

(iv) Information regarding the location of the reasonably maximally exposed individual, and regarding local human behaviors and characteristics, as needed to support selection of conceptual models and parameters used for the reference biosphere and reasonably maximally exposed individual.

(2) Information relative to materials of construction of the geologic repository operations area (including geologic media, general arrangement, and approximate dimensions), and codes and standards that DOE proposes to apply to the design and construction of the geologic repository operations area.

(3) A description and discussion of the design of the various components of the geologic repository operations area and the engineered barrier system including:

(i) Dimensions, material properties, specifications, analytical and design methods used along with any applicable codes and standards;

(ii) The design criteria used and their relationships to the preclosure and postclosure performance objectives specified at § 63.111(b), § 63.113(b), and § 63.113(c); and

(iii) The design bases and their relation to the design criteria.

(4) A description of the kind, amount, and specifications of the radioactive material proposed to be received and possessed at the geologic repository operations area at the Yucca Mountain site.

(5) A preclosure safety analysis of the geologic repository operations area, for the period before permanent closure, to ensure compliance with § 63.111(a), as required by § 63.111(c). For the purposes of this analysis, it is assumed that operations at the geologic repository operations area will be carried out at the maximum capacity and rate of receipt of radioactive waste stated in the application.

(6) A description of the program for control and monitoring of radioactive effluents and occupational radiological exposures to maintain such effluents and exposures in accordance with the requirements of § 63.111.

(7) A description of plans for retrieval and alternate storage of the radioactive wastes, should retrieval be necessary.

(8) A description of design considerations that are intended to facilitate permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(9) An assessment to determine the degree to which those features, events, and processes of the site that are expected to materially affect compliance with § 63.113—whether beneficial or potentially adverse to performance of the geologic repository—have been characterized, and the extent to which they affect waste isolation. Investigations must extend from the surface to a depth sufficient to determine principal pathways for radionuclide migration from the underground facility. Specific features,

events, and processes of the geologic setting must be investigated outside of the s[illegible] they affect performance of the geo[illegible]gic repository.

(10) An assessment of the anticipated response of the geomechanical, hydrogeologic, and geochemical systems to the range of design thermal loadings under consideration, given the pattern of fractures and other discontinuities and the heat transfer properties of the rock mass and water.

(11) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure, as required by § 63.113(b).

(12) An assessment of the ability of the proposed geologic repository to limit releases of radionuclides into the accessible environment as required by § 63.113(c).

(13) An assessment of the ability of the proposed geologic repository to limit radiological exposures to the reasonably maximally exposed individual for the period after permanent closure in the event of human intrusion into the engineered barrier system as required by § 63.113(d).

(14) An evaluation of the natural features of the geologic setting and design features of the engineered barrier system that are considered barriers important to waste isolation as required by § 63.115.

(15) An explanation of measures used to support the models used to provide the information required in paragraphs (c)(9) through (c)(14) of this section. Analyses and models that will be used to assess performance of the geologic repository must be supported by using an appropriate combination of such methods as field tests, in situ tests, laboratory tests that are representative of field conditions, monitoring data, and natural analog studies.

(16) 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.

(17) A description of the performance confirmation program that meets the requirements of subpart F of this part.

(18) An identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of license specifications. Special attention must be given to those items that may significantly influence the final design.

(19) An explanation of how expert elicitation was used.

(20) A description of the quality assurance program to be applied to the structures, systems, and components important to safety and to the engineered and natural barriers important to waste isolation. The description of the quality assurance program must include a discussion of how the applicable requirements of § 63.142 will be satisfied.

(21) A description of the plan for responding to, and recovering from, radiological emergencies that may occur at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities, as required by § 63.161.

(22) The following information concerning activities at the geologic repository operations area:

(i) The organizational structure of DOE as it pertains to construction and operation of the geologic repository operations area, including a description of any delegations of authority and assignments of responsibilities, whether in the form of regulations, administrative directives, contract provisions, or otherwise.

(ii) Identification of key positions that are assigned responsibility for safety at and operation of the geologic repository operations area.

(iii) Personnel qualifications and training requirements.

(iv) Plans for startup activities and startup testing.

(v) Plans for conduct of normal activities, including maintenance, surveillance, and periodic testing of structures, systems, and components of the geologic repository operations area.

(vi) Plans for permanent closure and plans for the decontamination or decontamination and dismantlement of surface facilities.

(vii) Plans for any 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.

(23) A description of the program to be used to maintain the records described in §§ 63.71 and 63.72.

(24) A description of the controls that DOE will apply to restrict access and to regulate land use at the Yucca Mountain site and adjacent areas, including a conceptual design of monuments that would be used to identify the site after permanent closure.

§ 63.22 Filing and distribution of application.

(a) An application for a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site that has been characterized, any amendments to the application, and an accompanying environmental impact statement and any supplements, must be signed by the Secretary of Energy or the Secretary's authorized representative and must be filed in triplicate with the Director.

(b) DOE shall submit 30 additional copies of each portion of the application and any amendments, and each environmental impact statement and any supplements. DOE shall retain another 120 copies for distribution in accordance with written instructions from the Director or the Director's designee.

(c) On notification of the appointment of an Atomic Safety and Licensing Board, DOE shall update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement must be served in the same manner.

(d) When an application, and any amendment to it is filed, copies must be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site for inspection by the public. These copies must be updated as amendments to the application are made. The environmental impact statement and any supplements to it must be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, must be produced at any public hearing held by the Commission on the application for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of these documents submitted as required by this part.

§ 63.23 Elimination of repetition.

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, if the references are clear and specific and copies of the information incorporated are made available to the public locations near the site of the proposed geologic repository, as specified in § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

(a) The application must be as complete as possible in light of the information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license—

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction;

(2) Conformance of construction of structures, systems, and components with the design;

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

Construction Authorization

§ 63.31 Construction authorization.

On review and consideration of an application and environmental impact statement submitted under this part, the Commission may authorize construction of a geologic repository operations area at the Yucca Mountain site if it determines:

(a) Safety.

(1) That there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received and possessed in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public; and

(2) That there is reasonable expectation that the materials can be disposed of without unreasonable risk to the health and safety of the public.

(3) In arriving at these determinations, the Commission shall consider whether—

(i) DOE has described the proposed geologic repository as specified at § 63.21;

(ii) The site and design comply with the performance objectives and requirements contained in subpart E of this part;

(iii) DOE's quality assurance program complies with the requirements of subpart G of this part;

(iv) DOE's personnel training program complies with the criteria contained in subpart H of this part;

(v) DOE's emergency plan complies with the criteria contained in subpart I of this part; and

(vi) DOE's proposed operating procedures to protect health and to minimize danger to life or property are adequate.

(b) Common defense and security. That there is reasonable assurance that the activities proposed in the application will not be inimical to the common defense and security.

(c) Environmental. That, after weighing the environmental, economic, technical, and other benefits against environmental costs, and considering available alternatives, the action called for is the issuance of the construction authorization, with any appropriate conditions to protect environmental values.

§ 63.32 Conditions of construction authorization.

(a) In a construction authorization for a geologic repository operations area at the Yucca Mountain site, the Commission shall include any conditions it considers necessary to protect the health and safety of the public, the common defense and security, or environmental values.

(b) The Commission shall incorporate provisions in the construction authorization requiring DOE to furnish periodic or special reports regarding:

(1) Progress of construction;

(2) Any data about the site, obtained during construction, that are not within the predicted limits on which the facility design was based;

(3) Any deficiencies, in design and construction, that, if uncorrected, could adversely affect safety at any future time; and

(4) Results of research and development programs being conducted to resolve safety questions.

(c) The construction authorization for a geologic repository operations area at the Yucca Mountain site will include restrictions on subsequent changes to the features of the geologic repository and the procedures authorized. The restrictions that may be imposed under this paragraph can include measures to prevent adverse effects on the geologic setting as well as measures related to the design and construction of the geologic repository operations area. These restrictions will fall into three categories of descending importance to public health and safety, as follows:

(1) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission;

(ii) 30 days notice of opportunity for a prior hearing; and

(iii) Prior Commission approval;

(2) Those features and procedures that may not be changed without—

(i) 60 days prior notice to the Commission; and

(ii) Prior Commission approval; and

(3) Those features and procedures that may not be changed without 60 days notice to the Commission. Features and procedures falling in this paragraph section may not be changed without prior Commission approval if the Commission, after having received the required notice, so orders.

(d) A construction authorization must be subject to the limitation that a license to receive and possess source, special nuclear, or byproduct material at the Yucca Mountain site geologic repository operations area may not be issued by the Commission until;

(1) DOE has updated its application, as specified at § 63.24; and

(2) The Commission has made the findings stated in § 63.41.

§ 63.33 Amendment of construction authorization.

(a) An application for amendment of a construction authorization must be filed with the Commission that fully describes any desired changes and follows, as far as applicable, the content requirements prescribed in § 63.21.

(b) In determining whether an amendment of a construction authorization will be approved, the Commission will be guided by the considerations that govern the issuance of the initial construction authorization, to the extent applicable.

License Issuance and Amendment

§ 63.41 Standards for issuance of a license.

A license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site may be issued by the Commission on finding that—

(a) Construction of the geologic repository operations area has been substantially completed in conformity with the application as amended, the provisions of the Atomic Energy Act, and the rules and regulations of the Commission. Construction may be considered substantially complete for the purposes of this paragraph if the construction of—

(1) Surface and interconnecting structures, systems, and components; and

(2) Any underground storage space required for initial operation, are substantially complete.

(b) The activities to be conducted at the geologic repository operations area will be in conformity with the application as amended, the provisions of the Atomic Energy Act and the Energy Reorganization Act, and the rules and regulations of the Commission.

(c) The issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public.

(d) Adequate protective measures can and will be taken in the event of a radiological emergency at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities.

(e) All applicable requirements of part 51 of this chapter have been satisfied.

§ 63.42 Conditions of license.

(a) The Commission shall include any 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 a license issued under this part.

(b) Whether stated in the license or not, the following are considered to be conditions in every license issued:

(1) The license is subject to revocation, suspension, modification, or amendment for cause, as provided by the Atomic Energy Act and the Commission's regulations.

(2) DOE shall, at any time while the license is in effect, on written request of the Commission, submit written statements to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

(3) The license is subject to the provisions of the Atomic Energy Act now or hereafter in effect and to all rules, regulations, and orders of the Commission. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to or by reason of rules, regulations, and orders issued in accordance with the terms of the Atomic Energy Act.

(c) Each license includes the provisions set forth in section 183 b–d, inclusive, of the Atomic Energy Act, whether or not these provisions are expressly set forth in the license.

(d) A license issued under this part includes the provisions set forth in section 114(d) of the Nuclear Waste Policy Act, as amended, defining the quantity of solidified high-level radioactive waste and spent nuclear fuel, until such time as a second repository is in operation, whether or not these provisions are expressly set forth in the license.

§ 63.43 License specification.

(a) A license issued under this part includes license conditions derived from the analyses and evaluations included in the application, including amendments made before a license is issued, together with any additional conditions the Commission finds appropriate.

(b) License conditions include items in the following categories:

(1) Restrictions as to the physical and chemical form and radioisotopic content of radioactive waste.

(2) Restrictions as to size, shape, and materials and methods of construction of radioactive waste packaging.

(3) Restrictions as to the amount of waste permitted per unit volume of storage space, considering the physical characteristics of both the waste and the host rock.

(4) Requirements relating to test, calibration, or inspection, to assure that the foregoing restrictions are observed.

(5) Controls to be applied to restrict access and to avoid disturbance to the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113.

(6) Administrative controls, which are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure that activities at the facility are conducted in a safe manner and in conformity with the other license specifications.

§ 63.44 Changes, tests, and experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the geologic repository operations area design or procedures that affects a design function, event sequence, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the Safety Analysis Report (SAR) (as updated) used in establishing the preclosure safety analyses or performance assessment* means:

(i) Changing any of the elements of the method described in the SAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the SAR to another method unless that method has been approved by NRC for the intended application, addition or removal.

(3) *Safety Analysis Report (SAR) (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as updated in accordance with § 63.24.

(4) *Geologic repository operations area as described in the SAR (as updated)* means:

(i) The structures, systems, and components important to safety or barriers important to waste isolation that are described in the SAR (as updated); and

(ii) The design and performance requirements for such structures, systems, and components described in the SAR (as updated).

(5) *Procedures as described in the SAR (as updated)* means those procedures that contain information described in the SAR (as updated) such as how structures, systems, and components important to safety, or important to waste isolation, are operated or controlled.

(6) *Tests or experiments not described in the SAR (as updated)* means any condition where the geologic repository operations area or any of its structures, systems, and components important to safety, or important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the SAR (as updated); or

(ii) Inconsistent with the analyses or descriptions in the SAR (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the SAR (as updated), make changes in the procedures as described in the SAR (as updated), and conduct tests or experiments not described in the SAR (as updated), without obtaining either an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, if:

(i) A change in the conditions incorporated in the construction authorization or license is not required; and

(ii) The change, test, or experiment does not meet any of the criteria in paragraph (b)(2) of this section.

(2) DOE shall obtain an amendment of construction authorization under § 63.33 or a license amendment under § 63.45, before implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the frequency of occurrence of an event sequence previously evaluated in the SAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an event sequence previously evaluated in the SAR (as updated);

(iv) Result in more than a minimal increase in the consequences of malfunction of structures, systems, components important to safety, or important to waste isolation, which were previously evaluated in the SAR (as updated);

(v) Create the possibility for an event sequence, or of a pathway for release of radionuclides, of a different type than any evaluated previously in the SAR (as updated);

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety, or important to waste isolation, with a different result than any evaluated previously in the SAR (as updated);

(vii) Result in a departure from a method of evaluation described in the SAR (as updated) used in establishing the preclosure safety analysis or the performance assessment.

(3) In implementing this paragraph, the SAR (as updated) is considered to include SAR changes resulting from evaluations performed pursuant to this section and from safety analyses performed under § 63.33 or § 63.45, as applicable, after the last Safety Analysis Report was updated under § 63.24.

(4) The provisions in this section do not apply to changes to the geologic repository operations area or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(c)(1) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site, of changes in procedures, and of tests and experiments made under paragraph (b) of this section. These records must include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require an amendment of construction authorization or license amendment under paragraph (b) of this section.

(2) No less frequently than every 24 months, DOE shall prepare a report containing a brief description of such changes, tests, and experiments, including a summary of the evaluation of each. DOE shall furnish the report to the appropriate NRC Regional Office shown in appendix D to part 20 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Any report submitted under this paragraph must be made a part of the public record of the licensing proceedings.

(d) Changes to the quality assurance program description required by § 63.21(c)(20) must be processed in accordance with § 63.144.

§ 63.45 Amendment of license.

(a) An application for amendment of a license may be filed with the Commission fully describing the changes desired and following as far as applicable the format prescribed for license applications.

(b) In determining whether an amendment of a license will be approved, the Commission will be guided by the considerations that govern the issuance of the initial license, to the extent applicable.

§ 63.46 Particular activities requiring license amendment.

(a) Unless expressly authorized in the license, a license amendment is required for any of the following activities:

(1) Any action that would make emplaced high-level radioactive waste irretrievable or that would substantially increase the difficulty of retrieving the emplaced waste;

(2) Dismantling of structures;

(3) Removal or reduction of controls applied to restrict access to or avoid disturbance of the site and to areas outside the site where conditions may affect compliance with §§ 63.111 and 63.113;

(4) Destruction or disposal of records required to be maintained under the provisions of this part;

(5) Any substantial change to the design or operating procedures from that specified in the license, except as authorized in § 63.44; and

(6) Permanent closure.

(b) An application for an amendment must be filed, and will be reviewed, as specified in § 63.45.

Permanent Closure

§ 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission must consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required by subpart F, and pertinent to compliance with § 63.113.

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed—such as land use controls, construction of monuments, and preservation of records—to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, these measures must include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed, fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders—such records to identify the location of the geologic repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, drip shields, waste packages, interactions between

natural and engineered systems, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of permanent closure, DOE shall also supplement its environmental impact statement and submit this statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site, DOE may apply for an amendment to terminate the license.

(b) The application must be filed and will be reviewed in accordance with the provisions of § 63.45 and this section.

(c) A license may be terminated only when the Commission finds with respect to the geologic repository:

(1) That the final disposition of radioactive wastes has been made in conformance with DOE's plan, as amended and approved as part of the license.

(2) That the final state of the geologic repository operations area conforms to DOE's plans for permanent closure and DOE's plans for the decontamination or decontamination and dismantlement of surface facilities, as amended and approved as part of the license.

(3) That the termination of the license is authorized by law, including sections 57, 62, and 81 of the Atomic Energy Act, as amended.

Subpart C—Participation by State Government, Affected Units of Local Government, and Affected Indian Tribes

§ 63.61 Provision of information.

(a) The Director shall provide the Governor and the Nevada State legislature, affected units of local government, and the governing body of any affected Indian Tribe, with timely and complete information regarding determinations or plans made by the Commission with respect to the Yucca Mountain site. Information must be provided concerning the site characterization, siting, development, design, licensing, construction, operation, regulation, permanent closure, or decontamination and dismantlement of surface facilities of the geologic repository operations area at the site.

(b) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to the document, that entity or its counsel is included on a service list prepared under part 2 of this chapter.

(c) Copies of all communications by the Director under this section must be placed in the Public Document Room and furnished to DOE.

§ 63.62 Site review.

(a) The Director shall make the NRC staff available to consult with representatives of the State of Nevada, affected units of local government, and affected Indian Tribes regarding the status of site characterization at the Yucca Mountain site.

(b) Requests for consultation must be made in writing to the Director.

(c) Consultation under this section may include:

(1) Keeping the parties informed of the Director's views on the progress of site characterization.

(2) Review of applicable NRC regulations, licensing procedures, schedules, and opportunities for State, affected units of local government, and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State, affected units of local government, and Tribal participation in license reviews.

§ 63.63 Participation in license reviews.

(a) The State, affected units of local government, and affected Indian Tribes may participate in license reviews as provided in subpart J of part 2 of this chapter.

(b) In addition, a State, or an affected unit of local government, or an affected Indian Tribe may submit a proposal to the Director to facilitate its participation in the review of the license application. The proposal may be submitted at any time and must contain a description and schedule of how the State, or affected unit of local government, or affected Indian Tribe wishes to participate in the review, or what services or activities the State, or affected unit of local government, or affected Indian Tribe wishes the NRC to carry out, and how the services or activities proposed to be carried out by the NRC would contribute to this participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as establishing additional public document rooms or employment exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State, or affected unit of local government, or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State, or affected unit of local government, or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described in paragraph (c) of this section, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State, or affected unit of local government, or affected Indian Tribe may bear;

(2) The proposed activities—

(i) Will enhance communications between NRC and the State, or affected unit of local government, or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director shall advise the State, or affected unit of local government, or affected Indian Tribe whether its proposal has been accepted or denied. If all or any part of a proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses to them, must be made available at the Public Document Room.

§ 63.64 Notice to State.

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide the notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

§ 63.65 Representation.

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature of Nevada), for an affected unit of local government, or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in this capacity.

Subpart D—Records, Reports, Tests, and Inspections

§ 63.71 Records and reports.

(a) DOE shall maintain records and make reports in connection with the licensed activity that are required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site must contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

§ 63.72 Construction records.

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

(b) The records required under paragraph (a) of this section must include at least the following—

(1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;

(2) A description of the materials encountered;

(3) Geologic maps and geologic cross-sections;

(4) Locations and amount of seepage;

(5) Details of equipment, methods, progress, and sequence of work;

(6) Construction problems;

(7) Anomalous conditions encountered;

(8) Instrument locations, readings, and analysis;

(9) Location and description of structural support systems;

(10) Location and description of dewatering systems;

(11) Details, methods of emplacement, and location of seals used; and

(12) Facility design records (e.g, design specifications and "as built" drawings).

§ 63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design, and construction of the geologic repository operations area that, were it to remain uncorrected, could—

(1) Adversely affect safety at any future time;

(2) Represent a significant deviation from the design criteria and design basis stated in the design application; or

(3) Represent a deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) DOE shall implement a program for evaluating and reporting deviations and failures to comply, to identify defects and failures to comply associated with substantial safety hazards, based on the applicable requirements in 10 CFR 50.55(e) as it applies to the construction authorization and design of the geologic repository operations area at the Yucca Mountain site.

(c) DOE shall implement a program of reporting specific events and conditions that is the same as that specified in 10 CFR 72.75.

(d) The requisite notification must be as specified in the applicable regulation. Copies of the written report must be sent to the NRC Operations Center, Document Control Desk, U.S. NRC, to the Director of NMSS, U.S. NRC, and to the NRC onsite representative.

§ 63.74 Tests.

(a) DOE shall perform, or permit the Commission to perform, those tests the Commission considers appropriate or necessary for the administration of the regulations in this part. This may include tests of—

(1) Radioactive waste,

(2) The geologic repository, including portions of the geologic setting and the structures, systems, and components constructed or placed therein,

(3) Radiation detection and monitoring instruments, and

(4) Other equipment and devices used in connection with the receipt, handling, or storage of radioactive waste.

(b) The tests required under this section must include a performance confirmation program carried out in accordance with subpart F of this part.

§ 63.75 Inspections.

(a) DOE shall allow the Commission to inspect the premises of the geologic repository operations area at the Yucca Mountain site and adjacent areas to which DOE has rights of access.

(b) DOE shall make available to the Commission for inspection, on reasonable notice, records kept by DOE pertaining to activities under this part.

(c)(1) DOE shall, on requests by the Director, Office of Nuclear Material Safety and Safeguards, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air-conditioning, light, electrical outlets, and janitorial services must be furnished by DOE. The office must be convenient to and have full access to the facility and must provide the inspector both visual and acoustic privacy.

(2) The space provided must be adequate to accommodate two full-time inspectors, and other transient NRC personnel and will be generally commensurate with other office facilities at the Yucca Mountain site geologic repository operations area. A space of 250 square feet either within the geologic repository operations area's office complex or in an office trailer or other onsite space at the geologic repository operations area is suggested as a guide. For locations at which activities are carried out under licenses issued under other parts of this chapter, additional space may be requested to accommodate additional full-time inspectors. The office space provided is subject to the approval of the Director, Office of Nuclear Material Safety and Safeguards. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) DOE shall afford any NRC resident inspector assigned to the Yucca Mountain site or other NRC inspectors identified by the Regional Administrator as likely to inspect the Yucca Mountain facility, immediate unfettered access, equivalent to access provided regular employees, after proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

§ 63.78 Material control and accounting records and reports.

DOE shall implement a program of material control and accounting (and accidental criticality reporting) that is the same as that specified in §§ 72.72, 72.74, 72.76, and 72.78 of this chapter.

Subpart E—Technical Criteria

§ 63.101 Purpose and nature of findings.

(a)(1) Subpart B prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives for postclosure performance of the geologic repository and other criteria that, if satisfied, support a finding of no unreasonable risk.

Postclosure performance objectives for the geologic repository include a requirement to limit radiological exposures to the reasonably maximally exposed individual, a requirement to limit releases of radionuclides to the accessible environment to protect ground water, and a requirement to limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion (see § 63.113(b), (c), and (d), respectively).

(2) Although the postclosure performance objectives specified at § 63.113 are generally stated in unqualified terms, it is not expected that complete assurance that the requirements will be met can be presented. A reasonable expectation, on the basis of the record before the Commission, that the postclosure performance objectives will be met, is the general standard required. Proof that the geologic repository will conform with the objectives for postclosure performance is not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable expectation, making allowance for the time period, hazards, and uncertainties involved, that the outcome will conform with the objectives for postclosure performance for the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Compliance demonstrations should not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. The performance assessments and analyses should focus upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values. Further, in reaching a determination of reasonable expectation, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

(b) Subpart B lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. Prior to closure, § 63.31(a)(1) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and stored in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. After permanent closure, § 63.31(a)(2) requires the Commission to consider whether there is a reasonable expectation the site and design comply with the postclosure performance objectives. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to paragraph (a)(2) of § 63.31.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency, the definitions in § 63.2 prevail.

(a) *The HLW facility at the Yucca Mountain site.* NRC exercises licensing and related regulatory authority over those facilities described in section 202 (3) and (4) of the Energy Reorganization Act of 1974, including the site at Yucca Mountain, as designated by the Energy Policy Act of 1992.

(b) *The geologic repository operations area.*

(1) These regulations deal with the exercise of authority with respect to a particular class of HLW facility—namely, a geologic repository operations area at Yucca Mountain.

(2) A *geologic repository operations area* consists of those surface and subsurface areas of the site that are part of a geologic repository where radioactive waste handling activities are conducted. The underground structure, backfill materials, if any, and openings that penetrate the underground structure (e.g., ramps, shafts and boreholes, including their seals), are designated the *underground facility*.

(3) The exercise of Commission authority requires that the geologic repository operations area be used for storage (which includes disposal) of *high-level radioactive wastes* (HLW).

(4) HLW includes irradiated reactor fuel as well as reprocessing wastes. However, if DOE proposes to use the geologic repository operations area for storage of radioactive waste other than HLW, the storage of this radioactive waste is subject to the requirements of this part.

(c) *Stages in the licensing process.* There are several stages in the licensing process. The *site characterization* stage, when the performance confirmation program is started, begins before submission of a license application, and may result in consequences requiring evaluation in the license review. The construction stage would follow after the issuance of a construction authorization. A period of operations follows the Commission's issuance of a license. The period of operations includes the time during which *emplacement* of wastes 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.

(d) *Areas related to isolation.* Although the activities subject to regulation under this part are those to be carried out at the geologic repository operations area, the licensing process also considers characteristics of adjacent areas that are defined in other ways. There must be an area surrounding the geologic repository operations area, that could include either a portion or all of the site, within which DOE shall exercise specified controls to prevent adverse human actions after permanent closure. There is an area, designated the geologic setting, which includes the geologic, hydrologic, and geochemical systems of the region in which the site and geologic repository operations area are located. The geologic repository operations area, plus the portion of the geologic setting that provides isolation of the radioactive waste, make up the geologic repository.

(e) *Performance objectives through permanent closure.* Before permanent closure, the geologic repository operations area is required to limit radiation levels and radiological exposures, in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, as specified at § 63.111(a).

(f) *Preclosure safety analysis.* Section 63.111 includes performance objectives for the geologic repository operations area for the period before permanent closure and decontamination or permanent closure, decontamination, and dismantlement of surface facilities. The preclosure safety analysis is a systematic examination of the site; the design; and the potential hazards, initiating events and their resulting event sequences and potential radiological exposures to workers and the public. 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 consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public). The analysis identifies structures, systems, and components important to safety.

(g) *Performance objectives after permanent closure.* After permanent closure, the geologic repository is required to:

(1) Limit radiological exposures to the reasonably maximally exposed individual, as specified at § 63.113(b);

(2) Limit releases of radionuclides to the accessible environment to protect ground water, as specified at § 63.113(c); and

(3) Limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion, as specified at § 63.113(d).

(h) *Multiple barriers.* Section 63.113(a) requires that the geologic repository include multiple barriers, both natural and engineered. Geologic disposal of HLW is predicated on the expectation that one or more aspects of the geologic setting will be capable of contributing to the isolation of radioactive waste and thus be a barrier important to waste isolation. Although there is an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. In addition, there are uncertainties in the isolation capability and performance of engineered barriers. Although the composition and configuration of engineered structures (barriers) can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeologic and natural analogs, there is a limited experience base for the performance of complex, engineered structures over periods longer than a few hundred years, considering the uncertainty in characterizing and modeling individual barriers. These uncertainties are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system is required in addition to the natural barriers provided by the geologic setting. The performance assessment provides an evaluation of the repository performance based on credible models and parameters including the consideration of uncertainty in the behavior of the repository system. Thus the performance assessment results reflect the capability of each of the barriers to cope with a variety of challenges (e.g., combinations of parameters leading to less favorable performance for individual barriers and combinations of barriers). A description of each barrier's capability (e.g., retardation of radionuclides in the saturated zone, waste package lifetime, matrix diffusion in the unsaturated zone), as reflected in the performance assessment, provides an understanding of how the natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository. The Commission believes that this understanding can increase confidence that the postclosure performance objectives specified at § 63.113(b) and (c) will be achieved and that DOE's design includes a system of multiple barriers.

(i) *Reference biosphere and reasonably maximally exposed individual.* The performance assessment will estimate the amount of radioactive material released to water or air at various locations and times in the future. To estimate the potential for future human exposures resulting from release of radioactive material from a geologic repository at Yucca Mountain, it is necessary to make certain assumptions about the location and characteristics of the reasonably maximally exposed individual. The environment inhabited by the reasonably maximally exposed individual, along with associated human exposure pathways and parameters, make up the reference biosphere, as described in § 63.305. The reasonably maximally exposed individual, as a hypothetical person living in a community with characteristics of the Town of Amargosa Valley, is a representative person using water with average concentrations of radionuclides as described at § 63.312. The reasonably maximally exposed individual is selected to represent those persons in the vicinity of Yucca Mountain who are reasonably expected to receive the greatest exposure to radioactive material released from a geologic repository at Yucca Mountain. Characteristics of the reference biosphere and the reasonably maximally exposed individual are to be based on current human behavior and biospheric conditions in the region, as described in § 63.305 and § 63.312.

(j) *Performance assessment.* Demonstrating compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment to quantitatively estimate radiological exposures to the reasonably maximally exposed individual at any time during the compliance period. The performance assessment is a systematic analysis that identifies the features, events, and processes (i.e., specific conditions or attributes of the geologic setting, degradation, deterioration, or alteration processes of engineered barriers, and interactions between the natural and engineered barriers) that might affect performance of the geologic repository; examines their effects on performance; and estimates the radiological exposures to the reasonably maximally exposed individual. The features, events, and processes considered in the performance assessment should represent a wide range of both beneficial and potentially adverse effects on performance (e.g., beneficial effects of radionuclide sorption; potentially adverse effects of fracture flow or a criticality event). Those features, events, and processes expected to materially affect compliance with § 63.113(b) or be potentially adverse to performance are included, while events (event classes or scenario classes) that are very unlikely (less than one chance in 10,000 over 10,000 years) can be excluded from the analysis. An event class consists of all possible specific initiating events that are caused by a common natural process (e.g., the event class for seismicity includes the range of credible earthquakes for the Yucca Mountain site). Radiological exposures to the reasonably maximally exposed individual are estimated using the selected features, events, and processes, and incorporating the probability that the estimated exposures will occur. Additionally, performance assessment methods are appropriate for use in demonstrating compliance with the postclosure performance objectives for ground-water protection and human intrusion, and are subject to the requirements for performance assessments specified at § 63.114 and applicable criteria in Subpart L (e.g., criteria for evaluating compliance with ground-water protection and individual protection standards).

(k) *Institutional controls.* Active and passive institutional controls will be maintained over the Yucca Mountain site, and are expected to reduce significantly, but not eliminate, the potential for human activity that could inadvertently cause or accelerate the release of radioactive material. However, because it is not possible to make scientifically sound forecasts of the long-term reliability of institutional controls, it is not appropriate to include consideration of human intrusion into a fully risk-based performance assessment for purposes of evaluating the ability of

the geologic repository to achieve the performance objective at § 63.113(b). Hence, human intrusion is addressed in a stylized manner as described in paragraph (l) of this section.

(l) *Human intrusion.* In contrast to events unrelated to human activity, the probability and characteristics of human intrusion occurring many hundreds or thousands of years into the future cannot be estimated by examining either the historic or geologic record. Rather than speculating on the nature and probability of future intrusion, it is more useful to assess how resilient the geologic repository would be against a human intrusion event. Although the consequences of an assumed intrusion event would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of human intrusion specified at §§ 63.321, 63.322 and 63.342 of subpart L of this part.

(m) *Performance confirmation.* A performance confirmation program will be conducted to evaluate the adequacy of assumptions, data, and analyses that led to the findings that permitted construction of the repository and subsequent emplacement of the wastes. Key geotechnical and design parameters, including any interactions between natural and engineered systems and components, will be monitored throughout site characterization, construction, emplacement, and operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified at § 63.113(b) and (c).

(n) *Ground-Water Protection.* Separate ground-water protection standards are designed to protect the ground water resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of ground water concentrations in the representative volume of water. Depending on the radionuclide, the estimated concentrations must either be below a specified concentration or result in an annual, drinking water dose to the whole body or any organ of no greater than 0.04 mSv (4 mrem). Although the estimation of radionuclide concentrations in the representative volume would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of ground-water protection specified at §§ 63.331, 63.332 and 63.342 of subpart L of this part.

Preclosure Performance Objectives

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) *Protection against radiation exposures and releases of radioactive material.*

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual TEDE (hereafter referred to as "dose") to any real member of the public located beyond the boundary of the site may not exceed the preclosure standard specified at § 63.204.

(b) *Numerical guides for design objectives.*

(1) The geologic repository operations area must be designed so that, taking into consideration Category 1 event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area must be designed so that, taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site will receive, as a result of the single Category 2 event sequence, the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysis.* A preclosure safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 must be performed. This analysis must demonstrate that:

(1) The requirements of § 63.111(a) will be met; and

(2) The design meets the requirements of § 63.111(b).

(d) *Performance confirmation.* The geologic repository operations area must be designed so as to permit implementation of a performance confirmation program that meets the requirements of subpart F of this part.

(e) *Retrievability of waste.*

(1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the geologic repository operations area must be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period is approved or specified by the Commission. This different time period may be established on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

(2) This requirement may not preclude decisions by the Commission to allow backfilling part, or all of, or permanent closure of the geologic repository operations area, before the end of the period of design for retrievability.

(3) For purposes of paragraph (e) of this section, a reasonable schedule for retrieval is one that would permit retrieval in about the same time as that required to construct the geologic repository operations area and emplace waste.

Preclosure Safety Analysis

§ 63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

The preclosure safety analysis of the geologic repository operations area must include:

(a) A general description of the structures, systems, components, equipment, and process activities at the geologic repository operations area;

(b) An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential event sequences;

(c) Data pertaining to the Yucca Mountain site, and the surrounding region to the extent necessary, used to identify naturally occurring and human-induced hazards at the geologic repository operations area;

(d) The technical basis for either inclusion or exclusion of specific, naturally occurring and human-induced hazards in the safety analysis;

(e) An analysis of the performance of the structures, systems, and components to identify those that are important to safety. This analysis identifies and describes the controls that are relied on to limit or prevent potential event sequences or mitigate their

consequences. This analysis also identifies measures taken to ensure the availability of safety systems. The analysis required in this paragraph must include, but not necessarily be limited to, consideration of—

(1) Means to limit concentration of radioactive material in air;

(2) Means to limit the time required to perform work in the vicinity of radioactive materials;

(3) Suitable shielding;

(4) Means to monitor and control the dispersal of radioactive contamination;

(5) Means to control access to high radiation areas or airborne radioactivity areas;

(6) Means to prevent and control criticality;

(7) Radiation alarm system to warn of significant increases of radiation levels, concentrations of radioactive material in air, and increased radioactivity in effluents;

(8) Ability of structures, systems, and components to perform their intended safety functions, assuming the occurrence of event sequences;

(9) Explosion and fire detection systems and appropriate suppression systems;

(10) Means to control radioactive waste and radioactive effluents, and permit prompt termination of operations and evacuation of personnel during an emergency;

(11) Means to provide reliable and timely emergency power to instruments, utility service systems, and operating systems important to safety if there is a loss of primary electric power;

(12) Means to provide redundant systems necessary to maintain, with adequate capacity, the ability of utility services important to safety; and

(13) Means to inspect, test, and maintain structures, systems, and components important to safety, as necessary, to ensure their continued functioning and readiness.

(f) A description and discussion of the design, both surface and subsurface, of the geologic repository operations area, including—

(1) The relationship between design criteria and the requirements specified at § 63.111(a) and (b); and

(2) The design bases and their relation to the design criteria.

Postclosure Performance Objectives

§ 63.113 Performance objectives for the geologic repository after permanent closure.

(a) The geologic repository must include multiple barriers, consisting of both natural barriers and an engineered barrier system.

(b) The engineered barrier system must be designed so that, working in combination with natural barriers, radiological exposures to the reasonably maximally exposed individual are within the limits specified at § 63.311 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of Subpart L of this part.

(c) The engineered barrier system must be designed so that, working in combination with natural barriers, releases of radionuclides into the accessible environment are within the limits specified at § 63.331 of subpart L of this part. Compliance with this paragraph must be demonstrated through a performance assessment that meets the requirements specified at § 63.114 of this subpart and §§ 63.303, 63.332 and 63.342 of subpart L of this part.

(d) The ability of the geologic repository to limit radiological exposures to the reasonably maximally exposed individual, in the event of human intrusion into the engineered barrier system, must be demonstrated through an analysis that meets the requirements at §§ 63.321 and 63.322 of subpart L of this part. Estimating radiological exposures to the reasonably maximally exposed individual requires a performance assessment that meets the requirements specified at § 63.114 of this subpart, and §§ 63.303, 63.305, 63.312 and 63.342 of subpart L of this part.

Postclosure Performance Assessment

§ 63.114 Requirements for performance assessment.

Any performance assessment used to demonstrate compliance with § 63.113 must:

(a) Include data related to the geology, hydrology, and geochemistry (including disruptive processes and events) of the Yucca Mountain site, and the surrounding region to the extent necessary, and information on the design of the engineered barrier system used to define parameters and conceptual models used in the assessment.

(b) Account for uncertainties and variabilities in parameter values and provide for the technical basis for parameter ranges, probability distributions, or bounding values used in the performance assessment.

(c) Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding and evaluate the effects that alternative conceptual models have on the performance of the geologic repository.

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

(a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers.

(c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste. The technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessments used to demonstrate compliance with § 63.113(b) and (c).

Land Ownership and Control

§ 63.121 Requirements for ownership and control of interests in land.

(a) *Ownership of land.*

(1) 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.

(2) These lands must be held free and clear of all encumbrances, if significant, such as:

(i) Rights arising under the general mining laws;

(ii) Easements for right-of-way; and

(iii) All other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) *Additional controls for permanent closure.* Appropriate controls must be established outside of the geologic repository operations area. 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.

(c) *Additional controls through permanent closure.* Appropriate controls must be established outside the geologic repository operations area. DOE shall exercise any jurisdiction or control of activities necessary to ensure the requirements at § 63.111(a) and (b) are met. Control includes the authority to exclude members of the public, if necessary.

(d) *Water rights.*

(1) DOE shall also have obtained such water rights as may be needed to accomplish the purpose of the geologic repository operations area.

(2) Water rights are included in the additional controls to be established under paragraph (b) of this section.

Subpart F—Performance Confirmation Program

§ 63.131 General requirements.

(a) The performance confirmation program must provide data that indicate, where practicable, whether:

(1) Actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review; and

(2) Natural and engineered systems and components required for repository operation, and that are designed or assumed to operate as barriers after permanent closure, are functioning as intended and anticipated.

(b) The program must have been started during site characterization, and it will continue until permanent closure.

(c) The program must include in situ monitoring, laboratory and field testing, and in situ experiments, as may be appropriate to provide the data required by paragraph (a) of this section.

(d) The program must be implemented so that:

(1) It does not adversely affect the ability of the geologic and engineered elements of the geologic repository to meet the performance objectives.

(2) It provides baseline information and analysis of that information on those parameters and natural processes pertaining to the geologic setting that may be changed by site characterization, construction, and operational activities.

(3) It monitors and analyzes changes from the baseline condition of parameters that could affect the performance of a geologic repository.

§ 63.132 Confirmation of geotechnical and design parameters.

(a) During repository construction and operation, a continuing program of surveillance, measurement, testing, and geologic mapping must be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of design changes needed to accommodate actual field conditions encountered.

(b) Subsurface conditions must be monitored and evaluated against design assumptions.

(c) Specific geotechnical and design parameters to be measured or observed, including any interactions between natural and engineered systems and components, must be identified in the performance confirmation plan.

(d) These measurements and observations must be compared with the original design bases and assumptions. If significant differences exist between the measurements and observations and the original design bases and assumptions, the need for modifications to the design or in construction methods must be determined and these differences, their significance to repository performance, and the recommended changes reported to the Commission.

(e) In situ monitoring of the thermomechanical response of the underground facility must be conducted until permanent closure, to ensure that the performance of the geologic and engineering features is within design limits.

§ 63.133 Design testing

(a) During the early or developmental stages of construction, a program for testing of engineered systems and components used in the design, such as, for example, borehole and shaft seals, backfill, and drip shields, as well as the thermal interaction effects of the waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

(b) The testing must be initiated as early as practicable.

(c) If backfill is included in the repository design, a test must be conducted to evaluate the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Tests must be conducted to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

(d) The waste package monitoring program must continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfactorily in service. Quality assurance includes

quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 63.142 Quality assurance criteria.

(a) *Introduction and Applicability.* DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied. DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) *Organization.* DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components.

(2) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

(3) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must have direct access to the levels of management as may be necessary to perform this function.

(c) *Quality assurance program.* DOE shall establish a quality assurance program that complies with the requirements of this subpart at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout facility life in accordance with those policies, procedures, or instructions.

(1) DOE shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.

(2) Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

(3) The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

(4) DOE shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

(d) *Design control.* (1) DOE shall establish measures to assure that applicable regulatory requirements and the design basis, as defined in § 63.2 and as specified in the license application, for those structures, systems, and components to which this subpart applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are important to waste isolation and important to safety functions of the structures, systems and components.

(2) DOE shall establish measures to identify and control design interfaces and for coordination among participating design organizations. These measures must include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(i) The design control measures must provide for verifying or checking the adequacy of design, such as by the

performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process must be performed by individuals or groups other than those who performed the original design. These individuals may be from the same organization. If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures must be applied to items such as: criticality physics, stress, thermal, hydraulic, and preclosure and postclosure analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests.

(ii) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.

(e) *Procurement document control.* DOE shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this section.

(f) *Instructions, procedures, and drawings.* Activities affecting quality must be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(g) *Document control.* DOE shall establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

(h) *Control of purchased material, equipment, and services.* DOE shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

(1) These measures must include appropriate provisions for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(2) Documentary evidence that material and equipment conform to the procurement requirements must be available at the high-level waste repository site before the material and equipment are installed or used. This documentary evidence must be retained at the high-level waste repository site and be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

(3) The effectiveness of the control of quality by contractors and subcontractors must be assessed by the licensee or applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

(i) *Identification and control of materials, parts, and components.* Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.

(j) *Control of special processes.* DOE shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(k) *Inspection.* DOE shall establish and execute a program for inspection of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(l) *Test control.* DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components important to safety will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

(m) *Control of measuring and test equipment.* DOE shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(n) *Handling, storage, and shipping.* DOE shall establish measures to control the handling, storage, shipping, cleaning

and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

(o) *Inspection, test, and operating status.* DOE shall establish measures to indicate the status of inspections and tests performed on individual items of the high-level waste repository by markings such as stamps, tags, labels, routing cards, or other suitable means. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of structures, systems, and components of the high-level waste repository, such as by tagging valves and switches, to prevent inadvertent operation.

(p) *Nonconforming materials, parts, or components.* DOE shall establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

§ 63.144 Quality assurance program change.

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows:

(a) DOE may change a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted every 24 months, in accordance with paragraph (b)(1) of this section. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC which is more recent than the quality assurance standard in DOE's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(b) DOE shall submit changes made to the NRC-accepted Safety Analysis Report quality assurance program description that do reduce the commitments to the NRC and receive NRC approval prior to implementation, as follows:

(1) The signed original must be submitted to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the Director, Office of Nuclear Material and Safeguards, U. S. Nuclear Regulatory Commission, Washington, DC 20555, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site or facility.

(2) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to describe how the requirements of § 63.142 will be satisfied and continues to satisfy the criteria of § 63.142 and the Safety Analysis Report quality assurance program description previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) DOE shall maintain records of quality assurance program changes that do reduce commitments.

Subpart H—Training and Certification of Personnel

§ 63.151 General requirements.

Operations of systems and components that have been identified as

important to safety in the Safety Analysis Report and in the license must ' performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

§ 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.

§ 63.153 Physical requirements.

The physical condition and the general health of personnel certified for operations that are important to safety may not be such as might cause operational errors that could endanger the public health and safety. Any condition that might cause impaired judgment or motor coordination must be considered in the selection of personnel for activities that are important to safety. These conditions need not categorically disqualify a person, so long as appropriate provisions are made to accommodate the conditions.

Subpart I—Emergency Planning Criteria

§ 63.161 Emergency plan for the geologic repository operations area through permanent closure.

DOE shall develop and be prepared to implement a plan to cope with radiological accidents that may occur at the geologic repository operations area, at any time before permanent closure and decontamination or decontamination and dismantlement of surface facilities. The emergency plan must be based on the criteria of § 72.32(b) of this chapter.

Subpart J—Violations

§ 63.171 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 63.172 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in this part 63 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in this part 63 that are not issued under sections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 63.1, 63.2, 63.5, 63.6, 63.7, 63.8, 63.15, 63.16, 63.21, 63.22, 63.23, 63.24, 63.31, 63.32, 63.33, 63.41, 63.42, 63.43, 63.45, 63.46, 63.51, 63.52, 63.61, 63.62, 63.63, 63.64, 63.65, 63.101, 63.102, 63.111, 63.112, 63.113, 63.114, 63.115, 63.121, 63.131, 63.132, 63.133, 63.134, 63.141, 63.142, 63.143, 63.153, 63.161, 63.171, 63.172, 63.201, 63.202, 63.203, 63.204, 63.301, 63.302, 63.303, 63.304, 63.305, 63.311, 63.312, 63.321, 63.322, 63.331, 63.332, 63.341, and 63.342.

Subpart K—Preclosure Public Health and Environmental Standards

§ 63.201 Purpose and scope.

This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site. For the purposes of demonstrating compliance with this subpart, to the extent there may be any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.202 Definitions for Subpart K.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

Member of the public means anyone who is not a radiation worker for purposes of worker protection.

Radioactive material means matter composed of or containing radionuclides subject to the Atomic Energy Act of 1954, as amended (42 U.S.C. sec. 2014 et seq.). Radioactive material includes, but is not limited to, high-level radioactive waste and spent nuclear fuel.

Spent nuclear fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

Storage means retention (and any associated activity, operation, or process necessary to carry out successful retention) of radioactive material with the intent or capability to readily access or retrieve such material.

Yucca Mountain repository means the excavated portion of the facility constructed underground within the Yucca Mountain site.

Yucca Mountain site means:

(1) The site recommended by the Secretary of DOE to the President under section 112(b)(1)(B) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10132(b)(1)(B)) on May 27, 1986; or

(2) The area under the control of DOE for the use of Yucca Mountain activities at the time of licensing, if the site designated under the Nuclear Waste Policy Act is amended by Congress prior to the time of licensing.

§ 63.203 Implementation of Subpart K.

DOE must demonstrate that normal operations at the Yucca Mountain site will and do occur in compliance with this subpart before the Commission grants or continues a license for DOE to receive and possess radioactive material within the Yucca Mountain site.

§ 63.204 Preclosure standard.

DOE must ensure that no member of the public in the general environment receives more than an annual dose of 0.15 mSv (15 mrem) from the combination of:

(a) Management and storage (as defined in 40 CFR 191.2) of radioactive material that:

(1) Is subject to 40 CFR 191.3(a); and

(2) Occurs outside of the Yucca Mountain repository but within the Yucca Mountain site; and

(b) Storage (as defined in § 63.202) of radioactive material inside the Yucca Mountain repository.

Subpart L—Postclosure Public Health and Environmental Standards

§ 63.301 Purpose and scope.

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE. For the purposes of demonstrating compliance with this subpart, to the extent that there may be any conflict with the requirements specified in this subpart and the requirements contained in Subparts A–J of this part, including definitions, the requirements in this subpart shall take precedence.

§ 63.302 Definitions for Subpart L.

All definitions in subpart K of this part, and the following:

Accessible environment means any point outside of the controlled area, including:

(1) The atmosphere (including the atmosphere above the surface area of the controlled area);

(2) Land surfaces;

(3) Surface waters;

(4) Oceans; and

(5) The lithosphere.

Aquifer means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

Controlled area means:

(1) The surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(i) South than 36°40′13.6661″ North latitude, in the predominant direction of ground-water flow; and

(ii) Than five kilometers from the repository footprint in any other direction; and

(2) The subsurface underlying the surface area.

Disposal means the emplacement of radioactive material into the Yucca Mountain disposal system with the intent of isolating it for as long as reasonably possible and with no intent of recovery, whether or not the design of the disposal system permits the ready recovery of the material. Disposal of radioactive material in the Yucca Mountain disposal system begins when all of the ramps and other openings into the Yucca Mountain repository are sealed.

Ground water means water that is below the land surface and in a saturated zone.

Human intrusion means breaching of any portion of the Yucca Mountain disposal system, within the repository footprint, by any human activity.

Passive institutional controls means:

(1) Markers, as permanent as practicable, placed on the Earth's surface;

(2) Public records and archives;

(3) Government ownership and regulations regarding land or resource use; and

(4) Other reasonable methods of preserving knowledge about the location, design, and contents of the Yucca Mountain disposal system.

Peak dose means the highest annual dose projected to be received by the reasonably maximally exposed individual.

Period of geologic stability means the time during which the variability of geologic characteristics and their future behavior in and around the Yucca Mountain site can be bounded, that is, they can be projected within a reasonable range of possibilities.

Plume of contamination means that volume of ground water in the predominant direction of ground-water flow that contains radioactive contamination from releases from the Yucca Mountain repository. It does not include releases from any other potential sources on or near the Nevada Test Site.

Repository footprint means the outline of the outermost locations of where the waste is emplaced in the Yucca Mountain repository.

Slice of the plume means a cross-section of the plume of contamination with sufficient thickness parallel to the prevalent direction of flow of the plume that it contains the representative volume.

Total dissolved solids means the total dissolved (filterable) solids in water as determined by use of the method specified in 40 CFR part 136.

Undisturbed performance means that human intrusion or the occurrence of unlikely natural features, events, and processes do not disturb the disposal system.

Undisturbed Yucca Mountain disposal system means that the Yucca Mountain disposal system is not affected by human intrusion.

Waste means any radioactive material emplaced for disposal into the Yucca Mountain repository.

Well-capture zone means the volume from which a well pumping at a defined rate is withdrawing water from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval.

Yucca Mountain disposal system means the combination of underground engineered and natural barriers within the controlled area that prevents or substantially reduces releases from the waste.

§ 63.303 Implementation of Subpart L.

DOE must demonstrate that there is a reasonable expectation of compliance with this subpart before a license may be issued. In the case of the specific numerical requirements in § 63.311 of this subpart, and if performance assessment is used to demonstrate compliance with the specific numerical requirements in §§ 63.321 and 63.331 of this subpart, compliance is based upon the mean of the distribution of projected doses of DOE's performance assessments which project the performance of the Yucca Mountain disposal system for 10,000 years after disposal.

§ 63.304 Reasonable expectation.

Reasonable expectation means that the Commission is satisfied that compliance will be achieved based upon the full record before it. Characteristics of reasonable expectation include that it:

(1) Requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance;

(2) Accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system;

(3) Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence; and

(4) Focuses performance assessments and analyses on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 63.305 Required characteristics of the reference biosphere.

(a) Features, events, and processes that describe the reference biosphere must be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(b) DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at

the time of submission of the license application.

(c) DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions consistent with present knowledge of factors that could affect the Yucca Mountain disposal system over the next 10,000 years.

(d) Biosphere pathways must be consistent with arid or semi-arid conditions.

Postclosure Individual Protection Standard

§ 63.311 Individual protection standard after permanent closure.

DOE must demonstrate, using performance assessment, that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) from releases from the undisturbed Yucca Mountain disposal system. DOE's analysis must include all potential pathways of radionuclide transport and exposure.

§ 63.312 Required characteristics of the reasonably maximally exposed individual.

The reasonably maximally exposed individual is a hypothetical person who meets the following criteria:

(a) Lives in the accessible environment above the highest concentration of radionuclides in the plume of contamination;

(b) Has a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada. DOE must use projections based upon surveys of the people residing in the Town of Amargosa Valley, Nevada, to determine their current diets and living styles and use the mean values of these factors in the assessments conducted for §§ 63.311 and 63.321;

(c) Uses well water with average concentrations of radionuclides based on an annual water demand of 3000 acre-feet;

(d) Drinks 2 liters of water per day from wells drilled into the ground water at the location specified in paragraph (a) of this section; and

(e) Is an adult with metabolic and physiological considerations consistent with present knowledge of adults.

Human Intrusion Standard

§ 63.321 Individual protection standard for human intrusion.

DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion could occur without recognition by the drillers. DOE must:

(a) Provide the analyses and its technical bases used to determine the time of occurrence of human intrusion (see § 63.322) without recognition by the drillers.

(b) If complete waste package penetration is projected to occur at or before 10,000 years after disposal:

(1) Demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) as a result of a human intrusion, at or before 10,000 years after disposal. The analysis must include all potential environmental pathways of radionuclide transport and exposure subject to the requirements at § 63.322; and

(2) If exposures to the reasonably maximally exposed individual occur more than 10,000 years after disposal, include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance.

(c) Include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance, if the intrusion is not projected to occur before 10,000 years after disposal.

§ 63.322 Human intrusion scenario.

For the purposes of the analysis of human intrusion, DOE must make the following assumptions:

(a) There is a single human intrusion as a result of exploratory drilling for ground water;

(b) The intruders drill a borehole directly through a degraded waste package into the uppermost aquifer underlying the Yucca Mountain repository;

(c) The drillers use the common techniques and practices that are currently employed in exploratory drilling for ground water in the region surrounding Yucca Mountain;

(d) Careful sealing of the borehole does not occur, instead natural degradation processes gradually modify the borehole;

(e) No particulate waste material falls into the borehole;

(f) The exposure scenario includes only those radionuclides transported to the saturated zone by water (e.g., water enters the waste package, releases radionuclides, and transports radionuclides by way of the borehole to the saturated zone); and

(g) No releases are included which are caused by unlikely natural processes and events.

Ground-Water Protection Standards

§ 63.331 Separate standards for protection of ground water.

DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of undisturbed performance after disposal, releases of radionuclides from waste in the Yucca Mountain disposal system into the accessible environment will not cause the level of radioactivity in the representative volume of ground water to exceed the limits in the following Table 1:

TABLE 1.—LIMITS ON RADIONUCLIDES IN THE REPRESENTATIVE VOLUME

Radionuclide or type of radiation emitted	Limit	Is natural background included?
Combined radium-226 and radium-228	5 picocuries per liter	Yes.
Gross alpha activity (including radium-226 but excluding radon and uranium).	15 picocuries per liter	Yes.
Combined beta and photon emitting radionuclides	0.04 mSv (4 mrem) per year to the whole body or any organ, based on drinking 2 liters of water per day from the representative volume.	No.

§ 63.332 Representative volume.

(a) The representative volume is the volume of ground water that would be withdrawn annually from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water to supply a given water demand. DOE must project the concentration of radionuclides released from the Yucca Mountain disposal system that will be in the representative volume. DOE must use the projected concentrations to

demonstrate a reasonable expectation that the Yucca Mountain disposal system complies with § 63.331. The DOE must make the following assumptions concerning the representative volume:

(1) It includes the highest concentration level in the plume of contamination in the accessible environment;

(2) Its position and dimensions in the aquifer are determined using average hydrologic characteristics which have cautious, but reasonable, values representative of the aquifers along the radionuclide migration path from the Yucca Mountain repository to the accessible environment as determined by site characterization; and

(3) It contains 3,000 acre-feet of water (about 3,714,450,000 liters or 977,486,000 gallons).

(b) DOE must use one of two alternative methods for determining the dimensions of the representative volume. The DOE must propose its chosen method, and any underlying assumptions, to NRC for approval.

(1) DOE may calculate the dimensions as a well-capture zone. If DOE uses this approach, it must assume that the:

(i) Water supply well(s) has (have) characteristics consistent with public water supply wells in the Town of Amargosa Valley, Nevada, for example, well-bore size and length of the screened intervals;

(ii) Screened interval(s) include(s) the highest concentration in the plume of contamination in the accessible environment; and

(iii) Pumping rates and the placement of the well(s) must be set to produce an annual withdrawal equal to the representative volume and to tap the highest concentration within the plume of contamination.

(2) DOE may calculate the dimensions as a slice of the plume. If DOE uses this approach, it must:

(i) Propose, for approval, where the location of the edge of the plume of contamination occurs. For example, the place where the concentration of radionuclides reaches 0.1% of the level of the highest concentration in the accessible environment;

(ii) Assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(iii) Assume that the volume of ground water contained within the slice of the plume equals the representative volume.

Additional Provisions

§ 63.341 Projections of peak dose.

To complement the results of § 63.311, DOE must calculate the peak dose of the reasonably maximally exposed individual that would occur after 10,000 years following disposal but within the period of geologic stability. No regulatory standard applies to the results of this analysis; however, DOE must include the results and their bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance.

§ 63.342 Limits on performance assessments.

DOE's performance assessments should not include consideration of very unlikely features, events, or processes, i.e., those that are estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. Unlikely features, events, and processes, or sequences of events and processes shall be excluded from the assessments for the human intrusion and ground water protection standards upon prior Commission approval for the probability limit used for unlikely features, events, and processes. In addition, DOE's performance assessments need not evaluate the impacts resulting from any features, events, and processes or sequences of events and processes with a higher chance of occurrence if the results of the performance assessments would not be changed significantly.

§ 63.343 Severability of individual protection and ground-water protection standards.

The individual protection and ground-water protection standards are severable.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

43. The authority citation for part 70 continues to read:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246, (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104–134, 110 Stat. 1321, 1321–349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.81 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.82 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

44. Section 70.17 is amended by revising paragraph (c) to read as follows:

§ 70.17 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of the regulations in this part to the extent that its activities are subject to the requirements of part 60 or part 63 of this chapter.

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

45. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224, (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

46. Section 72.44 is amended by revising paragraphs (g)(1) and (g)(3) to read as follows:

§ 72.44 License conditions.

* * * * *

(g) * * *

(1) Construction of the MRS may not begin until the Commission has authorized the construction of a repository under section 114(d) of NWPA (96 Stat. 2215, as amended by 101 Stat. 1330–230, 42 U.S.C. 10134 (d)) and part 60 or 63 of this chapter;

* * * * *

(3) The quantity of spent nuclear fuel or high-level radioactive waste at the site of the MRS at any one time may not

exceed 10,000 metric tons of heavy metal until a repository authorized under NWPA and part 60 or 63 of this chapter first accepts spent nuclear fuel or solidified high-level radioactive waste; and

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

47. The authority citation for part 73 continues to read as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 5841, 5844, 2297f).

Section 73.1 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 73.37(f) also issued under sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note). Section 73.57 is issued under sec. 606, Pub. L. 99–399, 100 Stat. 876 (42 U.S.C. 2169).

48. In § 73.1, paragraph (b)(6) is revised to read as follows:

§ 73.1 Purpose and scope.

* * * * *

(b) * * *

(6) This part prescribes requirements for the physical protection of spent nuclear fuel and high-level radioactive waste stored in either an independent spent fuel storage installation (ISFSI) or a monitored retrievable storage (MRS) installation licensed under part 72 of this chapter, or stored at the geologic repository operations area licensed under part 60 or part 63 of this chapter.

* * * * *

49. Section 73.51 is amended by revising paragraph (a) to read as follows:

§ 73.51 Requirements for the physical protection of stored spent nuclear fuel and high-level radioactive waste.

(a) *Applicability.* Notwithstanding the provisions of §§ 73.20, 73.50, or 73.67, the physical protection requirements of this section apply to each licensee that stores spent nuclear fuel and high-level radioactive waste pursuant to paragraphs (a)(1)(i), (ii), and (2) of this section. This includes—

(1) Spent nuclear fuel and high-level radioactive waste stored under a specific license issued pursuant to part 72 of this chapter:

(i) At an independent spent fuel storage installation (ISFSI) or

(ii) At a monitored retrievable storage (MRS) installation; or

(2) Spent nuclear fuel and high-level radioactive waste at a geologic repository operations area (GROA) licensed pursuant to part 60 or 63 of this chapter;

* * * * *

PART 75—SAFEGUARDS ON NUCLEAR MATERIAL—IMPLEMENTATION OF US/IAEA AGREEMENT

50. The authority citation for part 75 continues to read as follows:

Authority: Secs. 53, 63, 103, 104, 122, 161, 68 Stat. 930, 932, 936, 937, 939, 948, as amended (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 75.4 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

51. Section 75.4 is amended by revising paragraph (k)(5) to read as follows:

§ 75.4 Definitions.

* * * * *

(k) * * *

(5) Any location where the possession of more than 1 effective kilogram of nuclear material is licensed pursuant to parts 40, 60, 63, or 70 of this chapter or an Agreement State license.

* * * * *

Dated at Rockville, Maryland, this 23rd day of October, 2001.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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