

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 19, 20, 21, 30, 40, 51, 60, 61, and 63

RIN 3150-AG04

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing licensing criteria for disposal of spent nuclear fuel and high-level radioactive wastes in the proposed geologic repository at Yucca Mountain, Nevada. These criteria will address the performance of the repository system at Yucca Mountain, a system that must comprise both natural and engineered barriers. The proposed requirements are designed to implement a health-based, safety objective for long-term repository performance that is fully protective of the public health and safety, and the environment, and is consistent with national and international recommendations for radiation protection standards. Also included are licensing procedures, criteria for public participation, records and reporting, monitoring and testing programs, performance confirmation, quality assurance, personnel training and certification, and emergency planning. The proposed criteria will apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission proposes to modify its generic criteria for disposal of spent nuclear fuel and high-level radioactive wastes in geologic repositories at 10 CFR Part 60 to make clear that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

DATES: Submit comments by May 30, 1999. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Comments may be sent by mail to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (<http://www.nrc.gov>). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received and the regulatory analysis, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6681; e-mail tjm3@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

The Nuclear Waste Policy Act of 1982 (NWPAA, Public Law 97-425) directed NRC to develop technical criteria for

high-level radioactive waste (HLW) disposal, in mined geologic repositories, that: provide for the use of a system of multiple barriers; include restrictions on retrievability, as the Commission deems appropriate; and are not inconsistent with environmental standards promulgated by the Environmental Protection Agency (EPA) pursuant to the NWPAA. Existing NRC regulations at 10 CFR Part 60 contain generic criteria governing the licensing of the Department of Energy (DOE) to receive and possess source, special nuclear, and byproduct material at a geologic repository that is sited, constructed, and operated in accordance with NWPAA. Procedural requirements at Part 60 were promulgated in 1981 (46 FR 13971; February 25, 1981), and technical criteria were promulgated in 1983 (48 FR 28194; June 21, 1983). These technical criteria were amended in 1985 to add specific criteria for disposal in the unsaturated zone (50 FR 29641; July 22, 1985). Procedural amendments reflecting the passage of the NWPAA were published in 1986 (51 FR 27158; July 30, 1986), and procedures for implementation of the National Environmental Policy Act with respect to geologic repositories for HLW were added in 1989 (54 FR 27864; July 3, 1989). In 1996, NRC amended Part 60 to update generic criteria for preclosure activities at repository sites (61 FR 64267; December 4, 1996), incorporating changes that sought, in part, to achieve greater consistency between those criteria and the NRC's licensing requirements for independent storage of spent fuel and HLW at 10 CFR Part 72.

The technical criteria at Part 60 were promulgated initially, in 1983, on the assumption that EPA would issue standards limiting cumulative radionuclide releases from a geologic repository. In 1985, some 2 years after Part 60 was published, EPA issued final standards at 40 CFR Part 191, which contained not only cumulative release limits but also provided criteria for individual and ground-water protection, that had not been included in EPA's rulemaking proposal. In 1986, NRC proposed "conforming amendments" to incorporate the EPA standards into NRC's regulations (51 FR 22288; June 19, 1986). The proposed amendments were abandoned in 1987 when EPA's standards were vacated by the U.S. Court of Appeals. Also, in 1987, Congress amended NWPAA, redirecting the national waste program to focus exclusively on the characterization of the Yucca Mountain site as a potential geologic repository.

During the more than 15 years since the initial technical criteria at 10 CFR

Part 60 were promulgated, there has been considerable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain ("TPA 3.1-Sensitivity and Uncertainty Analyses," NUREG/CR-5549, in publication; "Total System Performance Assessment—1995: An Evaluation of the Potential Yucca Mountain Repository," DOE, 1995). These changes allow for the use of more effective and efficient methods of analysis for evaluating conditions at Yucca Mountain than do NRC's existing generic criteria. These 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.

In 1992, Congress directed EPA, at Section 801 of the Energy Policy Act of 1992, Public Law 102-486 (EnPA), to contract with the National Academy of Sciences (NAS) to advise EPA on the appropriate technical basis for public health and safety standards governing the Yucca Mountain repository. On August 1, 1995, the NAS Committee on Technical Bases for Yucca Mountain Standards issued its report, "Technical Bases for Yucca Mountain Standards." In its report, NAS recommended an approach and content that is significantly different from that adopted by EPA for its disposal standards at 40 CFR 191 (no longer applicable to sites characterized under Section 113(a) of NWPAs), as well as from that adopted by NRC for its existing generic regulations at Part 60.

EPA is obligated, under EnPA, to issue final public health and safety standards for Yucca Mountain that "prescribe the maximum annual effective dose equivalent to individual members of the public" and that are "based upon and consistent with" the NAS findings and recommendations. According to EnPA, EPA's new health-based disposal standards "* * * shall be the only such standards applicable to the Yucca Mountain site." After establishment of final EPA standards, NRC, under EnPA, has 1 year to modify its technical requirements and criteria under Section 121(b) of the NWPAs (i.e., the current Part 60 criteria) to be consistent with new EPA standards, and also to implement certain assumptions that are specified in the EnPA with regard to the effectiveness of postclosure oversight of the repository, to the extent consistent with the NAS report. Following repository closure, EnPA

requires that DOE continue its oversight of the Yucca Mountain site to "prevent any activity at the site that poses an unreasonable risk of—(1) breaching the repository's engineered or geologic barriers; or (2) increasing the exposure of individual members of the public to radiation beyond allowable limits." NRC's requirements and criteria are to assume, consistent with the findings and recommendations of NAS, that such oversight will be effective.

Because NRC must carry out a rulemaking to modify its requirements for geologic repository disposal within a very short period of time following EPA publication of final standards for Yucca Mountain, the Commission believes it must undertake its own rulemaking development in parallel with development of EPA's standards. Following publication of the NAS report, NRC staff met frequently with EPA staff to discuss the report and associated issues relating to development of new EPA standards and NRC regulations. NRC is continuing to work with EPA in the development of reasonable and implementable standards for Yucca Mountain that are protective of public health and safety. The Commission believes, as noted below, that it is in the best interest of the national program to proceed with promulgation of its implementing regulations. It is recognized that when EPA issues its final standards, or if new legislation affecting the regulation of the Nation's HLW program is enacted into law, these proposed regulations may need to be amended.

At the same time, the DOE program for characterizing the Yucca Mountain site as a potential geologic repository is continuing. A viability assessment of the site was completed in December 1998. Further, it is expected that DOE will publish a draft environmental impact statement (EIS) in 1999, with a final EIS to be completed in 2000, such that a site suitability recommendation can be made in 2001. Assuming that the Yucca Mountain site can be recommended for development as a geologic repository, DOE would then submit a license application to NRC in 2002.

In order for DOE to commence preparation of a license application and to permit timely and significant public involvement in the development of implementing regulations, the Commission believes it has an obligation to make public now how it would implement dose- or risk-based standards for Yucca Mountain.

As part of its broader efforts to improve the effectiveness of its programs and processes, the

Commission has a study of the NRC hearing process underway which includes the process that would be used for repository licensing. If, on the basis of this study, the Commission concludes that changes to the hearing process are warranted, it will propose them for adoption in a separate notice and comment rulemaking. In this rulemaking, the Commission is not seeking comment on potential changes to the hearing process. However, in the interest of openness, the Commission wishes to say that, at present, the Commission is inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste. No statute requires formal hearings in either case; EPA conducted none in certifying the Waste Isolation Pilot Project; and informal hearings allow for both greater efficiency and greater openness.

II. NAS Conclusions and Recommendations for Yucca Mountain

Pursuant to Section 801(a)(2) of EnPA, the NAS was directed to provide recommendations on reasonable standards for a repository at Yucca Mountain that address the following three issues:

(A) Whether a health-based standard, based on doses to individual members of the public, from releases to the accessible environment, will provide a reasonable standard for protection of the health and safety of the general public;

(B) Whether it is reasonable to assume that a system for postclosure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits; and

(C) Whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion, over a period of 10,000 years.

On August 1, 1995, NAS published its report entitled "Technical Bases for Yucca Mountain Standards." The report was prepared by a committee organized under the auspices of the National Research Council, which is jointly managed by the National Academy of Sciences and the National Academy of Engineering. The committee, consisting of 15 members representing engineering, geoscience, environmental, and risk disciplines, deliberated for more than 2 years, holding five public sessions in Las Vegas, Nevada, and Washington, DC, between May 1993 and April 1994.

With regard to the three questions posed in the EnPA, the NAS made the following findings:

(A) That an individual protection standard, expressed as a limit on individual risk rather than dose, would provide a reasonable basis for protecting the health and safety of the general public provided that the policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk. Further, NAS found that such a standard would be particularly appropriate for the Yucca Mountain site in light of the characteristics of the site.

(B) That it is not reasonable to assume that a system for post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(C) That it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

The specific conclusions and recommendations delineated in the Executive Summary of the NAS report (pp. 1 through 14) were:

(1) The standard should set "a limit on the risk to individuals of adverse health effects from releases from the repository." NAS explicitly recommended against quantitative release limits because they provide no additional protection relative to that provided by an individual risk limit. NAS declined to assign the appropriate level of risk, and stated that it views the determination of this level as a crucial policy judgment that should be addressed in a transparent rulemaking process. As a starting point in such a process, NAS suggested that consideration be given to risk levels comparable to those recommended by the International Commission on Radiological Protection (ICRP) (100 mrem/yr (1 mSv/yr) maximum individual dose from all sources, with 10–30 mrem/yr (0.1–0.3 mSv/yr) allocated for high-level waste disposal) (p. 4).

(2) For specifying the individual or individuals for whom the risk calculation is to be made, the NAS recommended that the critical-group approach, as defined by ICRP and modified for individual risk, should be used. The ICRP notes that the critical group concept is intended to ensure that no individual doses are unacceptably high, since the critical group represents

the extreme of the dose distribution to the entire population. The critical group risk calculated for comparison with the risk limit established in the standard, according to NAS, should be the mean of the risks to the members of a group whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of the discharges of radionuclides. For releases expected to occur in the far future, it will be necessary to define a hypothetical group of individuals by making assumptions about lifestyle, location, eating habits, and other factors. NAS cited the ICRP recommendation that present knowledge and cautious, but reasonable, assumptions be used in defining this group of individuals (pp. 5–6).

(3) NAS recommended that compliance assessment should be conducted over a time frame that includes the period where greatest risk occurs. NAS found there to be no scientific basis for limiting the time period of an individual-risk standard (pp. 6–7).

(4) In response to issue (A) specified at Section 801(a)(2) of EnPA, NAS concluded that "an individual-risk standard would protect public health, given the particular characteristics of the [Yucca Mountain] site, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk." As a suitable starting point for a determination of negligible individual risk, NAS suggested that consideration should be given to the risk equivalent of 1 mrem per year (0.01 mSv per year) as recommended by the National Council on Radiation Protection (pp. 7–8).

(5) NAS concluded that physical and geologic processes affecting Yucca Mountain "are sufficiently quantifiable and the associated uncertainties sufficiently boundable such that performance can be assessed over time frames during which the geological system is relatively stable or varies in a boundable manner." According to NAS, the geologic record suggests this time frame is on the order of a million years (p. 9).

(6) NAS concluded that it is not possible to predict on the basis of scientific analyses the societal factors necessary to define exposure scenarios, and that specification of such scenarios is a policy judgment best accomplished through a public rulemaking process (pp. 9–10).

(7) In response to issue (B) as specified at Section 801(a)(2) of EnPA, NAS concluded that "it is not

reasonable to assume that a system for postclosure oversight, based on active institutional controls, can be developed that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits." Despite its conclusion that there exists no scientific basis for judging whether such controls can prevent an unreasonable risk of intrusion, NAS, nonetheless, asserts that "a collection of prescriptive requirements, including active institutional controls, record-keeping, and passive barriers and markers, would help to reduce the risk of human intrusion, at least in the near term" (p. 11).

(8) With regard to issue (C) as specified at Section 801(a)(2) of EnPA, NAS concluded that it is not possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years. Because NAS could not find it technically feasible to assess the probability of intrusion into a repository over the long term, NAS concluded that it is not scientifically justified to incorporate alternative scenarios of human intrusion into a fully risk-based compliance assessment (p. 11).

(9) In order to assess whether the repository's performance would be substantially degraded as a consequence of a postulated intrusion, NAS considered a "stylized intrusion scenario consisting of one borehole of a specified diameter drilled from the surface through a canister of waste to the underlying aquifer." NAS recommended that "the estimated risk calculated from the assumption of such an assumed scenario be no greater than the risk limit adopted for the undisturbed-repository case because a repository that is suitable for safe long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion" (p. 12).

(10) NAS concluded that "there is no scientific basis for incorporating the ALARA [as low as is reasonably achievable] principle into the EPA standard or USNRC regulations for the repository" (p. 13).

(11) NAS concluded that "because it is the performance of the total system in light of the risk-based standard that is crucial, imposing subsystem performance requirements might result in suboptimal design." This conclusion was directed specifically to NRC, in the context of revisions NRC will need to make to its regulations in order to be consistent with a new risk-based EPA

standard for Yucca Mountain. NRC's existing generic regulations at 10 CFR Part 60 currently contain quantitative limits on the performance of specific subsystems such as those cautioned against by NAS.

III. Development of a New 10 CFR Part 63

As discussed above, the Commission is directed by EnPA to modify its requirements for geologic disposal within a very short time to implement site-specific standards for Yucca Mountain. The legislation also specifies the type of standards NRC is to implement (i.e., standards which limit individual dose, and which are based on and consistent with the NAS recommendations). In view of these constraints, the Commission is proposing to establish a new, separate part of its regulations at 10 CFR Part 63 that will apply only to the proposed repository at Yucca Mountain. The Commission is also proposing to leave its existing, generic regulations at 10 CFR Part 60 in place, modified only to indicate 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 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.

In establishing these criteria, the Commission seeks 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. 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 the creation of a new part of its regulations to accomplish these objectives is

preferable to modifying its generic requirements, given the fundamentally different approach laid out for Yucca Mountain by EnPA and NAS than was contemplated when the generic criteria were promulgated. More specifically, EnPA and NAS have specified an approach that would require the performance of a Yucca Mountain repository to comply with a health-based standard established in consideration of risk to a hypothetical critical group, and, further, that this would be the only quantitative standard for the post-closure performance of the repository. This approach is incompatible with the approach taken in the existing generic criteria which relies on quantitative, subsystem performance standards.

The Commission proposes to leave the existing generic requirements intact and in place, if needed, for sites other than Yucca Mountain. Although their application could be expected to be difficult, the Commission assumes that it would be afforded adequate time and resources in future years to amend its generic regulations for any additional repository site that might be authorized. Other alternatives to this approach have been considered but rejected. The Commission could defer development of proposed regulations until final EPA standards for Yucca Mountain are in place, thereby making it easier for the Commission to conform its regulations to established standards. However, the time schedule for development of the Yucca Mountain repository is aggressive, and DOE has stated that it needs to have implementing regulations in place by 2000. Only by initiating development of these regulations now can this milestone be met. Although the Commission may not know all the details of EPA's final standards at this time, the NAS recommendations with which EPA must be consistent have been public for more than 3 years.

Other options for revising NRC's generic criteria at Part 60, in addition to developing new site-specific standards for Yucca Mountain, were also considered but rejected: (1) creation of a new part for Yucca Mountain while simultaneously updating Part 60, and (2) updating Part 60 in such a way as to include a site-specific subpart for Yucca Mountain. Simultaneously revising generic criteria and developing Yucca Mountain-specific criteria would require more resources than the Commission has available at this time. Furthermore, the Commission can identify no foreseeable need for revised generic requirements and criteria because, among other things, no site other than Yucca Mountain is

undergoing characterization as a HLW repository.

IV. Part 63 Technical Criteria

The foundation for the Commission's proposed technical criteria at 10 CFR Part 63 is the specification of overall performance objectives for preclosure and postclosure phases of the repository and requirements that compliance with these overall performance objectives be demonstrated through an integrated safety analysis of preclosure operations, and through a performance assessment for long-term, postclosure performance. This risk-informed, performance-based approach does not include specification of design and siting criteria or quantitative subsystem requirements; however, the Commission is proposing specific requirements for the content of the assessments to ensure their adequacy and the sufficiency of the information provided to the Commission. The Commission believes that its proposed approach ensures protection of public health and safety and provides appropriate flexibility to DOE for demonstrating compliance, while ensuring that the information required to make a licensing decision will be provided to the Commission. The Commission's consideration of specific topics related to the proposed technical criteria is elaborated further in subsequent sections of this notice.

V. Individual Protection Standard for Postclosure Repository Performance

As already stated, the authority and responsibility for setting public health and safety standards for radioactive waste disposal at Yucca Mountain rest with EPA. It is NRC's responsibility to implement those standards in its licensing actions and ensure that public health and safety are protected. The Commission is proposing an individual dose limit which it believes is generally consistent with EnPA and with the conclusions and recommendations of NAS. Although EnPA required that EPA specify a limit based on individual dose, NAS recommended a limit be established on risk to individuals (i.e., the probability that an individual or individuals receive an adverse health effect). An equivalent level of radiation protection is afforded individuals by a standard expressed either as a risk or a dose limit when the evaluation of dose or risk considers the probability of incurring a dose and both limits are based on similar dosimetry assumptions (i.e., consistent dose to health effects conversion). In previous rulemakings, the Commission has used either implicitly or explicitly a constant total effective dose equivalent to health risk

coefficient (i.e., FR 39061; July 21, 1997), and thus, for a given probability of occurrence, the health risk can be related to a unique value of dose. Additionally, the Commission is proposing an individual dose limit because the Commission believes that a dose limit may be more readily understood by the public and is the form of a standard more frequently used to regulate nuclear activities. When 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. As a licensed, operating facility, a repository at Yucca Mountain would be subject to the existing regulations at 10 CFR Part 20 that require, among other things, doses to members of the general public to not exceed a total effective dose equivalent of (TEDE) 1 mSv (100 mrem) per year exclusive of the dose contribution from background radiation, medical procedures, and sanitary sewerage disposals. In addition, prior to permanent closure, repository operations would need to be conducted such that public exposures be maintained as low as reasonably achievable. When the repository is closed, surface facilities must be decommissioned in accordance with 10 CFR Part 20, Subpart E. Finally, during normal operations and anticipated operational occurrences, the annual dose to any real member of the public, located beyond the boundary of the site, shall not exceed a TEDE of 0.25 mSv (25 mrem). This final dose limit, used in this regulation, is adapted from the dose limits specified in 10 CFR Part 72,¹ for effluents and direct radiation during normal operations and anticipated operational occurrences, associated with a monitored retrievable storage installation (MRS). Like an MRS facility, the operations area at Yucca Mountain is expected to be a large industrial facility equipped to handle the loading, unloading, and decontamination of spent fuel and HLW shipping casks; the removal and packaging or repackaging of spent fuel assemblies and HLW canisters; and the sealing, handling, transport, stowage and periodic

monitoring of canisters to contain the spent fuel and HLW during operations. Because the activities contemplated for the operations area prior to repository closure pose similar radiological hazards, during normal operations and anticipated operational occurrences, to those posed at an operating MRS, the Commission is proposing that the dose limits for the operations area be comparable to those applicable for the MRS, from planned discharges and from direct radiation during operations. (Radiation from other fuel cycle operations, anticipated for an MRS or independent spent fuel installation (ISFSI) that might be co-located with other operating nuclear facilities, is not anticipated at the operations area, because fuel cycle operations are not likely to be located in the region). The 0.25 mSv (25 mrem) limit also provides consistency with requirements for other waste management facilities (e.g., 40 CFR 191.03(a), 10 CFR 72.104, and 10 CFR 61.40) and for license termination (10 CFR 20.1402). The protection standard is consistent with the national and international recommendations for radiation protection (National Council on Radiation Protection and Measurements and International Commission on Radiological Protection). The final dose limit used in this regulation and the requirement in 10 CFR 20.1101(b) to maintain doses to members of the public that are as low as is reasonably achievable (ALARA) will fully protect the public and the environment.

To identify an appropriate objective for repository performance after permanent closure, the Commission seeks to establish a constraint that, if met, would provide reasonable assurance that doses to members of the general public will remain below acceptable levels. International guidance on dose limits suggests establishing constraint limits for specific sources (such as a HLW repository) to ensure that exposure to members of the public from all sources, excluding background radiation, is less than the public dose limit. In the case of operational releases, compliance with the requirements of 10 CFR Part 20 can be expected, based on Commission experience with its other licensed facilities, to limit effluents far below the public annual dose limit of 1 mSv (100 mrem). For postclosure exposures, the performance of the repository must depend on passive systems limiting the exposure. Therefore, the performance objective for postclosure must be established such that the public would not receive doses, from all possible

sources, excluding background radiation, in excess of 1 mSv (100 mrem) per year.

The Commission proposes a limit of 0.25 mSv (25 mrem) to the total effective dose equivalent, received in a single year and weighted by the probability of occurrence, by the average member of the critical group, as the overall system performance objective for the repository, following permanent closure. This criterion would limit the dose received from all possible pathways to the critical group at Yucca Mountain, including direct exposure, drinking of contaminated water, eating food that was irrigated with contaminated groundwater or grown in contaminated soil, exposure to airborne releases, etc. The Commission believes that application of a single, all-pathway standard is protective of public health and safety, and obviates the need for separate, single pathway limits. The Commission established the 0.25 mSv (25 mrem) annual dose limit as the overall safety objective for both decommissioning of nuclear facilities (10 CFR 20.1402) and for low-level radioactive waste disposal facilities (10 CFR 61.41). It is within the range of international constraints that allocate doses from high level waste disposal to between 0.1 and 0.3 mSv (10 and 30 mrem) per year, and is comparable to the risk range recommended by NAS as a reasonable starting point for EPA's rulemaking (a risk range of between 10^{-5} and 10^{-6} per year, approximately equivalent to annual doses between 0.02 and 0.2 mSv (2 and 20 mrem)). The Commission believes that 0.25 mSv (25 mrem) per year is sufficiently below the public dose limit that no members of the public near Yucca Mountain would be expected to receive doses from all sources, excluding background radiation, in excess of 1 mSv (100 mrem) per year. Estimates of potential exposures at Yucca Mountain are expected to be probabilistic because these estimates will consider variability and uncertainty in the features and processes, and a range of events each with specific probability of occurrence over the time period of interest at the site. The Commission proposes that an expected annual dose, based on the probabilistic results, is representative of individual risk and would be compared to the individual protection standard for determining compliance. Calculation of the expected annual dose incorporates the probability that the estimated dose will occur (i.e., annual dose estimates consider the probability of the occurrence of the events and the

¹ As a matter of policy, NRC considers 0.25 mSv (25 mrem) TEDE as the appropriate dose limit within the range of potential doses represented by the current 10 CFR 72.104 limit of 0.25 mSv (25 mrem) (whole body), 0.75 mSv (75 mrem) (thyroid dose), and 0.25 mSv (25 mrem) (to any other critical organ). It is also important to note that the average individual exposure in the U.S. from natural background is approximately 3 mSv (300 mrem) per year or 3 times the Part 20 public dose limit and 12 times the standard proposed for Yucca Mountain.

uncertainty and variability of the parameter values used to describe the behavior of the geologic repository).

VI. Reference Biosphere and Critical Group for Yucca Mountain

In addition to establishing an individual protection limit as an overall system performance objective, as discussed above, it is necessary to specify the individual or individuals for whom the performance calculation is to be made, as well as the environment in which the individual(s) reside, and the relevant pathways for potential exposure. In this regard, the NAS observed that the appropriate objective should be 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." NAS recommended that the characteristics of the critical group and reference biosphere be defined in regulation. Citing guidance of ICRP, NAS recommended the critical group be representative of those individuals in the population expected to receive the highest dose equivalent, should be relatively homogeneous with respect to the location, habits, and metabolic characteristics that affect the doses received; and the habits and characteristics of the group should be based on present knowledge using cautious, but reasonable, assumptions. Although the ICRP guidance was developed for present day releases to existing populations that could be surveyed, monitored, and screened to find the few actual individuals that would be members of the critical group, the Commission has used the ICRP principles in developing specifications for the critical group and reference biosphere.

Demonstration of compliance with an individual dose limit over thousands of years requires the use of certain assumptions about the characteristics of the individual or group to be protected, as well as the characteristics of the biosphere in which the critical group resides, for purposes of analyzing the performance of the waste disposal facility. Difficulties in forecasting the characteristics of future society, especially those influencing exposure, lead to large uncertainties in the estimates of who will be exposed, by how much, and when.

The Commission is proposing to limit speculation by specifying the assumptions to be used by DOE in developing the assumed critical group and reference biosphere appropriate for

Yucca Mountain. The Commission is proposing criteria at § 63.115 for identifying a critical group and reference biosphere that the Commission believes provide a reasonable basis for demonstrating compliance and that preclude unbounded speculation. The Commission's intent here is to define characteristics that would otherwise be subject to unlimited speculation, and to identify how available information is to be used by DOE to identify the average member of the critical group. The identification of those individuals expected to receive the highest dose will be most sensitive to attributes such as location, percentage of diet from locally-produced food, lifestyle, and land use. Based on present day knowledge of the habits and characteristics of the local population in the vicinity of Yucca Mountain, § 63.115 specifies a farming critical group located approximately 20 km south from the underground facility (i.e., in the general location of U.S. Route 95 and Nevada Route 373, near Lathrop Wells). This section also directs DOE to use current conditions in the region surrounding Yucca Mountain to define the remaining attributes of the critical group.

Based on analysis to date, the Commission considers a farming critical group to be reasonably representative of those individuals expected to receive the highest dose from radionuclides released from a Yucca Mountain repository for a number of reasons. First, 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; inhalation and direct pathways from surface contamination exacerbated by the significant outdoor activity of a farming lifestyle). Second, the relatively large demand for ground water for irrigation increases the likelihood of drawing contaminated water to the surface where human exposures could occur. And third, farming activities currently exist in the Yucca Mountain region.

The 20 km location (near Lathrop Wells) represents an informed assumption regarding the accessibility of groundwater for irrigation considering current irrigation practices, depth to the water table, and the recognition that soil conditions at this location are generally similar to those further down gradient, near Amargosa Valley, where farming is currently practiced. Locations much closer to the proposed repository have soil conditions that are considerably less favorable for farming. Review of current

well use information for Nevada suggests that irrigation wells constructed for water table depths greater than 150 meters are rare. Because well cost is related to depth, it is economically preferable to establish irrigation wells in areas where the water table is near the surface. The water table at Yucca Mountain is deep (i.e., greater than 300 meters) and decreases with distance down-gradient, which would also be the eventual path for radionuclide releases in the ground-water pathway. The area near U.S. Route 95 and Nevada Route 373 is the general location where the depth to water is approximately 100 meters with more shallow depths to water occurring further south. Because current farming practices are concentrated in the Amargosa Farms region (approximately 30 km south of Yucca Mountain), the 20 km critical group distance is considered reasonably conservative.

Other activities that currently exist in the area represent more limited potential for exposures (e.g., casino resort/hotel, residential dwellings). Activities such as residential housing are certainly feasible at locations closer than 20 km, where potential release concentrations are likely to be higher. However, the bases for determining precise locations of such groups are likely to be highly speculative, and largely arbitrary, when compared to a farming critical group based on existing living patterns. Additionally, the small water demand of a residential community, and even smaller demand of a single residence, relative to a farming community, further increases the uncertainty of dose estimates. Finally, because releases to the groundwater are expected to be quite variable spatially, due to the characteristics of fractured rock, the likelihood of any particular, randomly selected, withdrawal well intercepting contaminated water, at a specific location, would be quite small.

Exposures to the average member of the critical group will increase with the amount of contaminated water, crops, and animal products consumed, assuming the ground water pathway is the most likely release pathway. Individuals expected to receive the highest dose would be those for whom locally-produced, contaminated food represents a significant fraction of their diet. The Commission is proposing that the consumption of locally produced food for the average member of the critical group be based on the mean of the range of the dietary habits consistent with the current conditions in the Yucca Mountain region. It is reasonable to assume that a farming community of

sufficient size (as opposed to a few isolated farms) would be needed to supply the range of locally produced food that is currently consumed in the Yucca Mountain region. Such a farming community of up to 100 individuals, residing on approximately 15 to 25 farms, is consistent with current conditions of the region (substantially more farms would increase water demand and further decrease radionuclide concentrations in pumped water; substantially fewer farms would restrict the availability of locally-produced food relative to the regional average). Thus, it would be expected that the average member of the critical group resides within a farming community and has dietary habits which will result in the exposures being among the highest.

Exposures to the average member of the critical group will also be affected by the degree to which the locally produced food is contaminated. Variability in farming and water well withdrawal practices, as well as the spatial variability of radionuclide concentrations in ground water, will produce variation in the amount and degree of contamination of locally produced food. The Commission considers it desirable to constrain the determination of the contamination levels of locally produced food because it is not possible to precisely determine concentrations in ground water at specific locations or to avoid speculation regarding individual farm and water well withdrawal practices. The concentration of radionuclides in the water used by a larger farming community, by contrast, can be determined by dividing the annual release of radionuclides to the location of the farming community by the annual water demands of the farming community. For a community of sufficient size, it can be assumed that water demand is large enough to "capture" the entirety of the contaminated plume. Thus, all the locally produced food of the farming community would be considered to be contaminated through the use of contaminated ground water. The Commission considers this reasonable because the average member of the critical group can be assumed to consume contaminated food in all categories of locally produced food. The use of mean values for defining dietary habits ensures that dose estimates would not be unduly biased by unusual habits of a few individuals, and speculation is minimized with respect to where crops are grown relative to the spatial distribution of concentration.

The biosphere in which the critical group resides affects the group's behavior and characteristics and defines how the group could be exposed to radionuclide releases from Yucca Mountain. The precise future state of the biosphere over the time period considered during a performance assessment is highly uncertain. Both natural and man-made processes may affect attributes of the biosphere (e.g., climate, topography, hydrology and soils), and thereby influencing exposure pathways. As noted earlier in this notice, NAS recommended that the assumptions about the biosphere make use of present knowledge and be cautious, but reasonable.

The Commission's proposed implementation of the reference biosphere concept contains four primary requirements. These include that (i) features, events, and processes that describe the reference biosphere shall be consistent with present knowledge and conditions in the region surrounding the Yucca Mountain site, (ii) biosphere pathways shall be consistent with arid or semi-arid conditions, (iii) climate evolution shall be consistent with the geologic record of natural climate change in the region surrounding Yucca Mountain, and (iv) evolution of the geologic setting shall be consistent with present knowledge of natural processes.

Reliance on present knowledge and conditions is considered reasonable for development of exposure scenarios because such exposure scenarios can be based on empirical knowledge rather than unconstrained speculation. The use of current information is intended to place primary emphasis on the provision of a framework for analysis of repository performance, rather than on the precise prediction of possible futures.

Requirements that the biosphere be based on arid or semiarid conditions and that climate evolution be consistent with present knowledge of natural climate change reflect a philosophy that, while societal behaviors cannot be predicted, certain aspects of the evolution of natural systems over long time frames can be predicted based on the geologic record. Climate change studies for the Yucca Mountain region indicate that the Yucca Mountain climate could become cooler and wetter during the next ice age; however, analyses of the fossil records from the previous ice age indicate that the climate in the area south of Yucca Mountain is likely to change, at most, to conditions consistent with a semiarid climate classification. Because the current interpretations of the fossil record support these choices for local

climate now and into the future, it is reasonable to limit the scope of assumed climate change to these possibilities. The change from arid to semiarid conditions is not expected to alter the biosphere sufficiently to cause major changes in potential exposure pathways to the critical group. For a farming critical group, a semiarid farming region would be expected to support agricultural crops similar to those grown in present day Amargosa Valley. Although specific biosphere and critical group parameters may change slightly with climate, major changes in behavior and exposure pathways for the critical group are not assumed.

DOE will need to establish and defend the particular characteristics, behaviors and attributes it assumes for the critical group and reference biosphere subject to the requirements and specifications of § 63.115. Then, as suggested by ICRP, a hypothetical individual representing the average member of the critical group, could be established using the mean values of the assumed characteristics, behaviors, and attributes. It is expected that DOE would conduct a habit survey to establish a realistic range of possible characteristics for the critical group, recognizing that its assumptions should be internally consistent and should not be driven by extreme habits. The Commission believes that its proposal of a farming critical group is reasonable for testing the ability of the geologic repository to comply with the performance objective at § 63.113 because it represents cautious, but realistic, assumptions of future living patterns in the vicinity of Yucca Mountain based on patterns observed there today. As this rulemaking progresses, the Commission's ongoing performance assessment analyses will continue to examine the influence of important assumptions such as the characteristics of the critical group including location, lifestyle, diet, and size. As part of this effort, the Commission encourages comments on the appropriateness of its proposed approach to defining the critical group and reference biosphere for Yucca Mountain. In particular, the Commission solicits comments on other candidate population groups, biosphere assumptions and potential exposure pathways that should be considered in the establishment of a "critical group" for Yucca Mountain.

VII. Compliance Period

The NAS recommended 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. This recommendation was founded on technical considerations only, and, as NAS acknowledged, did not address issues of policy. In selecting the length of time over which the individual dose limit should be applied, a regulatory agency must take into account technical, policy, and legal considerations. In fact, NAS noted that EPA might elect to establish consistent policies for managing comparable risks from disposal of long-lived hazardous materials. From a technical perspective, for example, the time-dependent variation of the hazard, along with the time required to evaluate adequately the waste isolation capability of both engineered and natural barriers, are of significance. From a policy perspective, on the other hand, the practical utility and relative uncertainty of extremely long projections of health consequences, along with the need to maintain a consistent regulatory approach for like hazards, need to be weighed. Having considered both technical and policy concerns, the Commission is proposing the use of 10,000 years for evaluating compliance with the system performance objective at § 63.113. Should EPA issue final standards for Yucca Mountain or Congress enact new high-level waste legislation into law that specify a different compliance period, the NRC will amend its criteria at 10 CFR Part 63, as necessary, to comply with EnPA requirements for consistency with final EPA standards.

The Commission makes its proposal on the basis of three considerations. First, the inherent radiological hazard of spent fuel decreases rapidly and significantly during the initial 10,000 years due to radioactive decay dominated by fission products, with the relative hazard diminished by approximately 90 percent at 100 years, 99 percent at about 1,000 years and 99.9 percent at 10,000 years. At 10,000 years following waste emplacement, the relative radiological hazard is within a factor of ten of the hazard posed by a quantity of 0.2 percent uranium ore equivalent to that which was necessary to produce the spent fuel (Final Environmental Impact Statement on the Management of Commercially Generated Radioactive Waste, DOE, 1980; NRC High-Level Radioactive Waste Program Annual Progress Report; Fiscal Year 1996, NRC, 1997). Beyond 10,000 years, the relative hazard of the disposed waste diminishes very slowly over several hundreds of thousands of years because decay at such late times is controlled by the activity of longer-lived radionuclides. A 10,000-year compliance period corresponds to the

time period when the waste is inherently most hazardous.

Second, analysis of repository performance over 10,000 years provides an opportunity to examine the impact of a range of geologic conditions (e.g., seismic events, fault movement, igneous activity, and climate variation on the scale of global changes due to glaciation) on the capability of the engineered and natural barriers to limit radiation exposures below the dose limit. It is possible that DOE may attempt to demonstrate that its engineered barrier system design is sufficiently robust as to preclude any significant releases during a 10,000-year compliance period. The Commission is aware of DOE's efforts to examine a variety of engineered barrier designs that it expects will extend the containment period of the waste package. However, the DOE has not finalized its repository design and thus it is premature, at this time, to assume that the expected lifetime of the engineered barrier system will exceed the compliance period. If, indeed, the waste package can be shown to preclude radionuclide releases beyond the compliance period, a 10,000-year evaluation, it might be argued, would only illustrate the effect of the natural system on the degradation of the engineered barriers and would fail to adequately display the capacity of extant natural barriers to restrict movement of radionuclides following release from the waste packages, and thereby, limit exposures to members of the critical group. The Commission expects that in conducting its performance assessment, DOE will account for the susceptibility of some fraction of the more than 7,000 emplaced canisters to early failures, attributable to such causes as manufacturing defect, lapses in quality assurance programs, etc. The ability of the geologic barriers to retard the transport of radionuclides released as a result of these early failures would clearly need to be evaluated. Furthermore, the assumed intrusion scenario specified at § 63.113(d) and discussed later in this notice requires a stylized analysis of the consequences of a compromised waste package, and will also test the contribution of the geologic barriers to overall performance. Irrespective of the projected lifetime of the waste package design, the capability of the natural barriers to limit exposures would need to be evaluated in the context of the multiple barrier requirement.

Finally, from a policy perspective, EPA has already codified a 10,000-year compliance period at 40 CFR 191

applicable to the Waste Isolation Pilot Plant (WIPP), a similar type of disposal system as that proposed at Yucca Mountain. A 10,000-year performance period is also referenced in EPA guidance on no-migration petitions for facilities seeking exemption from certain land-disposal restrictions for long-lived hazardous, nonradioactive materials. Additionally, a 10,000-year compliance period is specified in NRC's Draft Technical Position on a Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities (62 FR 29164; May 29, 1997). All of these land disposal situations, like HLW disposal, involve disposed wastes containing long-lived, hazardous materials which are of concern, because they can become mobile in the groundwater pathway.

The Commission proposes that a 10,000-year compliance period is appropriate for evaluating a Yucca Mountain repository because it: (1) includes the period when the waste is inherently most hazardous; (2) is sufficiently long, such that a wide range of conditions will occur which will challenge the natural and the engineered barriers, providing a reasonable evaluation of the robustness of the geologic repository; and (3) is consistent with other regulations involving geologic disposal of long-lived hazardous materials, including radionuclides.

VIII. Multiple Barriers and Defense in Depth

The defense-in-depth principle has served as a cornerstone of NRC's deterministic regulatory framework for nuclear reactors, and it provides an important tool for making regulatory decisions, with regard to complex facilities, in the face of significant uncertainties. NRC also has applied the concept of defense-in-depth elsewhere in its regulations to ensure safety of licensed facilities through requirements for multiple, independent barriers, and, where possible, redundant safety systems and barriers. Traditionally, the reliance on independence and redundancy of barriers has been used to provide assurance of safety when reliable, quantitative assessments of barrier reliability are unavailable. The Commission maintains, as it has in the past, that the application of the defense-in-depth concept to a geologic repository is appropriate and reasonable. The Commission now believes, however, that its implementation, in the context of a geologic repository, should be reexamined, in light of the advancement in methods to quantitatively assess the

components of a geologic repository system and with due consideration of the Commission's goal of a regulatory program and associated requirements that are risk-informed and performance-based.

Development of NRC's regulations for geologic disposal in 1983 represented a unique application of the defense-in-depth philosophy to a first-of-a-kind type of facility. While waste is being emplaced, and before a geologic repository is closed, its operation may be amenable to regulation comparable to other operating nuclear fuel cycle facilities licensed by NRC. Application of defense-in-depth principles for regulation of repository performance, for long time periods following closure, however, must account for the difference between a geologic repository and an operating facility with active safety systems and the potential for active control and intervention. A closed repository is essentially a passive system, and assessment of its safety over long timeframes is best evaluated through consideration of the relative likelihood of threats to its integrity and performance. Although it is relatively easy to identify multiple, diverse barriers that comprise the engineered and geologic systems, the performance of any of these systems and their respective subsystems cannot and should not be considered either truly independent or totally redundant.

As stated earlier, NWPA mandated that technical criteria developed by the Commission " * * * shall provide for the use of a system of multiple barriers in the design of the repository." How the performance of those barriers should be assessed, consistent with the Commission's policy of defense-in-depth, was a major issue throughout the development and promulgation of the Commission's generic regulations at 10 CFR Part 60 and continues to be of concern as the Commission contemplates new regulations for Yucca Mountain.

Well before NWPA was enacted, the Commission had considered the appropriate bases for establishing regulations for HLW disposal. In developing proposed generic technical criteria for Part 60, the Commission placed primary emphasis on the need to compensate for the large uncertainty that is inherent in the assessment of the long-term performance of HLW disposal systems. The Commission expressed its view, then, that the state-of-the-art in the earth sciences was such that all the uncertainties related to predicting long-term performance of a repository could not be resolved through consideration of the geologic setting alone.

It should be noted that during the late 1970s and early 1980s, when the Commission was first considering the development of proposed technical criteria for geologic repositories, quantitative techniques for assessing repository performance were in their infancy. The lack of experience with, and confidence in, quantitative methods for addressing the uncertainties associated with estimates of repository performance weighed heavily as the Commission considered options for formulating generic regulations for HLW disposal. As will be discussed later in this statement, the Commission now believes that the application of such methods has matured sufficiently to move away from its earlier approach.

As Part 60 was being developed, the Commission gave serious consideration to a "systems approach," that is, regulation of a repository system through a single figure of merit, that of overall system performance, leaving maximum flexibility for determining the extent and focus of site characterization, and for the designer to make trade-offs among components of the system. It was noted that this approach could include a requirement that the system design incorporate multiple barriers to compensate for uncertainty in overall system performance. It was believed, at the time, however, that compensation for uncertainties in *assessing* the system's overall performance could only be achieved by introducing conservatism. Intentional addition of conservatism, either by making the measure of performance unduly stringent or by using worst-case, bounding assumptions in the evaluation, was argued to be impractical from a regulatory point of view.

Instead, the Commission opted to prescribe minimum performance standards for each of the major system elements (as they were envisioned at the time) as well as to require the overall system to comply with the primary performance objective, namely, whatever standards EPA would eventually establish. This approach was thought to have two advantages over the systems approach, if the barriers were chosen judiciously. It was argued that barriers could be prescribed, generically, which act "independently," and that generic performance measures for these "independent" barriers could be selected that would reduce calculational uncertainty. Identification of such subsystem performance measures was expected to be helpful input to DOE's design process, without being overly restrictive. It is now recognized that NRC attempted to define such criteria on the basis of limited,

existing knowledge, without benefit of research and site-specific information that only later was acquired during characterization of a specific site at Yucca Mountain.

The vast majority of comments received on the proposed Part 60 favored a "systems approach." Nevertheless, in publishing its final rule (48 FR 28194; June 21, 1983), the Commission elected to retain the proposed approach, stating that " * * * in simply adopting the EPA standard as the sole measure of performance, it [the Commission] would have failed to convey in any meaningful way the degree of confidence which it expects must be achieved in order for it to be able to make the required licensing decisions' and, further that " * * * The Commission firmly believes that the performance of the engineered and natural barriers must each make a definite contribution in order for the Commission to be able to conclude that the EPA standard will be met."

In support of the final rule, the Commission examined how particular values for the performance of the proposed barriers would assist in concluding that compliance with the EPA standards had been demonstrated, given an assumed set of anticipated processes and events. Final EPA standards still had not been promulgated, so analyses were conducted based on NRC staff assumptions regarding the final standards. These analyses, based on a simplified modeling study for a hypothetical repository located in a variety of saturated geologic media, were documented as NUREG-0804—"Staff Analyses of Public Comments on Proposed Rule 10 CFR Part 60, Disposal of High-Level Radioactive Wastes in Geologic Repositories." For many, but by no means all, of the cases examined, compliance with the proposed subsystem performance objectives did increase the probability of meeting the assumed EPA standards. NRC was not able to demonstrate, however, that compliance with the subsystem criteria alone was sufficient to meet the assumed EPA standards, nor that compliance with the assumed EPA standards would suffice to assure compliance with the subsystem criteria. For the cases analyzed, however, it was asserted that the analyses " * * * demonstrate that compliance with 10 CFR Part 60 can substantially increase confidence that the assumed EPA standard[s] will be met."

Lastly, in order to address concerns that quantitative subsystem performance criteria may unduly restrict the

applicant's flexibility, the Commission modified the proposed rule to explicitly recognize the potential need to change the subsystem objectives to account for unique features of a specific site or design. This flexibility was provided at § 60.113 (b).

Since their promulgation, the subsystem criteria in § 60.113, in particular, have not gained broad acceptance in the technical community. These criteria have been criticized as overly prescriptive, lacking in both a strong technical basis and a clear technical nexus to the overall performance objective (i.e., the EPA standards), and unclear in their wording.

In contrast to the state of performance assessment technology assumed at the time Part 60 criteria were put in place, the NAS Committee on Technical Bases for Yucca Mountain Standards found, in 1995, that the physical and geologic processes relevant to a Yucca Mountain repository: "* * * are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance [of a repository] can be assessed over timeframes during which the geological system is relatively stable or varies in a boundable manner." As has been described earlier, it was a lack of confidence in this capability to quantify overall performance and adequately bound uncertainty that factored prominently in the Commission's decision to include quantitative subsystem requirements in the Part 60 regulations. Also, as discussed earlier, NAS cautioned against implementation of multiple barriers through the use of subsystem performance requirements. In addition, the Commission's Advisory Committee on Nuclear Waste (ACNW) recently recommended that the Commission implement the concept of defense in depth by ensuring that the effectiveness of individual barriers be identified explicitly in the total system performance assessment (TSPA), but specifically did not endorse the establishment of rule-based subsystem requirements for Yucca Mountain. The ACNW noted that "* * * an overall performance-based regulation in the context of a risk-based standard is a superior tool for promoting safety relative to imposed subsystem requirements. (see letters dated October 31, 1997 and March 6, 1998)."

Upon review of this regulatory history, the Commission is persuaded that much of the basis for NRC's initial development of the specific numerical values for the subsystem criteria was generic judgment with regard to what was (and was not) feasible with regard

to the quantitative assessment of long-term repository performance. Because the stated goal was to compensate for uncertainty, there was never any attempt to derive the subsystem performance criteria from a specified dose or risk level or from some projected dose or risk reduction expected to be achieved by their application. Furthermore, after 15 years of experience in working with the requirements of Part 60, the Commission is concerned that, for the Yucca Mountain site, the application of the subsystem performance criteria at § 60.113 may impose significant additional expenditure of resources on the nation's HLW program, without producing any commensurate increase in the protection of public health and safety.

Specifically, when the Part 60 subsystem criteria were selected, they were intended to be separate, "independent," easily-determined measures of subsystem performance, determination of which would require only application of technology that was readily available. Extensive experience with site-specific performance assessment has shown them to be none of these. For example, because container performance, release rate, and ground-water travel time will be derived from the same general data and knowledge base as the TSPA, they are subject to many, if not all, of the same uncertainties. Furthermore, waste package performance and release rate are both a function of available water; therefore, it is arguable whether the existing (or any other) subsystem measures can provide truly independent assurance of total system performance.

Nevertheless, despite its reconsideration of the merits of establishing quantitative criteria for the performance of repository subsystems, the Commission continues to believe that multiple barriers, as required by NWPA, must each make a definite contribution to the isolation of waste at Yucca Mountain, so that the Commission may find, with reasonable assurance, that the repository system will be able to achieve the overall safety objective over timeframes of thousands of years. Geologic disposal of HLW is predicated on the expectation that a portion of the geologic setting will act as a barrier, both to water reaching the waste, and to dissolved radionuclides migrating away from the repository, and thus, contribute to the isolation of radioactive waste. Although there exists an extensive geologic record ranging from thousands to millions of years, this record is subject to interpretation and includes many uncertainties. These

uncertainties can be quantified generally and are addressed by requiring the use of a multiple barrier approach; specifically, an engineered barrier system, consisting of one or more distinct engineered barriers, is required in addition to the natural barriers implicit in a geologic setting. Similarly, although the composition and configuration of engineered structures, as well as their capacity to function as barriers, can be defined with a degree of precision not possible for natural barriers, it is recognized that except for a few archaeological analogues, there is no experience base for the performance of complex, engineered structures over periods longer than a few hundred years. It is expected that DOE will demonstrate that the natural barriers and the engineered barrier system will work in combination to enhance overall performance of the geologic repository.

The Commission believes that this approach to multiple barriers is consistent with the NAS conclusions and recommendations cited above. The Commission also recognizes, and believes it is important to acknowledge that experience and improvements in the technology of performance assessment, acquired over more than 15 years, now provide significantly greater confidence in the technical ability to assess comprehensively overall repository performance, and to address and quantify the corresponding uncertainty. In addition to extensive reviews of evolving TSPAs produced by DOE and its contractors, the Commission, itself, has developed and exercised its own technical capability in the field of repository performance assessment (See, for example, Bonano, E. J., et al., "Demonstration of a Performance Assessment Methodology for High-Level Waste Disposal in Basalt Formation," NUREG/CR-4759, U.S. Nuclear Regulatory Commission, Washington, DC, 1989; "Initial Demonstration of the NRC's Capability to Conduct a Performance Assessment for a High-Level Waste Repository," NUREG-1327, 1992; "NRC Iterative Performance Assessment Phase 2—Development of Capabilities for Review of a Performance Assessment for a High-Level Waste Repository," NUREG-1464, 1995).

Drawing from this experience, the Commission is now proposing to require that DOE evaluate the behavior of barriers important to waste isolation in the context of the performance of the geologic repository. The Commission does not intend to specify numerical goals for the performance of individual barriers. Such an approach will require DOE to provide an analysis that: (1)

identifies those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; (2) describes the capability of these barriers to isolate waste, taking into account uncertainties in characterizing and modeling the barriers; and (3) provides the technical basis for the description of the capability of these barriers. In implementing this approach, the Commission proposes to incorporate flexibility into its regulations by requiring DOE to demonstrate that the geologic repository comprises multiple barriers but not prescribe which barriers are important to waste isolation or the methods to describe their capability to isolate waste.

DOE could select from a variety of methods in order to demonstrate the capability of barriers to isolate waste. Regardless of the method and the level of quantification, it is expected that the capability of individual barriers to perform their intended function and the relationship of that function to limiting radiological exposure would be described. In parallel with this rulemaking, NRC staff is developing guidance in the form of a Yucca Mountain Review Plan. In this review plan, guidance will be provided on acceptable methods for demonstrating compliance with the multiple barrier requirement that could include, but not necessarily be limited to, performing sensitivity analyses, modeling the behavior of individual barriers, quantifying how individual barriers contribute to performance, and delineating the capabilities of the barriers to isolate waste. The Commission believes that it is appropriate to afford DOE flexibility in selecting the methods to demonstrate the waste isolation capability of the multiple barriers that must comprise its repository design. The proposed requirements will provide for a system of multiple barriers and an understanding of the resiliency of the geologic repository provided by the barriers important to waste isolation to ensure defense in depth and increase confidence that the postclosure performance objective will be achieved.

IX. Performance Assessment

Demonstration of compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment that quantitatively estimates the expected annual dose, over the compliance period and weighted by probability of occurrence, to the average member of the critical group. Performance

assessment is a systematic analysis of what can happen at the repository after permanent closure, how likely it is to happen, and what can result, in terms of dose to the average member of the critical group. Taking into account, as appropriate, the uncertainties associated with data, methods, and assumptions used to quantify repository performance, the performance assessment is expected to provide a quantitative evaluation of the overall system's ability to achieve the performance objective (§ 63.113 (b)). Consistent with EnPA and the NAS recommendations, the Commission proposes that the results of performance assessment shall be the sole quantitative measure used to demonstrate compliance with the postclosure individual dose limit.

In order to find that issuance of a license will not constitute an unreasonable risk to the health and safety of the public, the Commission must have reasonable assurance that the required performance assessment has demonstrated that, following permanent closure, for the duration of the compliance period and considering the likelihood of occurrence of adverse natural events, expected annual exposures to the average member of the critical group will not exceed the individual dose limit of .25 mSv (25 mrem) TEDE. Although the performance objective for the geologic repository after permanent closure (§ 63.113) is generally stated in unqualified terms, it is not expected that complete assurance that the requirement will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the performance objective will be met is the general standard that is required. Proof that the geologic repository will be in conformance with the objective 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 assurance, making allowance for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with the objective for postclosure performance of the geologic repository. Demonstrating compliance, by necessity, 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. Further, in reaching a determination of reasonable assurance, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity or redundancy among the multiple barriers of the geologic repository.

Because of the significance of the performance assessment as the sole quantitative measure of compliance, it is essential that the performance assessment be scientifically defensible and transparent. For this reason, the Commission considers it important to specify, at § 63.114, requirements for a complete and high-quality performance assessment. A defensible performance assessment should contain a technical rationale for those features, events, and processes that have been included in the performance calculation, as well as those that have been considered but were excluded. The features, events, and processes (i.e., specific conditions or attributes of the geologic setting; degradation, deterioration, or alteration of the engineered barriers; and interactions between the natural and engineered barriers) considered for inclusion in the assessment should represent a wide range of beneficial and detrimental effects on performance. Features, events, and processes should be considered in light of available data and current scientific understanding, and alternative conceptual models that are consistent with such data and understanding should be evaluated. Inclusion of alternative models should be based, however, on reasonable interpretation of available information, and should not be driven by open-ended speculation. To this end, the Commission is proposing to constrain speculation by defining a lower limit on the probability of events and processes that need to be considered and requiring inclusion of only those features and processes, and higher probability events that significantly change the expected annual dose.

The performance assessment will rely, by necessity, on computer modeling to determine whether a proposed geologic repository meets the performance objectives. Such reliance on computer simulation has become commonplace for determining the likely performance of complex engineered systems. In most applications, it is accompanied by a rigorous testing program, involving model "validation" and "verification," to ensure that the simulated system behavior is sufficiently consistent with empirically observed behavior to meet the need of the application at hand. The Commission expects that DOE will take

reasonable and practical measures to ensure that its performance assessment provides a credible representation of a geologic repository at Yucca Mountain. For example, assurance of the soundness of the performance assessment cannot and will not involve the comparison of simulated behavior of a geologic repository with empirical observation over tens of kilometers and tens of thousands of years. At best, assurance for the performance assessment will involve comparison of simulations with observations drawn from an integrated program of laboratory tests, field tests, and analog studies that starts with site characterization and continues, as appropriate, through the performance confirmation period. To the extent that DOE's performance assessment provides a credible representation of a geologic repository, the Commission expects no more than that and believes that no more is needed. When the NWPA became law in 1982, and when it was revisited in 1987, and again in 1992, the limits on human knowledge that are attendant to confirming performance of a geologic repository were well known. The Commission does not believe that these laws were passed with the intention of creating an impossible task. Accordingly, the Commission has included, at §§ 63.101(a)(2) and 63.101(b), explanations regarding the purpose and nature of the findings it will make.

To be transparent, DOE's performance assessment must contain an evaluation of the performance of the geologic repository relative to compliance with the individual dose limit and an explanation of how the estimated performance was achieved. Section 63.113(b) requires that compliance with the individual dose limit be demonstrated through the calculation of an expected annual dose. The expected annual dose is the expected value of the annual dose considering the probability of the occurrence of the events and the uncertainty, or variability, in parameter values used to describe the behavior of the geologic repository (the expected annual dose is calculated by accumulating the dose estimates for each year, where the dose estimates are weighted by the probability of the events and the parameters leading to the dose estimate). Demonstration of compliance with the individual dose limit will need to include an estimate of the expected annual dose to the average member of the critical group that, for any single year within the compliance period, is below the limit. Explanation of how the estimated performance was

achieved should reveal an understanding of the relationship between the performance of individual components or subsystems of the geologic repository and the total system performance. Such understanding would be used to build confidence that the expected annual dose, as asserted in the license application, is a reasonable estimate of the performance of the geologic repository. Consistent with a performance-based philosophy, the Commission proposes to permit DOE the flexibility to select the approach for demonstrating this relationship that is most appropriate to its analysis.

X. Institutional Controls

The Commission is proposing to require DOE to institute active, as well as passive, control measures to reduce the potential for inadvertent human intrusion into the site. Reasonably prudent, active institutional controls, consistent with the requirements of Section 801(c) of EnPA, should be maintained at the site for as long as possible. The Commission is also proposing that DOE's passive control measures should be designed to serve their intended purpose for as long as practicable.

Section 801(b) of EnPA requires that: * * * the Commission's requirements assume, to the extent consistent with the findings and recommendations of the National Academy of Sciences, that following repository closure, the inclusion of engineered barriers and the Secretary's postclosure oversight of the Yucca Mountain Site, in accordance with Subsection (c) shall be sufficient to:

(A) prevent any activity at the site that poses an unreasonable risk of breaching the repository's engineered or geologic barriers; and

(B) prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits.

However, as was discussed earlier in this notice, NAS concluded that it is not reasonable to assume that a system for postclosure oversight, based on active institutional controls, can be developed that will eliminate entirely, over thousands of years, the possibility of human activity that could degrade the long-term performance of the repository.

XI. Human Intrusion

The geologic record provides a basis for evaluating the likelihood of geologic processes and events, but no similar record of extended duration exists that can be used to constrain either the probability that human intrusion could occur or the characteristics of such

intrusion. Although designs can seek to warn potential intruders or to mitigate effects associated with intrusion that does occur, they cannot remove the potential for intrusion to occur. Similarly, repositories cannot be designed to mitigate the full range of possible ways that human intrusion could occur. Therefore, the Commission is proposing to require that DOE take reasonable and prudent steps to reduce the likelihood of human intrusion, and that DOE's repository design must still perform as intended, if an assumed, limited intrusion does occur.

As noted earlier, the NAS also concluded that it is not possible to make scientifically supportable predictions of the probability of human intrusion breaching the repository's geologic or engineered barriers over a period of 10,000 years. The NAS report recommended that human intrusion be excluded from the performance assessment, but that the consequences of an assumed human intrusion scenario should be calculated to determine if repository performance would be substantially degraded as a result of the intrusion.

The Commission agrees with the NAS recommendations to consider human intrusion apart from the risk-based performance assessment. To permit consideration of the potential detriment from human intrusion in the evaluation of repository performance, the Commission proposes that DOE be required to perform a consequence analysis that includes an assumed intrusion scenario as specified at § 63.113(d). This consequence analysis would be identical to the performance assessment, except that a specified human intrusion scenario is assumed to occur. In the event of this assumed scenario, the repository is required to perform such that the expected annual dose to the average member of the critical group is also within allowable limits. Hazards to the intruders themselves (drillers, miners, etc.) or to the public from material brought to the surface by the assumed intrusion should not be included in this analysis, according to NAS. This is because, NAS asserts, analyses of these hazards would be unlikely to provide any useful basis for judging the resilience of a particular repository or design to intrusion.

The Commission does not intend to speculate on the virtual infinity of human intrusion scenarios that could be contemplated, nor does it intend for this analysis to address the full range of possible intrusions that could occur. Rather, the Commission intends that this analysis show that the repository exhibits some resilience to a breach of

engineered and geologic barriers from events that are reasonably of concern. Therefore, the Commission is proposing an assumed human intrusion scenario that results in the breach of both engineered and geologic barriers. The Commission believes that current practices provide a solid basis for establishing properties for the intrusion scenario that avoid speculation. Therefore, the Commission is proposing that DOE use current practices for resource exploration to establish properties (e.g., diameter of the borehole, drilling rate, composition of drilling fluids) for the intrusion scenario. However, because the Commission intends for this analysis to show that the repository can still adequately perform if its barriers are breached, the Commission is requiring DOE to assume that the borehole is not adequately sealed to prevent infiltrating water.

Elsewhere in its regulations (e.g., 10 CFR Part 60), the Commission has limited the extent to which reliance may be placed on active institutional controls to prevent unacceptable radiological exposures from the disposal of other radioactive wastes. Consistent with this approach, the Commission is proposing that the intrusion scenario be assumed to occur 100 years after repository closure.

The Commission is mindful that a single stylized intrusion scenario should not be taken as a prediction of the likely manner or frequency of intrusion. As NAS stated in its report, a "calculation of consequences for such an intrusion removes from consideration a number of imponderables, each of which would otherwise need to be treated separately, including the probability that an intrusion borehole would intersect a waste canister, the probabilities of detection and remediation, and the effectiveness of institutional controls and markers to prevent intrusion. This scenario should not be interpreted as either an optimistic or pessimistic estimate of what might actually occur * * * We believe that the simplest scenario that provides a measure of the ability of the repository to isolate waste and thereby protect the public is the most appropriate scenario to use for this purpose."

Bearing this in mind, the Commission solicits comment on the appropriateness of its proposed intrusion scenario, and the assumed timing of its occurrence, as a reasonable measure for evaluating the consequences of intrusion at a repository at Yucca Mountain.

XII. Preclosure Performance Objective

The Commission is proposing performance objectives at § 63.111 to ensure that the geologic repository operations area is designed and operated to protect against radiation exposures and releases of radioactivity prior to permanent closure. Specifically, protection of the worker and general public is ensured by requiring that (1) the exposure limits codified at 10 CFR Part 20 are maintained, and (2) during normal operations and anticipated operational occurrences, the annual dose to any real member of the public, located beyond the boundary of the site, shall not exceed a TEDE of 0.25 mSv (25 mrem). The 0.25 mSv (25 mrem) limit was included to provide consistency with requirements for the MRS and other waste management facilities (e.g., 40 CFR 191.03(a), 10 CFR 72.104, and 10 CFR 61.40). Additionally, numerical guides for design objectives have been specified for Category 1 design basis events and Category 2 design basis events. Category 1 design basis events are those events that are expected to occur one or more times before permanent closure. Included in Category 1 design basis events are events that occur regularly or moderately frequently, and that are sometimes identified as "normal operations" associated with receiving, handling, packaging, storing, emplacing, and retrieving high-level waste. Also included in Category 1 design basis events are those events that occur one or more times during the operating lifetime of a facility, and that are sometimes identified as "anticipated operational occurrences" or "accidents." Category 2 design basis events are those events that have at least one chance in 10,000 of occurring before permanent closure. For an operational period of 100 years, this corresponds to an annual probability of occurrence of 10^{-6} . Category 2 design basis events are unlikely, but credible and potentially significant events. The Commission incorporated similar definitions of design basis events and associated dose limits in its generic regulations at 10 CFR Part 60 (61 FR 64257) for evaluation of preclosure repository performance. The primary purpose of those most recent amendments to the Commission's generic criteria, in addition to achieving greater consistency with Part 72 requirements, was to improve clarity and sufficiency of the requirements to protect health and safety for the full range of credible conditions or events that could occur at an operating repository, including low-probability events that have potentially

serious consequences. The Commission believes that the performance objectives established by these amendments are suitable for inclusion in its proposed criteria for preclosure operation at a Yucca Mountain repository.

XIII. Integrated Safety Analysis of Activities at the Geologic Repository Operations Area

The Commission is proposing that compliance with the preclosure performance objectives would be demonstrated through an integrated safety analysis (ISA) of the geologic repository operations area (GROA). The ISA is a systematic examination of potential hazards at the GROA. It identifies the potential hazards, the potential for initiating event sequences, and describes potential event sequences and their consequences, as well as the site, structures, systems, components, equipment, and activities of personnel intended to mitigate or prevent the accident sequence. Its purpose is to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified such that the GROA will comply with the preclosure requirements for protection against radiation exposures and releases of radioactive material specified in § 63.111. As used here, integrated means joint consideration of safety measures that, considered separately, might not achieve the overall health and safety protection desired. Such integration would include, but not be limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures.

A fundamental aspect of the ISA is the identification and analysis of Category 1 and Category 2 design basis events. Category 1 events as described above represent "normal operations" while Category 2 events represent unlikely but credible events which would challenge the design of the GROA to maintain exposures within allowable limits. 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 believes the proposed approach, which does not include specification of general design criteria, is appropriate because prescriptive design criteria may unnecessarily encumber DOE, given the ongoing nature of site characterization of the underground facility and evolution of facility design. The information the Commission needs to make a finding of reasonable assurance that the GROA will comply with the risk-informed, preclosure requirements at § 63.111, will be provided by the ISA. The Commission proposes criteria, at § 63.112, for the content of the ISA.

XIV. Quality Assurance

As is currently required by the generic criteria at 10 CFR Part 60, the Commission is proposing that DOE implement a quality assurance program, for the geologic repository, based on the criteria of Appendix B of 10 CFR Part 50. Although an essentially equivalent quality assurance program for the independent storage of spent nuclear fuel and HLW is specified at Subpart G of 10 CFR Part 72, the Commission believes it to be appropriate to continue to reference Appendix B for the geologic repository at Yucca Mountain for purposes of maintaining continuity between data collected, during site characterization, pursuant to Part 60 requirements and those that will be collected once Part 63 requirements take effect. The Commission is seeking comment on the merits of this approach.

XV. Emergency Planning

When the Commission published final generic criteria for geologic disposal in 1983, licensing requirements for emergency planning were reserved for a later date. On June 22, 1985 (60 FR 32430), the Commission published final amendments to 10 CFR Part 72 that codified generic emergency planning licensing requirements for independent spent fuel storage installations (ISFSIs) and monitored retrievable storage facilities (MRS). These amendments provided for enhanced requirements for offsite emergency planning at MRS facilities (as well as at any ISFSIs that conduct similar operations) because of the broader scope of activities that could be performed at these facilities relative to those conducted at simpler storage installations. Like an MRS facility, a

Geologic Repository Operations Area (GROA) at Yucca Mountain is expected to be a large industrial facility equipped to handle the loading, unloading, and decontamination of a large number of spent fuel and HLW shipping casks arriving by rail, heavy haul, and legal weight truck. It will also include facilities to open shipping canisters that are unsuitable for disposal, as well as to package bare fuel assemblies, commercial and defense spent fuel, and commercial and defense HLW in disposable canisters, and seal them for emplacement in the repository. Packaging operations will be conducted in a radiologically-controlled area that can support remote dry and pool-handling operations. At this time, a final GROA design has not been selected by DOE.

In promulgating final amendments at 10 CFR Part 72, the Commission conducted an analysis of potential onsite and offsite consequences of accidental release associated with the operation of an MRS. This analysis is contained in NUREG-1092. Because the activities contemplated for the GROA prior to repository closure pose similar radiological hazards to those analyzed for operations at an MRS, the Commission is proposing that the emergency planning licensing requirements for preclosure operations at the Yucca Mountain repository be comparable to those already codified in § 72.32 (b). Therefore, the Commission is proposing to require, at Subpart I, § 63.161, that DOE develop, and be prepared to implement, a plan to cope with radiological emergencies that may occur at the GROA prior to permanent closure, that is based on the criteria of § 72.32(b).

XVI. Changes, Tests and Experiments

The Commission is proposing to set out, at § 63.44, 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. DOE would be required to maintain records of changes made and tests undertaken pursuant to this section. Comparable provisions exist at 10 CFR 50.59 for licensees of production and utilization facilities (e.g. nuclear reactors) and at 10 CFR 72.48 for licensees of facilities for the independent storage of spent nuclear fuel and HLW. The intent of these requirements is to permit licensees to make changes, or to conduct tests at a licensed facility, provided that the changes maintain the level of safety documented in the original licensing

basis (such as in the safety analysis report); the changes do not alter a license condition; and the changes do not introduce a previously unreviewed safety question.

Recently, the Commission proposed amendments to Parts 50 and 72 (63 FR 56098; October 21, 1998), to address a number of issues concerning the implementation of these provisions for reactors and independent spent fuel storage facilities. In particular, the proposed amendments attempt to revise criteria for determining when an unreviewed safety question exists. The Commission has become concerned that differing interpretations of these requirements as they relate to an increase in the probability of an accident, or an increase in consequences, have contributed to disputed inspection and enforcement findings. Too stringent an interpretation of the meaning of the requirements could result in diversion of licensee and NRC resources for review of inconsequential changes. Too high a threshold for NRC approval could lead to an erosion of safety without explicit NRC review, particularly with respect to the cumulative effect of multiple changes.

The Commission acknowledges that these issues are still under review within the Commission, and may well undergo further modification based upon that review or on public comments received. That being said, the Commission sees merit in the establishment of a uniform policy approach for addressing the change process issue. To this end, at the same time the Commission solicits comment on proposed requirements at § 63.44 that are comparable to existing regulations for other facilities, the Commission also seeks comment on the suitability, for a repository at Yucca Mountain, of an approach substantially equivalent to that proposed last year for nuclear reactors and spent fuel storage facilities. Alternative criteria for § 63.44, that could be used to implement such an approach for a repository at Yucca Mountain, is presented below, and should be viewed as a template for discussion.

Section 63.44 Changes, Tests, and Experiments

(a) Definitions:

(1) *Change* means a modification, addition or removal.

(2) *Final Safety Analysis Report (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as modified as a result of changes made

pursuant to § 63.44, and as updated in accordance with § 63.24.

(3) *Procedures as described in the Final Safety Analysis Report (as updated)* means information in the Final Safety Analysis Report (as updated) regarding how structures, systems, and components important to safety are operated or controlled and information describing conduct of operations.

(4) *Reduction in margin of safety associated with any license specification* means that the input assumptions, analytical methods, acceptance conditions, criteria and limits of the safety analyses, presented in the Final Safety Analysis Report (as updated), that established any license specification requirement, are altered in a nonconservative manner.

(5) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any condition where the geologic repository operations area or any of its systems, structures, and components important to safety, or barriers important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the controlling parameters of the design bases as described in the Final Safety Analysis Report (as updated); or

(ii) Inconsistent with the analyses in the Final Safety Analysis Report (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the Final Safety Analysis Report (as updated), make changes in the procedures as described in the Final Safety Analysis Report (as updated), and conduct tests or experiments not described in the Final Safety Analysis Report (as updated), without obtaining either an amendment of construction authorization pursuant to § 63.33 or a license amendment pursuant to § 63.45, if a change in the conditions incorporated in the construction authorization or license is not required, and 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 pursuant to § 63.33 or a license amendment pursuant to § 63.45, prior to implementing a change, test, or experiment if it would:

(i) Result in more than a minimal increase in the probability of occurrence of an event previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the

last Final Safety Analysis Report was updated pursuant to § 63.24;

(ii) Result in more than a minimal increase in the probability of occurrence of a malfunction of structures, systems, components important to safety, or barriers important to waste isolation, which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(iii) Result in more than a minimal increase in the consequences of an event previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(iv) Result in more than a minimal increase in the consequences of malfunction of structures, systems, components important to safety, or barriers important to waste isolation, which were previously evaluated in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(v) Create the possibility for a design basis event, or of a pathway for release of radionuclides, of a different type than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(vi) Create the possibility for a malfunction of structures, systems, and components important to safety, or barriers important to waste isolation, with a different result than any evaluated previously in either the Final Safety Analysis Report (as updated), or in evaluations performed pursuant to this section and safety analyses performed pursuant to §§ 63.33 or 63.45, as applicable, after the last Final Safety Analysis Report was updated pursuant to § 63.24;

(vii) Result in a reduction in the margin of safety associated with any license specification;

(viii) Result in a significant increase in occupational exposure;

(ix) Result in a significant unreviewed environmental impact.

(c)(1) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site and of changes in procedures it has made pursuant to this section if these changes constitute changes in the geologic repository operations area as described in the Final Safety Analysis Report (as updated). DOE shall also maintain records of tests and experiments carried out pursuant to paragraph (b) of this section. These records shall 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 pursuant to paragraph (b)(2) of this section.

(2) DOE shall prepare annually, or at such shorter interval as may be specified in the license, 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 of 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 pursuant to this paragraph shall be made a part of the public record of the licensing proceedings.

As noted above, the criteria for changes, tests and experiments that a licensee may conduct without prior NRC approval or license amendment continue to be the subject of generic consideration by the Commission, and may change subject to public comment received on this notice, or on the proposed rulemaking for Parts 50 and 72, discussed earlier. For example, in the supplementary information accompanying the latter, the Commission identified a range of possible definitions for what may constitute a "reduced margin of safety," including its deletion as a criterion. Also, it should be noted that, depending on the outcome of the Commission's generic deliberations, it may be necessary to modify §§ 63.44 and 63.46, as proposed in this notice, to eliminate, altogether, the concept of an "unreviewed safety question."

Irrespective of the specific approach and criteria selected, the Commission is also interested in whether criteria for changes, tests and experiments should apply solely to the Safety Analysis Report or to the contents of the entire license application, as proposed.

XVII. Relationship to Generic Criteria at 10 CFR Part 60

The proposed criteria will apply specifically and exclusively to the proposed repository at Yucca Mountain. Consistent with this intent, the Commission proposes to modify its generic criteria at 10 CFR Part 60 to make clear that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain.

Corresponding administrative changes to Parts 2, 19, 20, 21, 30, 40, 51, and 61 are being proposed to reflect the potential of licensing a HLW geologic repository under proposed Part 63 as well as Part 60. In appropriate sections of Parts 2, 19, 20, 21, 30, 40, 51, and 61 where Part 60 is mentioned, a reference to Part 63 is added.²

XVIII. Section-by-Section Analysis of Part 63

Subpart A—General Provisions

This subpart, except for § 63.2, "Definitions," contains proposed 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 usage in this part, as appropriate.

Section 63.1 *Purpose and scope*. This section defines the purpose and scope of Part 63 to be limited 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, and 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: 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 proposed 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 proposed 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 in as much as both activities have been completed previously. 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 proposed 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 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 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

² Although the NRC has recently published final rule amendments to update its rules of practice in Subpart J of Part 2 for the licensing proceeding on disposal of HLW at a geologic repository (62 FR 71729; December 30, 1998), any further changes to Subpart J that are necessary to conform to the addition of Part 63 will be deferred until completion of this rulemaking.

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

Subpart C—Participation by State Government and Affected Indian Tribes

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

Section 63.61 *Provision of information*. This section states that NRC shall provide to the Governor, the Nevada State legislature, and any affected Indian Tribe timely and complete information regarding determinations made by the Commission with respect to the Yucca Mountain site. NRC shall also make this information available to the public and DOE.

Section 63.62 *Site review*. This section states that NRC shall consult with the State of Nevada and affected Indian Tribes regarding site characterization activities.

Section 63.63 *Participation in license reviews*. This section sets forth procedures for State and local governments 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, 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 affected Indian Tribe provide the Commission with the authority basis for such a representation.

Subpart D—Records, Reports, Tests, and Inspections

This subpart contains proposed 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 design and construction of the geologic repository operations area, if the uncorrected deficiency could be a safety hazard, 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 proposed performance objectives for the geologic repository area through permanent closure (preclosure) and the geologic repository after permanent closure (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 proposes 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. The Commission is proposing an individual dose limit that is believed to be generally consistent with the Energy Policy Act of 1992 and the findings and recommendations of the National Academy of Sciences’ technical bases for Yucca Mountain Standards. When final EPA standards for Yucca Mountain are published, the Commission will amend its regulations to be consistent with the standards, if necessary.

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

Section 63.112 *Requirements for integrated safety analysis of the geologic repository operations area*. This section specifies the requirements for the

integrated safety analysis used to demonstrate compliance with the performance objective through permanent closure provided at §§ 63.111(a)(1) and 63.111(a)(2).

Section 63.113 *Performance objective 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 individual annual dose limit, conduct a performance assessment, and assess the consequences of a specified human intrusion event.

Section 63.114 *Requirements for performance assessment*. This section specifies the requirements for the performance assessment used to demonstrate compliance with the individual dose limit specified at § 63.113(b).

Section 63.115 *Required characteristics of the reference biosphere and critical group*. This section specifies characteristics of the reference biosphere and critical group to be used by DOE in their performance assessment.

Section 63.121 *Requirements for ownership and control of interests in land*. This section requires DOE to have permanent control of the site. It states that DOE shall set up controls necessary to prevent adverse human actions that could affect the repository. DOE is required to obtain water rights needed for the repository.

Subpart F—Performance Confirmation Program

This subpart contains proposed 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 in situ testing of such features as borehole and shaft seals, backfill, and the thermal interaction

effects of waste packages, backfill, rock, and groundwater.

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 proposed provisions that are similar to the quality assurance provisions of 10 CFR Part 60.

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 *Applicability*. This section indicates that the quality assurance program applies to all systems, structures, and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto.

Section 63.143 *Implementation*. This section indicates that the quality assurance program is to be based on the criteria of Appendix B of 10 CFR Part 50, as applicable and appropriately supplemented as required by § 63.142.

Subpart H—Training and Certification of Personnel

This subpart contains proposed 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 proposed 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 proposed 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 §§ 161b, 161i, or 161o except for the sections listed in § 63.172(b).

XIX. Section-by-Section Analysis of Changes to Other Parts

Section-by-section analysis of changes to Parts 2, 19, 20, 21, 30, 40, 51, and 61.

10 CFR Part 2

Section 2.101 *Filing of applications* is amended to add 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 reference to Part 63 in the procedures for notification in this section.

Section 2.104 *Notice of hearing* is amended to add reference to Part 63 in the procedures for notification of hearings.

Section 2.105 *Notice of proposed action* is amended to add 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 pursuant to Part 63.

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."

10 CFR Part 20

Section 20.1002 *Scope* is amended to make Part 63 subject to the regulations in Part 20.

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 *Definitions* are amended to include Part 63.

By changes to § 21.21 *Notification of failure to comply or of a defect and its evaluation*, Part 63 is made subject to the regulations for reporting defects and noncompliance.

10 CFR Part 30

Changes to § 30.11 *Specific exemptions* make DOE exempt from Part 30 regulations for activities subject to Part 63.

10 CFR Part 40

Changes to § 40.14 *Specific exemptions* make DOE exempt 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 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 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 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 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.

Section 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 reference to Part 63 in the definition of a geologic repository.

XX. Specific Questions for Public Comment

The Commission welcomes comments on all aspects of this proposed rule, and is especially interested in receiving comments on the following:

1. The Commission solicits comments on the appropriateness of its proposed approach to defining the critical group and reference biosphere for Yucca Mountain. In particular, the Commission solicits comments on any other candidate population groups, biosphere assumptions and potential exposure pathways that should be considered in the establishment of a "critical group" for Yucca Mountain.

2. The Commission solicits comments on the appropriateness of its proposed human intrusion scenario, and the assumed timing of its occurrence, as a reasonable measure for evaluating the consequences of intrusion at a repository at Yucca Mountain.

3. The Commission solicits comment on the merits of requiring DOE to implement a quality assurance program for the geologic repository based on the criteria of Appendix B of 10 CFR Part 50.

4. The Commission solicits comments on the suitability of alternative criteria for proposed § 63.44. These alternative criteria are included in the statement of considerations discussion of proposed § 63.44 and are substantially equivalent to that proposed last year for nuclear reactors and spent fuel storage facilities.

5. The Commission solicits comments on whether the approach and criteria for changes, tests, and experiments at § 63.44 should apply solely to the Safety Analysis Report or to the contents of the entire license application, irrespective of whether proposed § 63.44 or the alternative criteria presented in the statement of consideration are selected.

XXI. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the Federal government's writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed above.

XXII. Finding of No Significant Environmental Impact: Availability

Pursuant to Section 121(c) of the Nuclear Waste Policy Act, this proposed 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.

XXIII. Paperwork Reduction Act Statement

This proposed rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information 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 collection of information. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Records Management Branch (T-6F-33), 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-AG04), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by March 24, 1999. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

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.

XXIV. Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examines the alternatives considered by NRC. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. 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.

XXV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed 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.

XXVI. Backfit Statement

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

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, Special nuclear material, Source 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 power plants and reactors, Nuclear materials, 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, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

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 proposing to adopt the following amendments to 10 CFR Parts 2, 19, 20, 21, 30, 40, 51, and 60 and to add 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, 183, 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). Sections 2.205(j) also issued under Pub. L. 101-410, 104 Stat. 890, as amended by section 31001(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). 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 Parts 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)(i) If a tendered document is acceptable for docketing, the applicant will be requested to—

(A) 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;

(B) 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

(C) 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.

(ii) 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 will be 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).

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 Parts 60 or 63 of this chapter, or for the amendment to such license for which a notice of proposed action has been previously published.

* * * * *

PART 19—NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS

7. 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).

8. 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 pursuant to 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 § 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.

9. 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 71 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter.

* * * * *

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

10. 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, 133, 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).

11. 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, 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.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

12. 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).

13. 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 Parts 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]

14. Section 21.3 is amended by adding the number 63 after “10 CFR Parts 30, 40, 50 (other than nuclear power plants), 61” in paragraph (2) in the definition of *basic components*, *commercial grade item*, *dedication*, and in the definition of *substantial safety hazard* between “61” and “70”.

15. 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, 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, or 72 of this chapter.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

16. 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 (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).

17. Section 30.11 is amended by revising paragraph (c) to read as follows:

§ 30.11 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Parts 60 or 63 of this chapter.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

18. 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).

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).

19. Section 40.14 is amended by revising paragraph (c) to read as follows:

§ 40.14 Specific exemptions.

* * * * *

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Parts 60 or 63 of this chapter.

* * * * *

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

20. 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)).

21. 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 Parts 60 or 63 of this chapter.

* * * * *

22. Section 51.22 is amended by revising paragraphs (c)(3), (c)(10), 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 pursuant to 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.

* * * * *

(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 Parts 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.

23. 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 procedures set out in paragraph (a) of this section shall be followed.

24. 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 Parts 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 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 required time and manner of submission.)

* * * * *

PART 60—DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN GEOLOGIC REPOSITORIES

25. 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).

26. 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

27. 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).

28. 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 Parts 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.

* * * * *

29. In Section 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 Parts 60 or 63 is not considered a land disposal facility.

* * * * *

30. 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 Parts 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.

* * * * *

31. 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.
- 63.16 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 and Affected Indian Tribes

- 63.61 Provision of information.
- 63.62 Site review.
- 63.63 Participation in license reviews.
- 63.64 Notice to State.
- 63.65 Representation.

Subpart D—Records, Reports, Tests, and Inspections

- 63.71 Records and reports.
- 63.72 Construction records.
- 63.73 Reports of deficiencies.
- 63.74 Tests.
- 63.75 Inspections.
- 63.78 Material control and accounting records and reports.

Subpart E—Technical Criteria

- 63.101 Purpose and nature of findings.
63.102 Concepts.

PERFORMANCE OBJECTIVES

- 63.111 Performance objectives for the geologic repository operations area through permanent closure.

INTEGRATED SAFETY ANALYSIS

- 63.112 Requirements for integrated safety analysis of the geologic repository operations area.
63.113 Performance objective for the geologic repository after permanent closure.

PERFORMANCE ASSESSMENT

- 63.114 Requirements for performance assessment.

CHARACTERISTICS OF THE REFERENCE BIOSPHERE AND CRITICAL GROUP

- 63.115 Required characteristics of the reference biosphere and critical group.

LAND OWNERSHIP AND CONTROL

- 63.121 Requirements for ownership and control of interests in land.

Subpart F—Performance Confirmation Program

- 63.131 General requirements.
63.132 Confirmation of geotechnical and design parameters.
63.133 Design testing.
63.134 Monitoring and testing waste packages.

Subpart G—Quality Assurance

- 63.141 Scope.
63.142 Applicability.
63.143 Implementation.

Subpart H—Training and Certification of Personnel

- 63.151 General requirements.
63.152 Training and certification program.
63.153 Physical requirements.

Subpart I—Emergency Planning Criteria

- 63.161 Emergency plan for the geologic repository operations area through permanent closure.

Subpart J—Violations

- 63.171 Violations.
63.172 Criminal penalties.

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).

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 § 60.1, "Purpose and scope," 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 locating of such a facility; *Provided*, that the Secretary of the Interior finds, on the petition of the appropriate governmental officials of the Tribe, that such effects are both substantial and adverse to the Tribe.

Annual dose means the total effective dose equivalent (TEDE as defined at § 20.1003) received in a single year by the average member of the critical group only as a result of radioactive materials released from the geologic repository.

Barrier means any material or structure that prevents or substantially delays movement of water or radioactive materials.

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.

Critical group means the hypothetical group of individuals reasonably expected to receive the greatest exposure to radioactive materials released from the geologic repository.

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 restraints 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.

Design basis events means:

(1) Those natural and human-induced events that are expected to occur one or more times before permanent closure of the geologic repository operations area (referred to as Category 1 events); and

(2) Other natural and man-induced events that have at least one chance in 10,000 of occurring before permanent closure of the geologic repository (referred to as Category 2 events).

Director means the Director of the Nuclear Regulatory Commission's Office of Nuclear Material Safety and Safeguards.

Disposal means the emplacement of radioactive wastes 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 and the underground facility.

Expected annual dose means the expected value of the annual dose

considering the probability of the occurrence of the events and the uncertainty, or variability, in parameter values used to describe the behavior of the geologic repository.

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.

Groundwater means all liquid water that occurs below the land surface.

High-level radioactive waste or HLW means:

- (1) Irradiated reactor fuel;
- (2) Liquid wastes resulting from the operation of the first-cycle solvent extraction system, or equivalent, and the concentrated wastes from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuel; and
- (3) Solids into which such liquid wastes have been converted.

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 design basis events; or
- (2) To prevent or mitigate Category 2 design basis events that could result in doses equal to or greater than the values

specified in § 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 reasonable assurance that high-level waste can be disposed without exceeding the requirements of § 63.113(b).

Integrated safety analysis means an analysis to identify hazards and their potential for initiating event sequences, the potential event sequences and their consequences, and the site, structures, systems, components, equipment, and activities of personnel, that are relied on for safety. As used here, integrated means joint consideration of safety measures that otherwise might conflict, including, but not limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures.

Isolation means inhibiting the transport of radioactive material to the location of the critical group so that radiation exposures will not exceed the requirements of § 63.113(b).

Performance assessment means a probabilistic analysis that:

- (1) Identifies the features, events and processes that might affect the performance of the geologic repository; and
- (2) Examines the effects of such features, events, and processes on the performance of the geologic repository; and
- (3) Estimates the expected annual dose to the average member of the critical group as a result of releases from the geologic repository.

Performance confirmation means the program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objective at § 63.113(b) will be met.

Permanent closure means final backfilling of the underground facility, if appropriate, and the sealing of shafts, ramps, and boreholes.

Public Document Room means the place at 2120 L Street NW., Washington, DC, 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.

Reference biosphere means the description of the environment inhabited by the critical group. 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 intentionally removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means that part of the earth's crust beneath the regional water table in which all voids, large and small, are ideally 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.

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

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."

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.

Water table means that surface in a groundwater body, separating the unsaturated zone from the saturated zone, at which the water pressure is atmospheric.

§ 63.3 License required.

(a) DOE shall 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 pursuant to this part.

(b) DOE shall 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 shall be 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 2120 L Street NW, Washington DC, or 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 provided that the copy or microform is authenticated by authorized personnel and that 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 will be considered binding on the Commission.

§ 63.6 Exemptions.

The Commission may, upon application by DOE, any interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not endanger life nor property nor the common defense and security, and are 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 U.S. Nuclear Regulatory Commission has submitted the information collection requirements of general applicability contained in this part to the Office of Management and Budget for approval, as required by the Paperwork Reduction Act (44 U.S.C. 3501, *et seq.*). The Office of Management and Budget has approved the information collection requirements contained in this part under control number 3150-XXXX.

(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 has no application 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.

(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 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 shall 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 shall be provided to the Administrator of the appropriate Regional Office 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) Before submittal of an application for a license to be issued under this part, DOE shall conduct a program of site characterization with respect to the Yucca Mountain site.

(b) Investigations to obtain the required information shall be conducted in such a manner as to limit, to the extent practical, adverse effects on the long-term performance of the geologic repository at Yucca Mountain.

§ 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 not less than once every 6 months to the Commission on the nature and extent of such activities and the information that has been developed, and on the progress of waste form and waste package research and development. The semiannual reports shall 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

²In 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.

site characterization shall 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 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, such comments shall be made whenever the Director 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.

(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, under this section, including the reports described in paragraph (b) of this section, shall 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 Boards, other presiding officers, or the Director, in any such proceeding.

LICENSE APPLICATION

§ 63.21 Content of application.

(a) An application shall consist of general information and a Safety Analysis Report. An environmental impact statement shall be prepared in accordance with the Nuclear Waste Policy Act of 1982, as amended, and shall accompany the application. Any Restricted Data or National Security Information shall be separated from unclassified information.

(b) The general information shall 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 detailed plan to provide 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 shall 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 shall 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 shall 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;

(iv) Information regarding the location of the critical group, and regarding local human behaviors and characteristics, as needed to support selection of conceptual models and parameters used for the reference biosphere and critical group.

(2) An integrated 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 shall be 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.

(3) 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.

(4) A description and discussion of the design of the engineered barrier system including:

(i) The principal design criteria and their relationships to the postclosure performance objective specified at § 63.113(b); and

(ii) The design bases and their relation to the principal design criteria.

(5) 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(b)—whether beneficial or potentially adverse to performance of the geologic repository—have been characterized, and the extent to which they affect waste isolation.

Investigations shall 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 shall be investigated outside of the site if they affect performance of the geologic repository.

(6) 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 groundwater.

(7) An assessment of the performance of the proposed geologic repository for the period after permanent closure, as required by § 63.113(c). The assessment shall also include a comparative evaluation of alternatives to the major design features that are important to waste isolation, with particular attention to the alternatives that would provide longer containment and isolation of radioactive materials.

(8) An assessment of the ability of the proposed geologic repository to limit radiological exposures in the event of limited human intrusion into the engineered barrier system as required by § 63.113(d).

(9) An explanation of measures used to support the models used to perform the assessments required in paragraphs (c)(5) through (c)(8) of this section.

Analyses and models that will be used

to assess performance of the geologic repository shall 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.

(10) An explanation of how expert elicitation was used in the assessments required in paragraphs (c)(5) through (c)(8) of this section.

(11) 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.

(12) 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.

(13) 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 shall be given to those items that may significantly influence the final design.

(14) A description of the program for control and monitoring of radioactive effluents and occupational radiation exposures to maintain such effluents and exposures in accordance with the requirements of § 63.111.

(15) 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.

(16) 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 dismantlement of surface facilities, as required by § 63.161.

(17) A description of the program to be used to maintain the records described in §§ 63.71 and 63.72.

(18) A description of design considerations that are intended to facilitate permanent closure and decontamination or dismantlement of surface facilities.

(19) A description of plans for retrieval and alternate storage of the radioactive wastes, should retrieval be necessary.

(20) A description of the performance confirmation program that meets the requirements of Subpart F.

(21) An identification of those structures, systems, and components of the geologic repository, both surface and

subsurface, which 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.

(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 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.

§ 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, and any amendments thereto, and an accompanying environmental impact statement and any supplements, shall be signed by the Secretary of Energy or the Secretary's authorized representative and shall be filed in triplicate with the Director.

(b) Each portion of such application and any amendments, and each environmental impact statement and any supplements, shall be accompanied by 30 additional copies. Another 120

copies shall be retained by DOE for distribution in accordance with written instructions from the Director or the Director's designee.

(c) DOE shall, on notification of the appointment of an Atomic Safety and Licensing Board, 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 shall be served in the same manner.

(d) At the time of filing of an application and any amendments thereto, copies shall be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site, for inspection by the public, and updated as amendments to the application are made. The environmental impact statement and any supplements thereto shall be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, shall 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 such documents submitted in accordance with the requirements of 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, *provided*, that such references are clear and specific and that copies of the information so incorporated are made available to the public locations near the site of the proposed geologic repository, as provided pursuant to § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

(a) The application shall be as complete as possible in the light of 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.* That there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. In arriving at this determination, the Commission shall consider whether:

(1) DOE has described the proposed geologic repository as specified at § 63.21.

(2) The site and design comply with the performance objectives and requirements contained in Subpart E of this part.

(3) DOE's quality assurance program complies with the requirements of Subpart G of this part.

(4) DOE's personnel training program complies with the criteria contained in Subpart H of this part.

(5) DOE's emergency plan complies with the criteria contained in Subpart I of this part.

(6) 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 issuance of the construction authorization, with any appropriate conditions to protect environmental values.

§ 63.32 Conditions of construction authorization.

(a) A construction authorization for a geologic repository operations area at the Yucca Mountain site shall include such conditions as the Commission finds to be necessary to protect the health and safety of the public, the common defense and security, or environmental values.

(b) The Commission will incorporate, in the construction authorization, provisions 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 shall 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 shall not be issued by the Commission until;

(1) DOE has updated its application, as specified in § 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 shall be filed with the Commission, fully describing any changes desired and following as far as applicable the contents 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 deemed to be 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 dismantlement of surface facilities.

(e) All applicable requirements of Part 51 of this chapter have been satisfied.

§ 63.42 Conditions of license.

(a) A license issued pursuant to this part shall include such conditions, including license specifications, as the Commission finds to be necessary to protect the health and safety of the public, the common defense and security, and environmental values.

(b) Whether stated therein or not, the following shall be deemed conditions in every license issued:

(1) The license shall be 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 shall be 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 shall be 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 shall be deemed to contain 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 shall be deemed to contain the provisions set forth in Section 114(d) of the Nuclear Waste Policy Act, prohibiting emplacement of a quantity of spent fuel containing in excess of 70,000 metric tons of heavy metal or a quantity of solidified high-level radioactive waste resulting from the reprocessing of such a quantity of spent 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 shall include license conditions derived

from the analyses and evaluations included in the application, including amendments made before a license is issued, together with such additional conditions as the Commission finds appropriate.

(b) License conditions shall 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)(1) Following authorization to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site, DOE may:

(i) Make changes in the geologic repository operations area as described in the application;

(ii) Make changes in the procedures as described in the application; and

(iii) Conduct tests or experiments not described in the application, without prior Commission approval, provided the change, test, or experiment involves neither a change in the license conditions incorporated in the license nor an unreviewed safety question.

(2) A proposed change, test, or experiment shall be deemed to involve an unreviewed safety question if:

(i) The likelihood of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the application is increased;

(ii) The possibility of an accident or malfunction of a different type than any previously evaluated in the application is created; or

(iii) The margin of safety, as defined in the basis for any license condition, is reduced.

(b) DOE shall maintain records of changes in the geologic repository operations area at the Yucca Mountain site and of changes in procedures made pursuant to this section, to the extent that such changes constitute changes in the geologic repository operations area or procedures as described in the application. Records of tests and experiments carried out pursuant to paragraph (a) of this section shall also be maintained. These records shall include a written safety evaluation that provides the basis for the determination that the change, test, or experiment does not involve an unreviewed safety question. DOE shall prepare annually, or at such shorter intervals as may be specified in the license, a report containing a brief description of such changes, tests, and experiments, including a summary of the safety evaluation of each. DOE shall furnish the report to the appropriate NRC Regional Office shown in Appendix D of 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 pursuant to this paragraph shall be made a part of the public record of the licensing proceedings.

§ 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, an amendment of the license shall be required with respect to any of the following activities:

(1) Any action that would make emplaced high-level radioactive waste irretrievable or which would substantially increase the difficulty of retrieving such 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;

(6) Permanent closure; and

(7) Any other activity involving an unreviewed safety question.

(b) An application for such an amendment shall be filed, and shall be reviewed, in accordance with the provisions of § 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 shall 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.

(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, such measures shall 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, waste interaction with the host rock, 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, so as 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 such closure, DOE shall also supplement its environmental impact statement and submit such statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or dismantlement of surface facilities at the Yucca Mountain site, DOE may apply for an amendment to terminate the license.

(b) Such application shall be filed and will be reviewed in accordance with the provisions of § 63.45 and this section.

(c) A license shall 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 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 and Affected Indian Tribes

§ 63.61 Provision of information.

(a) The Director shall provide to the Governor and the Nevada State legislature, and to the governing body of any affected Indian Tribe, timely and complete information regarding determinations or plans made by the Commission with respect to 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 Yucca Mountain site.

(b) Notwithstanding paragraph (a) of this section, the Director is not required to distribute any document to any entity if, with respect to such document, that entity or its counsel is included on a service list prepared pursuant to Part 2 of this chapter.

(c) Copies of all communications by the Director under this section shall be placed in the Public Document Room, and copies thereof shall be furnished to DOE.

§ 63.62 Site review.

(a) The Director shall make NRC staff available to consult with representatives of the State of Nevada and affected Indian Tribes regarding the status of site characterization at the Yucca Mountain site.

(b) Requests for consultation shall 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 and Tribe participation in the Commission's regulatory activities.

(3) Cooperation in development of proposals for State and Tribe participation in license reviews.

§ 63.63 Participation in license reviews.

(a) 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.

(b) In addition, a State or an affected Indian Tribe may submit to the Director a proposal to facilitate its participation in the review of the license application. The proposal may be submitted at any time and shall contain a description and schedule of how the State or affected Indian Tribe wishes to participate in the review, or what services or activities the State or affected Indian Tribe wishes NRC to carry out, and how the services or activities proposed to be carried out by NRC would contribute to such 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 or 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 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 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 above, 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 Indian Tribe may bear;

(2) The proposed activities:

(i) Will enhance communications between NRC and the State or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

(e) The Director will advise the State or affected Indian Tribe whether its proposal has been accepted or denied, and if all or any part of proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses thereto, shall 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 such 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 thereof) 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 such representative capacity.

Subpart D—Records, Reports, Tests, and Inspections

§ 63.71 Records and reports.

(a) DOE shall maintain such records and make such reports in connection with the licensed activity as may be

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 shall 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)(2).

§ 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)(2).

(b) The records required under paragraph (a) of this section shall 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; and

(11) Details, methods of emplacement, and location of seals used.

§ 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) Be a substantial safety hazard;

(2) Represent a significant deviation from the design criteria and design bases stated in the application; or

(3) Represent a deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) The notification shall be in the form of a written report, copies of which

shall be sent to the Director and to the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter.

§ 63.74 Tests.

(a) DOE shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part. These 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 shall 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 shall be furnished by DOE. The office shall be convenient to and have full access to the facility and shall provide the inspector both visual and acoustic privacy.

(2) The space provided shall 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 that is provided shall be 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 of this part 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 and other criteria that, if satisfied, will support such a finding of no unreasonable risk.

(2) Although the performance objective for the geologic repository after permanent closure specified at § 63.113 is generally stated in unqualified terms, it is not expected that complete assurance that the requirement will be met can be presented. A reasonable assurance, on the basis of the record before the Commission, that the performance objective will be met is the general standard that is required. Proof that the geologic repository will be in conformance with the objective 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 assurance, making allowance for the time period, hazards, and uncertainties involved, that the outcome will be in conformance with the objective for postclosure performance of 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. Further, in reaching a determination of reasonable assurance, 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 of this part also lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. In particular, § 63.31(a) 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 disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. As stated in that paragraph, in arriving at this determination, the Commission will consider whether DOE has demonstrated that the geologic repository complies with the criteria contained in this subpart. 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 reasonable assurance as specified in paragraph (a) of this section.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency with definitions found in § 63.2, those definitions shall 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) This part deals 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 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 must 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 exposures, in both restricted and unrestricted areas, and releases of radioactive materials to unrestricted areas, as specified at § 63.111(a).

(f) Integrated safety analysis. Section 63.111 includes performance objectives for the geologic repository operations area for the period before permanent closure and decontamination or dismantlement of surface facilities. The integrated safety analysis is a systematic examination of the geologic repository operations area's hazards and their potential for initiating event sequences; the potential event sequences and their consequences; and the site, structures, systems, components, equipment, and activities of personnel, to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified. As used here, integrated means joint consideration of safety measures that otherwise might conflict, including, but not limited to, integration of fire protection, radiation safety, criticality safety, and chemical safety measures. The results of this analysis will support a determination regarding compliance of the geologic repository operations area with the requirements specified at § 63.111.

(g) Performance objective after permanent closure. After permanent closure, the geologic repository is required to limit the expected annual dose to the average member of the critical group, as specified at § 63.113(b).

(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 a portion 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 archaeological analogues, 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. It is intended that natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository and increase confidence that the postclosure performance objective at § 63.113(b) will be achieved.

(i) Reference biosphere and critical group. 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 a critical group. The environment inhabited by the critical group, along with associated human exposure pathways and dose assessment parameters, make up the reference biosphere. The critical group 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 critical group are to be based on current human behavior and biospheric conditions in the region.

(j) Performance assessment. Demonstrating compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment to quantitatively estimate the expected annual dose, over the compliance period, to the average member of the critical group. 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 expected annual dose. 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 of very low probability of occurrence (less than one chance in 10,000 over 10,000 years) can be excluded from the analysis. The expected annual dose to the average member of the critical group is estimated using the selected features, events, and processes, and incorporating the probability that the estimated dose will occur.

(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. Because it is not possible to make scientifically sound forecasts of the long-term reliability of such controls, however, it is not appropriate to integrate 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 postulated intrusion as specified at § 63.113(d). Although the consequences of an assumed intrusion event is a separate analysis, the analysis is identical to the performance assessment required by § 63.113(c); except that it assumes the occurrence of a postulated human intrusion event.

(m) Performance confirmation. A performance confirmation program will be conducted to verify the assumptions, data, and analyses that support the performance assessment, and any findings, based thereon, that permitted construction of the repository. Key geologic, hydrologic, geomechanical, and other physical parameters will be monitored throughout site characterization, construction, emplacement, and operation to detect any significant changes in the conditions assumed in the performance assessment that may affect compliance with the performance objective at § 63.113(b).

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 shall meet the requirements of Part 20 of this chapter.

(2) During normal operations, and for Category 1 design basis events, the annual dose to any real member of the public, located beyond the boundary of the site shall not exceed a TEDE of 0.25 mSv (25 mrem).

(b) Numerical Guides for Design Objectives. (1) The geologic repository operations area shall be designed so that taking into consideration Category 1 design basis events and until permanent closure has been completed, radiation exposures and radiation levels in both restricted and unrestricted areas, and 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 shall be designed so that taking into consideration Category 2 design basis events and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site, will receive 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 shall not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin shall not exceed 0.5 Sv (50 rem).

(c) Integrated safety analysis. An integrated safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 shall be performed. This analysis shall include a demonstration 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 shall be designed so as to permit implementation of a performance confirmation program that meets the requirements of Subpart F of this part.

(e) Retrieval of waste. (1) The geologic repository operations area shall 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 shall 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 shall 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 this paragraph, 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.

INTEGRATED SAFETY ANALYSIS

§ 63.112 Requirements for integrated safety analysis of the geologic repository operations area.

The integrated safety analysis of the geologic repository operations area shall 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 accident/event sequences that would result in unacceptable consequences (i.e., design basis events).

(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 major design structures, systems, and components, both surface and subsurface, to identify those that are important to safety, including identification and description of controls that are relied on to limit or prevent potential accidents or mitigate their consequences, and including identification of measures taken to ensure the availability of identified

safety systems. The analysis required in this paragraph shall 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 area;

(6) Means to 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 design basis events;

(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 principal design criteria and the requirements specified at § 63.111(a) and (b); and

(2) The design bases and their relation to the principal design criteria.

§ 63.113 Performance objective for the geologic repository after permanent closure.

(a) The geologic repository shall include multiple barriers, consisting of both natural barriers and an engineered barrier system.

(b) The engineered barrier system shall be designed so that, working in combination with natural barriers, the expected annual dose to the average

member of the critical group shall not exceed 0.25 mSv (25 mrem) TEDE at any time during the first 10,000 years after permanent closure, as a result of radioactive materials released from the geologic repository.

(c) The ability of the geologic repository to limit radiological exposures to those specified in paragraph (b) of this section shall be demonstrated through a performance assessment that meets the requirements specified at § 63.114, uses the reference biosphere and critical group specified at § 63.115, and excludes the effects of human intrusion.

(d) The ability of the geologic repository to limit radiological exposures to those specified in paragraph (b) of this section, in the event of limited human intrusion into the engineered barrier system, shall be demonstrated through a separate performance assessment that meets the requirements specified at § 63.114 and uses the reference biosphere and critical group specified at § 63.115. For the assessment required by this paragraph, it shall be assumed that the human intrusion occurs 100 years after permanent closure and takes the form of a drilling event that results in a single, nearly vertical borehole that penetrates a waste package, extends to the saturated zone, and is not adequately sealed.

PERFORMANCE ASSESSMENT

§ 63.114 Requirements for performance assessment.

Any performance assessment used to demonstrate compliance with § 63.113(b) shall:

(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 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 of the geologic setting in the performance assessment. Specific features, events, and processes of the geologic setting must be evaluated in detail if the magnitude and time of the resulting expected annual dose 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 expected annual dose 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).

(h) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(i) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the barriers.

(j) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste.

CHARACTERISTICS OF THE REFERENCE BIOSPHERE AND CRITICAL GROUP

§ 63.115 Required characteristics of the reference biosphere and critical group.

(a) Reference biosphere. (1) Features, events, and processes that describe the reference biosphere shall be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(2) Biosphere pathways shall be consistent with arid or semi-arid conditions.

(3) Climate evolution shall be consistent with the geologic record of natural climate change in the region surrounding the Yucca Mountain site.

(4) Evolution of the geologic setting shall be consistent with present knowledge of natural processes.

(b) Critical group. (1) The critical group shall reside within a farming

community located approximately 20 km south from the underground facility (in the general location of U.S. Route 95 and Nevada Route 373, near Lathrop Wells, Nevada).

(2) The behaviors and characteristics of the farming community shall be consistent with current conditions of the region surrounding the Yucca Mountain site. Changes over time in the behaviors and characteristics of the critical group including, but not necessarily limited to, land use, lifestyle, diet, human physiology, or metabolics; shall not be considered.

(3) The critical group resides within a farming community consisting of approximately 100 individuals, and exhibits behaviors or characteristics that will result in the highest expected annual doses.

(4) The behaviors and characteristics of the average member of the critical group shall be based on the mean value of the critical group's variability range. The mean value shall not be unduly biased based on the extreme habits of a few individuals.

(5) The average member of the critical group shall be an adult. Metabolic and physiological considerations shall be consistent with present knowledge of adults.

LAND OWNERSHIP AND CONTROL

§ 63.121 Requirements for ownership and control of interests in land.

(a) Ownership of land. (1) Both the geologic repository operations area and the site 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) These lands shall 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. Appropriate controls shall be established outside of the site. 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) 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 shall 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) Geologic 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 shall have been started during site characterization and it will continue until permanent closure.

(c) The program shall 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 shall 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 shall be conducted to ensure that geotechnical and design parameters are confirmed and to ensure that appropriate action is taken to inform the Commission of changes needed in design to accommodate actual field conditions encountered.

(b) Subsurface conditions shall be monitored and evaluated against design assumptions.

(c) As a minimum, measurements shall be made of rock deformations and displacement; changes in rock stress

and strain; rate and location of water inflow into subsurface areas; changes in groundwater conditions; rock pore water pressures, including those along fractures and joints; and the thermal and thermomechanical response of the rock mass as a result of development and operations of the geologic repository.

(d) These measurements and observations shall 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 shall 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 shall 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 in-situ testing of such features as borehole and shaft seals, backfill, and the thermal interaction effects of the waste packages, backfill, rock, and groundwater shall be conducted.

(b) The testing shall be initiated as early as practicable.

(c) A backfill test section shall be constructed to test the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Test sections shall be established to test 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 shall be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program shall 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 shall be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program shall 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 shall be duplicated in the laboratory experiments.

(d) The waste package monitoring program shall 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 subsystems 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 Applicability.

The quality assurance program applies to all systems, structures, 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, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria of Appendix B of 10 CFR Part 50, as applicable, and appropriately supplemented by additional criteria, as required by § 63.142.

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 shall 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 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 shall 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 such 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 dismantlement of surface facilities. The emergency plan

shall 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 pursuant to 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 pursuant to 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: Sections 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, 63.153, 63.171, and 63.172.

Dated at Rockville, Maryland, this 12th day of February, 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

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