

AFFIRMATION V O T E

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

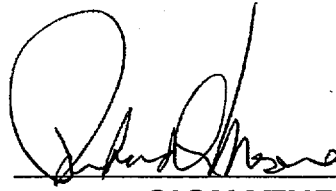
SUBJECT: SECY-01-0127 - DRAFT FINAL RULE: 10 CFR PART 63,
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A
PROPOSED GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN NEVADA

Approved X with comment Disapproved Abstain

Not Participating Request Discussion

COMMENTS:

See attached comments.



SIGNATURE

August 10, 2001

DATE

Entered on "STARS" Yes No

COMMENTS OF CHAIRMAN MESERVE ON SECY-01-0127

SECY-01-0127 presents the draft final rule that would establish licensing criteria for a proposed geologic repository at Yucca Mountain, Nevada. The paper reflects a very significant effort for which the staff should be commended.

The Energy Policy Act of 1992 requires that NRC establish technical requirements and criteria that are consistent with standards for Yucca Mountain that are promulgated by EPA. Pub. L. No. 102-486, § 801, 106 Stat. 2921 (1992). EPA has recently promulgated its standards. 66 Fed. Reg. 32,073 (June 13, 2001). As a result, the draft final rule before us modifies NRC's proposed rule not only to respond to public comments, but also to implement the EPA standards.

The final EPA standards depart significantly from the NRC proposed rule by including a 15 mrem/yr individual protection standard and a 4 mrem/yr ground-water protection standard using EPA's maximum contaminant levels (MCLs). 40 C.F.R. §§ 197.20, 197.30. I am of the view that the 25 mrem/yr dose limit published in NRC's proposed rule is fully protective of public health and safety. I also am convinced that a separate standard to protect ground water is unnecessary and imposes needless burdens on the Department of Energy (DOE) that do not have a commensurate health and safety benefit. Moreover, I continue to be troubled by the use of outdated dosimetry by EPA in defining the MCLs for ground-water protection; the MCLs lack scientific foundation and have the unfortunate consequence of establishing differences in protection on a radionuclide-by-radionuclide basis.

Nonetheless, we are bound by law to implement the EPA standards. Accordingly, the staff has appropriately modified the NRC proposed rule to implement the EPA standards fully and thoughtfully. Subject to the comments noted below, I approve publication of the final rule in the Federal Register. In addition, I certify that the final rule does not have a significant financial impact on a substantial number of small entities.

1. The final rule and Statement of Considerations (SOC) should be revised to use "total effective dose equivalent" (TEDE) instead of "annual committed effective dose equivalent" (annual CEDE) for radiological doses to members of the public in the general environment and to the reasonably maximally exposed individual (RMEI). Although the final EPA standards employ the term "annual committed effective dose equivalent" (40 C.F.R. §§ 197.2, 197.20), TEDE and annual CEDE in this application are the same.¹ I favor the use of

¹ There are differences between TEDE and annual CEDE in some contexts. Specifically, in determining the external dose component of TEDE, our rule specifies use of the deep-dose equivalent. See 10 C.F.R. § 20.1003. The deep-dose equivalent is a point measurement that does not sum the doses to the organs or tissue through use of weighting factors. See 10 C.F.R. § 20.1201(c). This approach may reflect the fact that compliance with Part 20 is customarily assessed using a Thermo-Luminescent Device (TLD) or a film badge, and

TEDE in Part 63 because this is the standard NRC terminology. The needless proliferation of terminology for equivalent concepts should be avoided. The SOC should be modified to reflect this change and more thoroughly explain that TEDE is equivalent to annual CEDE in application to Yucca Mountain. Of course, in applying TEDE to members of the public in the general environment and to the RMEI, staff should provide for the use of effective dose equivalent, as opposed to deep-dose equivalent, when considering external exposures (as allowed under 10 C.F.R. § 20.1003).

As a separate matter, the differences in approach and terminology revealed by this issue and the recent confusion surrounding the assessment of external dose by some licensees (SECY-01-0140) demonstrate the need for staff to address when it is appropriate to use effective dose equivalent rather than deep-dose equivalent for assessing the dose from external sources of radioactivity.

2. The EPA standard defines the RMEI as a rural-residential exposed through the same general pathways as a subsistence farmer. 66 Fed. Reg. 32,092 (June 13, 2001). In describing the RMEI in the SOC for Part 63, staff indicates that the RMEI is a member of a farming community (SECY-01-0127, Attachment 2, at 84). Because the terminology is different, some might perceive a conflict between the EPA standards and Part 63. The staff should ensure that the appearance of a conflict is avoided in preparing the final *Federal Register* notice.

the results of such measurements reflect deep-dose equivalent. By contrast, in determining annual CEDE, the external dose component is determined using the effective dose equivalent, which involves summing the products of organ doses and weighting factors. See 40 C.F.R. § 197.2. In those situations in which the two measures of external dose differ, the effective dose equivalent approach probably provides a better estimate for measuring radiation risk.

In the context of compliance with the individual protection standard at Yucca Mountain, the external dose would clearly be very small in comparison to the committed dose. (The principal pathway of exposure is ingestion, which would result in internal exposure.) Moreover, Part 20 does allow for consideration of weighting factors for individual organs in the case of external exposures on a case-by-case basis. See 10 C.F.R. § 20.1003, Footnote 2 to Table on Organ Dose Weighting Factors. As a result, in assessing compliance with the individual protection standard, the staff intends to use effective dose equivalent for assessing external exposure. The computer codes used by NRC in decommissioning and HLW disposal currently calculate external doses using effective dose equivalent and not deep-dose equivalent. See NUREG/CR 6676, "Probabilistic Dose Analysis Using Parameter Distributions Developed for RESRAD and RESRAD-Build Codes," 3-1 (July 2000); NUREG-1464, "NRC Iterative Performance Assessment," 7-5 (October 1995); and NUREG/CR-5512, "Residual Contamination from Decommissioning, User's Manual DandD Version 2.1," Vol. 2, E-1 (April 2001). Consequently, the application of TEDE (using organ weighting factors for external doses) in assessing compliance with dose limits for members of the public in the general environment and the individual protection standard in connection with a geologic repository will yield exactly the same result as applying annual CEDE. See SECY-01-0127, Attachment 2, at 12.

3. The staff uses the term "soluble radionuclides" in the context of the human intrusion scenario. See § 63.322. Without further clarification, the term might invite debate as to what radionuclides should be considered as soluble. The staff should provide clarification as to the intended meaning of this term.

4. EPA's standard has three separate components -- the individual protection standard, the ground-water standards, and the human intrusion standard. In the draft final Part 63, the staff has indicated that only the individual protection and ground-water protection standards are severable. See § 63.343. In preparing the final *Federal Register* notice, the staff should work with EPA to ensure that the severability requirement is consistent with the EPA standard.

5. In § 63.322, the staff uses the term "unlikely natural processes and events," but provides no probability cutoffs for defining these events. This omission could result in uncertainty as to what natural processes and events should be considered. Consequently, following issuance of the final Part 63, staff should initiate an expedited rulemaking to establish the annual probability of occurrence that is seen to constitute an unlikely event or process.

6. The definition of high-level radioactive waste in § 63.202 is not appropriate for inclusion in the NRC rule (although it is appropriate in the EPA rule), because it would suggest incorrectly that the NRC intends to leave to another rulemaking the determination of whether irradiated reactor fuel should be deemed HLW.² A more appropriate approach is to adopt subpart (A) of the definition from the Nuclear Waste Policy Act of 1982 (42 U.S.C. § 10101(12)), as amended, as item (1) of the regulatory definition; add "irradiated reactor fuel" as item (2) of the definition; and to retain subpart (B) of the statutory definition as item (3) of the regulatory definition. Moreover, the definition of the term "high-level waste" in § 63.2 should be conformed to that in § 63.202.

7. The term "ground water" is defined in one part of the regulations to include the vadose zone (§ 63.2) and in another part to exclude that zone (§ 63.302). This will create needless confusion in the implementation of the rule. The staff should develop one definition that applies in all cases, but maintains consistency with the EPA standard.

8. Section 63.16(d) provides that the Director of NMSS "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." It is unclear whether this requirement is intended to apply to comments that the NRC might make concerning its review of DOE's Yucca Mountain Science and Engineering Report (YMS&ER) and related documents. However, I note that the staff has not proposed the solicitation of public comments in its schedule for completing its review of the YMS&ER and, if public comment were required, a substantial change in schedule could be required.

² As currently drafted, high-level radioactive waste is defined in § 63.202 to encompass highly radioactive material from reprocessing and "[o]ther highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation." This section does not mention spent fuel.

Through Commission meetings with stakeholders on DOE's Viability Assessment and Draft Environmental Impact Statement, as well as from Advisory Committee on Nuclear Waste and NRC staff meetings with stakeholders on various technical issues, the Commission is aware of stakeholder concerns regarding the sufficiency of DOE's site characterization of Yucca Mountain. As a result, it is my view that additional input from stakeholders is unnecessary at this juncture. Although some stakeholders may want to provide direct input on the NRC's preliminary sufficiency comments, I believe that the Commission is in a position to make an informed decision without further stakeholder input. Moreover, although DOE's schedule for receiving comments has slipped, DOE has also delayed submitting documents supporting the YMS&ER to the staff. Consequently, it is unlikely that sufficient time will be available to provide for an extensive public involvement in NRC's preliminary site sufficiency comments. Therefore, the provision should be altered to make clear that the NRC comments on the YMS&ER will not themselves be subject to public comment.

9. I suggest a variety of edits to the draft *Federal Register* notice. These are reflected on the attached pages.

Valley, Las Vegas, and Caliente, Nevada, on June 15, 16, and 17, respectively. In developing this final rule, NRC considered comments received at these meetings along with written comments sent to NRC. The NRC also held a facilitated round table discussion on defense in depth as applied to a possible repository at Yucca Mountain on November 2, 1999, in Las Vegas.

The EPA published final radiation protection standards for the potential Yucca Mountain repository (40 CFR Part 197) on June 13, 2001 (66 FR 32073). The EPA standards differ ~~somewhat~~ from the performance objectives proposed by the Commission at 10 CFR Part 63.

EPA established an annual individual protection dose limit of 0.15 mSv (15 mrem), and EPA included separate ground-water protection criteria in its final standards. *for the purpose of protecting groundwater* In formal comments on EPA's proposed standards, dated November 3, 1999, the NRC staff supported a somewhat different approach. The NRC approach, which the Commission believes is adequately protective of public health and safety and groundwater, used a comprehensive, all-pathway limit. However, the ultimate decision was EPA's to make and, as called for under the EnPA, the Commission will change its technical requirements and criteria to be consistent with EPA's final standards.

II. Implementation of the Environmental Protection Agency Final Standards

The U.S. Environmental Protection Agency (EPA) published Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, at 40 CFR Part 197 on June 13, 2001 (66 FR 32073). The Energy Policy Act of 1992, Pub. L. 102-486 (EnPA) directs the Commission to modify its technical requirements and criteria to be consistent with these standards. The Commission has imported the EPA standards into its final

However, the EPA standards do not specify a frequency for unlikely features, events, and processes, and acknowledges a value is to be specified by NRC (66 FR 32135). NRC fully supports excluding unlikely features, events, and processes from analyses for estimating compliance with the standards for human intrusion and ground-water protection. ^{Although} While we have provided no specific quantitative value for determining when exclusion of unlikely features, events, and processes is appropriate, the final regulations allow DOE to exclude unlikely features, events, and processes from the specified analyses with the prior approval of the Commission. The Commission recognizes that specification of a probability limit for unlikely features, events, and processes, as is done for "very" unlikely features, events, and processes, would be a more direct approach. Although the Commission considers a frequency for unlikely features, events, and processes would fall somewhere between 10^{-8} to 10^{-4} per year, the Commission has decided not to specify a value in the regulations at this time. The Commission considers this approach to be consistent with the intent of EPA's final standards and may revisit the question of specifying a numerical value by rulemaking in the future.

TOTAL EFFECTIVE DOSE EQUIVALENT

The EPA standards use the term "annual committed effective dose equivalent" (annual CEDE) to denote the total dose resulting from internal and external exposure to radiation resulting from a single year's exposure. A distinction is made between internal and external doses, because internal exposures (e.g., ingestion and inhalation of radionuclides) continue as long as the radioactive material remains within the body, and disproportionately affect internal organs, depending on where a particular radionuclide is retained in the body. Thus, internal exposure is determined by calculating a CEDE that takes into account the fact that internally

necessary, to conform to the new, site-specific standards to be developed by EPA. These same commenters noted that certain portions of proposed Part 63 depart significantly from Part 60 (e.g., there are no quantitative subsystem requirements) and, in the view of several commenters, weaken the safety requirements for any proposed repository at Yucca Mountain.

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

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

approximately 20 km for Yucca Mountain). Generally, commenters asked NRC to set standards similar to, or more stringent than, those for WIPP. Some argued that a greater level of protection for people near Yucca Mountain was needed to offset potential exposures from other sources in the region (i.e., the Beatty low-level waste site and the Nevada Test Site, NTS).

Response. Final EPA standards adopted numerical limits that are comparable to those applied at WIPP. ~~In setting these limits, EPA took into consideration potential doses to the RMEI from other sources in the region.~~ Consistent with the views expressed by a majority of commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain, and is adopting final Part 63 criteria that are consistent with those limits, as required by law.

1.3 Multi-Staged Licensing

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

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

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

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

repository. The Commission believes that it is DOE's responsibility to specify the important geotechnical and design parameters to be evaluated through observation and measurement during construction and operation, subject to NRC approval through review and evaluation of the license application. DOE will provide this information in their performance confirmation plan included in the license application. If necessary, the NRC staff will provide guidance to DOE in this area through pre-licensing interactions and/or the YMRP. Section 63.132(c) has been revised to reflect these considerations.

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

Section 63.134 (Monitoring and testing waste packages) provides specific requirements for monitoring and testing waste packages consistent with the objectives of the performance confirmation program established at § 63.131(a). Waste packages are important engineered components designed to operate as barriers after permanent closure. Because the assumed long-term performance of waste package materials is based on short-term experimental data, monitoring waste package performance and related laboratory experiments are appropriate performance confirmation activities. ^{Although} While the NRC recognizes the need for reasonable cost constraints, it is important to note that it is DOE's responsibility to develop the details of a

3.1 Post-closure Safety Assessment

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

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

Response. Although repository post-closure performance is evaluated with respect to a single performance measure, ^{for individual protection} the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the post-closure performance objective ^{is} satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain. The Commission believes the approach for performance assessment in the proposed rule is appropriate and is retained in the

63 not only requires DOE to account for uncertainty in its performance assessment but also contains a number of other requirements (e.g., use of multiple barriers, performance confirmation program) to compensate for residual uncertainties in estimating performance. The Commission will consider all these requirements in determining whether it has sufficient confidence (i.e., reasonable expectation) that DOE has demonstrated or has not demonstrated the safety of the repository. Specification of an acceptable level of uncertainty is neither practical nor appropriate due to the limited knowledge currently available to support any such specification and the range of uncertainties that would need to be addressed. The Commission believes the approach for performance assessment in the proposed rule, which includes the treatment of uncertainty, is appropriate and has retained this approach in the final rule.

The previous response, under Issue 1, discussed the requirements for the performance assessment. Many of these requirements, as discussed above, address uncertainty in the performance assessment. Some of these uncertainties will be directly included in the DOE's estimate of performance. For example, DOE is expected to conduct uncertainty analyses (i.e., evaluation of how uncertainty in parameter values affects uncertainty in the estimate of dose), including the consideration of disruptive events and associated probability of occurrence. Other uncertainties are not necessarily quantified but are considered during the development of the conceptual models for the performance assessment (e.g., consideration of alternative models, inclusion and exclusion of FEPs). If NRC were to specify an acceptable level of uncertainty, the specified value would be somewhat arbitrary because: (1) understanding of the site is evolving as site studies continue; (2) repository design options are still being evaluated; and (3) differences in the types of uncertainties (e.g., variability in measured parameters, modeling assumptions, expert judgment, etc.) complicate the specification. *The approach defined in* Part 63, which requires DOE to fully address uncertainties in its performance assessment rather than requiring DOE to meet a specific level of

uncertainty, is ~~considered an appropriate approach~~. The treatment of uncertainty in DOE's performance assessment will be an important part of NRC's review.

Regardless of the uncertainty in the performance assessment, Part 63 contains additional provisions to increase confidence that the post-closure performance objectives will be met. These provisions include requirements for multiple barriers, a performance confirmation program, and implementation of a QA program (see discussion under Issue 1). However, it should be kept in mind that the performance assessment evaluates "potential" doses, not "actual" doses. For example, Part 63 requires the performance assessment to assume for the next 10,000 years that the reasonably maximally exposed individual (RMEI) is a member of a community that: (1) exists where it will intercept potential releases from the repository and (2) uses ground water but never tests the quality of this water nor treats the ground water to remove any contaminants. This specification is considered appropriately conservative for evaluating performance but most likely is not an "accurate" prediction of what will happen during the next 10,000 years (see discussion under RMEI Characteristics and Reference Biosphere for more information on the RMEI). Although the Commission does not require an "accurate" prediction of the future, uncertainty in performance estimates cannot be so large that the Commission cannot find a reasonable expectation that the post-closure performance objectives will be met (see discussion under Reasonable Expectation). At this time, the Commission is not aware of any information that suggests the uncertainties are so large that NRC will be unable to make a regulatory decision regarding the safety of a potential repository at Yucca Mountain.

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

where and how an individual would be exposed, and (2) the dose limit should reflect impacts from either future energy development or past releases on the local community, such as ground-water releases from the NTS or the Beatty Low-Level Waste facility, in developing the standard.

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

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

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

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

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

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

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

the individual dose, (2) disagreed with the use of a negligible individual dose value to screen possible release scenarios, and (3) viewed a dose distribution over the population as more informative to the regulators and public, allowing a more risk-informed decision to be made.

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

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

including location and number of individuals, for other less exposed groups, unbounded speculation could make any resulting population dose distribution unsupportable.

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

Collective dose is useful for comparing options but it does not provide adequate protection of the individual. Collective dose is the total dose received by all exposed people, regardless of distance or magnitude of exposure, over all time from a source. In general, most analyses tend to truncate the dose by calculating over a certain time frame and a given environmental area. Truncated collective dose can provide an overall measure of radiological impact on society or on parts of society but is only useful as an aid to compare options (e.g., DOE has considered individuals living within 84 km (52 miles) of the Yucca Mountain site for evaluating population doses in the DEIS). Because the calculation of collective dose results in a single value [in person-Sv (person-rem)], it gives no indication of the range or variability of individual doses or the time when the doses could occur. Meanwhile, the use of an individual dose limit to the RMEI assures that *the vast majority* ~~all other members~~ of the population receive lower doses. The Commission believes that using an individual all-pathway dose assessment provides to the regulator and the public a meaningful measure for making decisions regarding public health and safety.

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

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

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

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

constraint that is a small fraction (15 percent) of the public dose limit, and which provides a significant margin of safety to ensure that public health and safety and the environment are protected.

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

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

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

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission will incorporate, a dose limit of 0.15 mSv/year (15 mrem/year). The Commission

However, consistent with the EPA standards, the Commission has incorporated a dose limit of 0.15 mSv/yr (15 mrem/yr) in final Part 63.

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

3.3 Calculation of Expected Dose

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

Comment. The public noted that while a specialist may know that the "expected dose" and the "mean dose" are equivalent, to many people "expected" implies the most likely outcome. The same commenter asserted that the mean value derived from the performance assessment is not the most likely, but rather a value that is unlikely to be exceeded. The commenter sought clarification on whether the "expected annual dose" is the mean or the median dose or some other statistical measure. Some members of the public approved of the use of the mean dose rather than the median or mode and noted that mean should provide a reasonable degree of conservatism. Furthermore, some commenters asserted that use of the "expected annual dose"

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

3.4 Infant and Children Dose Standard

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

Comment. Many commenters were concerned that the dose limits in Part 63 may not be sufficiently protective of sensitive populations such as children or infants that may be more susceptible to the effects of radiation. Others were concerned that by focusing the dose limit on protecting humans, the environment was not adequately protected.

Response. The international community and the Federal agencies (including EPA) agree ^{follow} ICRP's current guidelines that the overall annual dose to members of the public from all sources ^{do not exceed} that the overall annual public dose limit from all sources should be 1 mSv (100 mrem), which is ^{in order to} protective of all individuals and the environment. The purpose of the public dose limit is to limit the lifetime risk from radiation to a member of the general public. The conversion factor used to equate dose into risk is based on data from various populations exposed to very high doses of radiation such as the atomic bomb survivors, and these populations contained individuals of all ages. Therefore, variation of the sensitivity to radiation with age and gender is built into the standards which are based on a lifetime exposure. A lifetime exposure includes all stages of life,

These guidelines also hold the exposure from a single practice should be limited to a fraction of this overall dose.

from birth to old age. For ease of implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive.

Consequently, the limit of 0.15 mSv/yr (15 mrem/yr), which is a small fraction of the annual public dose limit, is protective of children as well as other age groups, because the variation of sensitivity with age and gender was accounted for in the selection of the lifetime risk limit, from which the annual public dose limit was derived. For more information on the selection of the 0.15 mSv/yr (15 mrem/yr) limit, see the discussion under the Individual Dose Limit.

Experimental studies have shown that many flora and fauna tend to be much more resistant to radiation than humans. Therefore, except in cases where large concentrations of radionuclides can enter the environment and no reasonable exposure scenarios exist for humans, one of the principles of radiation protection is that by protecting the public, the environment is protected. In the case of Yucca Mountain and long-term releases, the primary pathway will be through the ground water. While the contaminated ground water may rise up to the surface environment around Ash Meadows (approximately 40 km (25 miles) from Yucca Mountain), the contaminants will ^{be} have been diluted to much lower concentrations than those used in calculating the dose to the RMEI. Therefore, if the RMEI is protected from doses in excess of the dose limit, the environment is also protected.

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Provide reference

The International Community and the Federal Agencies regularly review the basis for the public dose limit to evaluate whether new information would suggest a change in the public dose limit. Should the public dose limit in Part 20 change, NRC would evaluate if changes to Yucca Mountain's dose limit are necessary.

consideration of the local biosphere, using the "critical group approach" specified by the ICRP and employing "cautious but reasonable assumptions." The ICRP has generally defined the critical group to be a relatively homogenous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of radionuclide releases (International Commission on Radiological Protection, "Recommendations of the ICRP," *Annals of the ICRP*, Vol. 1, No. 3 [1977]. [ICRP Publication 26] and International Commission on Radiological Protection, "Radiological Protection Principles for the Disposal of Solid Radioactive Waste," Pergamon Press, Oxford, 1985. [ICRP Publication 46])

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

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

Finally, with regard to the suggestion that the NRC staff's understanding of drilling and pumping practices in the area is outdated, the Commission does not share this view. Rotary drilling technology, first introduced into the U.S. in the early 1900's, is still used to drill most wells in the U.S., including those in the Amargosa Desert area. The Commission is also aware that there are now more efficient submersible pumps capable of pumping ground water from greater depths. However, the costs of developing deep ground-water resources increase proportionally with depth, regardless of pump efficiencies.

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

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

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

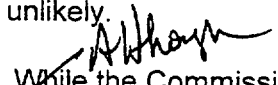
In summary, the requirement that the RMEI use water of average contaminant concentration, in a volume of water (3,000 acre-feet) reflective of a farming community, is conservative. Because the RMEI is defined as that person reasonably likely to receive the highest doses, the selection of RMEI characteristics must take into consideration both the magnitude of the dose likely to be received and the likelihood that a dose will actually occur at that location. The Commission believes that EPA selected the characteristics of the RMEI based on cautious and reasonable assumptions for the community of individuals likely to receive the highest doses. For these reasons, the Commission has adopted EPA's definition of the RMEI, as it appears at 40 CFR 197 and added the additional requirement for water usage by the RMEI.

3.6 Critical Group Characteristics and Reference Biosphere

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

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

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

Response.  While the Commission finds that limiting the dose received by the average member of the critical group is protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use 40 CFR 197's mean dose to the RMEI as the measure to compare with the dose limit. The RMEI approach has been characterized as providing a similar level of protection to that achieved by protecting the average member of the critical group, as was proposed for Part 63. In its comments to EPA on the proposed 40 CFR 197, the NAS noted that the reasonably maximally exposed individual is very

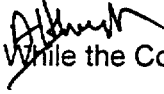

similar to the internationally used critical group approach. Additionally, NRC quoted, in the proposed rule, the International Commission on Radiological Protection which stated that it may be convenient to define the critical group in terms of a single hypothetical individual. The International Atomic Energy Agency's (IAEA's) Biosphere Modeling and Assessment working group has taken it further and calls such a hypothetical individual a reasonably maximally exposed individual (BIOMASS, 1999). ^{Althugh} While there are slight differences between the EPA's reasonably maximally exposed individual and NRC's proposed average member of the critical group, they are virtually the same (especially in view of the IAEA's guidance). As noted earlier, the Commission has adopted the RMEI approach to be consistent with 40 CFR 197.

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

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

community is conservative (i.e., protective). One commenter questioned the accuracy of the reported population count for Amargosa Valley.

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

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

Regarding the two additional requirements, the final regulations specify: (1) the water demand to be used in estimating exposure to the RMEI (see response to Issue 2 under Critical Group Location); and (2) that the RMEI is an adult with metabolic and physiological considerations consistent with present knowledge. Specification of the RMEI as an adult is: (1) consistent with the NAS recommendations for specifying the exposure scenario by rule; (2) consistent with the proposed regulation characteristics for the exposure scenario; (3) consistent with the criteria for the RMEI specified in the EPA standards (i.e., drinks 2 liters of water per day); and (4) consistent with the EPA's Draft Federal Radiation Protection Guidance for Exposures of

replaced with the RMEI for consistency with EPA's standards.

~~Although~~
While it is beyond the capabilities of present-day science to determine "with certainty" that a future ice age will occur, the present paleoclimatic data support that (1) ice ages have occurred in past history, (2) climate changes in the past have exhibited a cyclical pattern, and (3) the cycle is likely to lead back to another ice age. The NRC has extensively investigated relevant research on future climate change in the vicinity of Yucca Mountain and has summarized the available information in an Issue Resolution Status Report (Nuclear Regulatory Commission. Issue Resolution Status Report Key Technical Issue: Unsaturated and Saturated Flow Under Isothermal Conditions, Revision 2, Vol 1. Washington DC: Nuclear Regulatory Commission, June 1999). The Commission encourages members of the public who are interested in the topic of past and future climate change in the vicinity of Yucca Mountain to obtain a copy of this report from the NRC Public Document Room (PDR) or from the NRC website

~~(www.nrc.gov/NMSS/DWM/usfic.html)~~. (For more information about obtaining reports from the NRC PDR, mail a request to U.S. Nuclear Regulatory Commission, Public Document Room, Mail Stop O1F13, Washington DC 20555, or e-mail pdr@nrc.gov.) The NAS committee was also familiar with the science behind future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is unlikely but not impossible, in the next 10,000 years is probable but not assured; however, over a million-year time frame, the climate is virtually certain to pass through several glacial-interglacial cycles (i.e., ice ages). The Commission believes there is sufficient information in the paleoclimate record to justify including climate change in the final regulations regarding effects on repository performance.

Climate change was included in the proposed regulations for the reference biosphere in § 63.115 because the NRC believed there was sufficient scientific evidence supporting the

potential for climate change over the long time frames considered by the performance assessment calculations. ^{Although} While NRC analyses suggest that inclusion of climate change in the biosphere is not likely to significantly change the local climate conditions and assumed exposure conditions, the Commission believes it is important to include the consideration for climate in both the geosphere and the biosphere performance assessment calculations to ensure that the conceptual model of the environment is consistent with our scientific understanding of reasonably anticipated natural events such as climate change. The NRC also believes it is important for DOE to include these processes in their performance assessment calculations and do the necessary technical analyses to ensure the processes have been adequately considered and addressed.

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

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

3.8 Multiple Barriers and Defense-in-Depth

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

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

results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in a system's overall performance.

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

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

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

Response. In general, the Commission believes that a repository system should reflect the philosophy of defense in depth. The Commission expects that if a repository system is made up of multiple barriers, then it will be more tolerant of unanticipated failures and external

challenges. The final regulations specify criteria for quantitatively evaluating post-closure performance (e.g., individual protection, ground-water protection, and evaluation of human intrusion). These criteria help ensure defense in depth by requiring calculations that provide risk insights into the impact on performance of specific system attributes and external conditions. DOE must evaluate the performance of the repository system, as it performs as a result of compliance with general design criteria (e.g., required use of multiple barriers and identification of the repository by markers). DOE must also evaluate the system's response to various external challenges (e.g., disruptive events treated in the performance assessment, as well as a specified human intrusion scenario).

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

The proposed rule would have required DOE to: (1) identify barriers; (2) describe quantitatively each barrier's ability to contribute to waste isolation; and (3) provide technical bases for the barriers' capabilities as part of the overall demonstration of compliance with the individual protection standard (see § 63.114 (h)-(j) of the proposed rule). Although not necessarily required as a separate demonstration, this required information on the capability of barriers, integral to the performance assessment, illustrates the resilience, or lack of resilience of the repository to unanticipated failures or external challenges. Also, quantitative insights about defense in depth of the proposed repository emerge directly from the quantitative evaluations in the performance assessment. The performance assessment must include analyses of the effects of unlikely, but credible, external challenges on overall performance (In its analyses, DOE

must consider disruptive events that have an annual probability of occurrence greater than 10^{-8}). Disruptive events may degrade performance of the engineered barriers or reduce the effectiveness of natural barriers or both. Also, DOE must evaluate uncertainty about the performance of engineered barriers and that of the natural barriers in the performance assessment. For example, uncertainty about the corrosion rate of the waste package will necessarily affect the estimated lifetime of the package. Likewise, uncertainty about geochemical sorption will affect estimates of the time it takes specific radionuclides to travel in the geosphere. As with the disruptive events, the proper consideration of uncertainty in the performance assessment should ^{en} assure an evaluation of the range of response of individual barriers to various challenges (e.g., higher than normal corrosion rates, lower than normal geochemical sorption). Thus, a complete performance assessment (*i.e.*, one that complies with §63.114) will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged.

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

particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

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

of samples and data, scientific studies, performance of tests and experiments, controlling geological and engineering materials samples, facility design and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. These terms are defined in § 63.2.

Based on the above discussion, the NRC considers the applicability of the QA program to be adequately described in Subpart G to Part 63. Because proposed Part 63 referred to Appendix B for QA requirements and Appendix B does not use the terms important to safety and important to waste isolation, requirements from Appendix B ^{are} ~~will be~~ incorporated into final Part 63, ~~and~~ modified accordingly to address their applicability to the high-level waste repository.

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

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

Response. The Commission agrees that the use of the criteria specified at § 63.44 is not

matter, and, consistent with its obligations under law, has adopted the dose limits published by EPA in its standards for Yucca Mountain.

Issue 2: Will there be more public meetings?

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

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

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

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

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

Response. NRC maintains a local onsite representative's office, with a small staff, in Las Vegas, Nevada, as a means of keeping abreast of DOE activities ~~at the Yucca Mountain site.~~ ^{and interacting with other stakeholders} This office allows our onsite representatives physical proximity to the site and the opportunity to

~~On various~~
interact with the principal DOE staff engaged in site characterization activities. At this time, the NRC has no plans to expand the size of the onsite representative's office. However, the size of the office, as well as the scope of NRC's activities conducted there, is subject to reexamination. Meanwhile, the public is encouraged to contact our staff at the onsite representative's office at:

1551 Hillshire Drive, Suite A

Las Vegas, Nevada 89137-1048

Telephone 702/794-5046

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

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

Response. Section 116(c) of the NWPAA directs DOE to provide funding to AULGs so that they may participate in activities required or authorized under sections 116 and 117 of the NWPAA. ^{Although} While these activities primarily involve DOE's interactions with the State, affected Indian tribes, and AULGs, the Commission believes that it would not be inconsistent with the intent of the statute to include AULGs at appropriate points in the regulations under Part 63, Subpart C, and has revised the regulations accordingly. The Commission is not adding EPA to §

Part 2, Subpart J, "Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High-Level Radioactive Waste at a Geologic Repository" (Subpart J) (54 FR 14925; April 14, 1989). Section 2.1014(c) of Subpart J permits intervention of AULGs in a repository licensing proceeding without the need to establish "party" status:

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

See also the definition of "party" in § 2.1001 which, as amended in 1998 (63 FR 71729; December 30, 1998), defines a "party" to mean the DOE, the NRC staff, the host State, any AULG as defined in section 2 of the NWPA, any affected Indian Tribe as defined in section 2 of the NWPA, and a person admitted under the criteria in § 2.1014. These regulations relieve the State, affected Indian Tribes, and AULGs from the need to meet the standing requirements in order to be admitted as a party in the proceeding. The State, an affected Indian Tribe, and an AULG must still submit contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii), and at least one contention must satisfy these requirements, or the State, affected Indian Tribe, or AULG shall not be permitted to participate as a party. [§ 2.1014(a)(3) (1999)]

All of the above is in the context of the existing hearing procedures in Part 2. The Commission recently proposed revisions to Part 2 (66 FR 19610 (April 16, 2001)). Even under the proposed revisions, however, a "party" in a Subpart J proceeding continues to be defined as including the host State, any affected unit of local government and any affected Indian Tribe, provided that these entities file an acceptable contention. Thus, the Commission has not

Sketch

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

With respect to the meaning of the term "individuals with unusual habits and sensitivities," the Commission believes the commenter refers to the findings and recommendations of NAS. Both these recommendations and final EPA standards require that DOE base the characteristics of the representative group for post-closure dose calculations (the community in which the RMEI resides) on lifestyles and dietary habits (i.e., reliance on well water, extent to which food is grown locally, types of foodstuffs eaten) of individuals currently living in the Yucca Mountain region. NAS explained that specification of the representative group should avoid extreme cases defined by unreasonable assumptions regarding the factors affecting dose. NAS also stated that a reasonable and practicable objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with "unusual habits or sensitivities" (pp. 51-52, "Technical Bases for Yucca Mountain Standard," National Research Council, 1995). Hence, the

terms "unusual habits" and "sensitivities" were used to exclude unreasonable assumptions about the ~~from~~ the characteristics of a hypothetical, future population group or RMEI. ~~The Commission~~ is quite certain that the NAS did not use these words to imply any judgment with regard to the behaviors or mental state of individuals residing near the site today. The Commission will continue to strive to explain more clearly ~~complex technical and regulatory issues~~ *the risks associated with the Yucca Mountain potential repository at*

for safety.

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

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

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

Response: The NRC understands the importance of a strong public outreach program. NRC held five public meetings in Nevada during the public comment period on proposed Part 63. Comments made at those meetings were instrumental in NRC deciding to extend the public comment period for the proposed rule. However, these meetings also demonstrated to NRC that ~~it we can and need to do better in our~~ *improve its* public outreach efforts. The NRC has held seven additional public information workshops in Nevada since the public comment period closed on Part 63. We

will continue to meet with the people of Nevada and continue to seek the public's views on how we can carry out our responsibilities in a more effective manner. We also intend to keep the public better informed about our independent regulatory activities and oversight. The NRC will also continue to work on providing displays and fact sheets that use plain English.

The Commission notes also that DOE maintains three visitor centers that are intended to keep the public informed. They are located in Beatty, Pahrump, and Las Vegas. DOE also sponsors regular field trips to the Yucca Mountain site itself. ~~lastly~~, DOE maintains an Internet web page with information that is regularly updated on activities at the site and developments in the program; it can be found at <http://www.ymmp.gov>. With regard to the comments proposing that activities and future events be published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. For those that are interested, the State of Nevada, Nye County, Clark County, Eureka County, Inyo County, California, and others also maintain web sites with information about the Yucca Mountain program. They are located, respectively, at <http://www.state.nv.us/nucwaste>, <http://www.nyecounty.com>, <http://www.co.clark.nv.us/complan/Nucwaste.htm>, <http://Yuccamountain.org> and <http://sdsc.edu/Inyo/yucca-pg.htm>.

Finally, the Commission notes that the NRC staff has maintained a schedule of meetings with DOE on its web page (<http://www.nrc.gov/nmss/dwm/hlw/hlm>) for several years. Important NRC documents related to the HLW program are also distributed to DOE. Effective November 1, 1999, NRC is making HLW program documents generated and received available on its Electronic Public Reading Room located at <http://www.nrc.gov/nrc/adams/index.html>. Documents generated prior to November 1, 1999, can currently be found at the designated library reading rooms (in Nevada).

to DOE, the state, and attached units of local government and other stakeholders.

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

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

Response. The NRC is developing a regulatory framework for the licensing of the proposed high-level waste repository with the promulgation of Part 63 and development of the Yucca Mountain Review Plan. This framework will clearly define the geologic disposal regulations DOE must meet and provide specific guidance to DOE on the information and evaluations necessary to demonstrate compliance with the regulations. As an independent regulatory agency, NRC's overall safety mission is to protect public health and safety, the environment, and common defense and security. NRC's regulatory role in any licensing action is to apply the applicable regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved.

The NRC Safety Philosophy will be applied to DOE's license application. This basic NRC Safety Philosophy, which is applicable to all the agency's licensing actions, is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

"LICENSEE RESPONSIBILITY embodies the principal that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing,

and other activities on those areas where the need, and the likely safety and safeguards benefit, are greatest."

To state it more succinctly, the safe operation of any nuclear facility is the responsibility of the licensee. This philosophy is an important foundation for how the NRC staff is to conduct its reviews in general, and licensing reviews in particular. Implementing this philosophy means that (1) the NRC does not select sites or designs ~~or participate~~ with licensees or applicants in selecting proposed sites or designs; (2) NRC's role is not to monitor all licensee activities but to oversee and audit them; and (3) the three outcomes available to NRC at the conclusion of a licensing review are: (1) grant the application; (2) grant the application subject to certain conditions agreed upon by the licensee; or (3) deny the application. Other than rejecting an applicant or licensee's proposal, NRC has no power to compel a licensee to come forward or to require a licensee to prepare a totally different proposal. ✓ delete

The interactions of the NRC staff and the DOE staff with respect to all activities preparatory to DOE's submission of a license application are governed by the "Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions," which was initially signed in 1983 and was revised in 1998, and by the NRC Staff's Policy Statement on Staff Meetings Open to the Public (59 FR 48340; September 20, 1994). These documents provide that meetings between the two staffs will be open to the public as specified in the Policy Statement and that management commitments will be documented in correspondence subsequent to the interactions. Thus, procedures are in place to ^{en}sure an appropriate open relationship between the potential regulator and the potential licensee.

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

word climatological is not needed; therefore, the language in proposed Part 63 will be retained in final Part 63.

6 Beyond the Scope of This Rulemaking

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

6.1 Hearing Process

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

Comment. Some commenters, including EPA, urged NRC to change its hearing process to provide for informal, legislative-style hearings for repository licensing. One commenter suggested that the Commission itself be the hearing board. NEI expressed the view that a legislative-style hearing process is more conducive to effective scientific inquiry than formal adjudicatory procedures. NRC's decision on whether to adopt an informal process for repository licensing, in NEI's view, should not be tied to the generic question whether to revise the overall hearing process but, instead, should be the subject of a separate rulemaking. However, another

into this section rather than merely referencing Appendix B in the rule. The introduction of the language from Appendix B into the final Part 63 has not changed any requirements in the proposed Part 63. This approach specifies the quality assurance requirements and ~~more clearly~~ removes any ambiguity regarding which portions of Appendix B are applicable to Yucca Mountain.

Section 63.143 Implementation.

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

Section 63.144 Quality assurance program changes.

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

Subpart K – Preclosure Public Health and Environmental Standards

Section 63.201 Purpose and scope.

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

Section 63.202 Definitions for subpart K.

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

Subpart L – Public Health and Environmental Standards for Disposal

This subpart contains provisions that are similar to the public health and environmental standards for disposal specified at 40 CFR Part 197.

Section 63.301 Purpose and scope.

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

Section 63.302 Definitions for subpart L.

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


Section 63.303 Implementation of subpart L.

This section provides a functional overview of this subpart.

Section 63.304 Reasonable expectation.

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

Section 63.305 Required characteristics of the reference biosphere.

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

INDIVIDUAL PROTECTION STANDARD

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

Section 63.332 Representative volume.

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

ADDITIONAL PROVISIONS

Section 63.341 Projection of peak dose

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

Section 63.342 Limits on performance assessments.

This section specifies how DOE will ~~determine~~ ^{identify} which features, processes, and events will be considered in the dose assessments described in subpart L.

Section 63.343 Severability of individual protection and ground-water protection standards.

(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 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in doses exceeding the values specified at § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable expectation that high-level waste can be disposed without exceeding the requirements of §§ 63.113(b) and (c).

Initiating event means a natural or human induced event that causes an event sequence.

Isolation means inhibiting the transport of radioactive material to:

¹These 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."

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Federal Register, at which public records of the Commission pertaining to a geologic

repository at the Yucca Mountain site are made available for public inspection.

Radioactive waste or waste means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reasonably maximally exposed individual means the hypothetical person meeting the criteria specified at § 63.312.

Reference biosphere means the description of the environment inhabited by the reasonably maximally exposed individual. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of permanently removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

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

(i) Changing any of the elements of the method described in the SAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the SAR to another method unless that method has been approved by NRC for the intended application, addition or removal.

(3) *Safety Analysis Report (SAR) (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as updated in accordance with § 63.24.

(4) *Geologic repository operations area as described in the SAR (as updated)* means:

(i) The structures, systems, and components important to safety or ^{barrier} important to waste isolation that are described in the SAR (as updated); and

(ii) The design and performance requirements for such structures, systems, and components described in the SAR (as updated).

(5) *Procedures as described in the SAR (as updated)* means those procedures that contain information described in the SAR (as updated) such as how structures, systems, and components important to safety, or important to waste isolation, are operated or controlled.

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

(i) Outside the reference bounds of the design bases as described in the SAR (as updated); or

(ii) Inconsistent with the analyses or descriptions in the SAR (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the SAR (as updated), make changes in the procedures as described in the SAR (as updated),

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

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

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

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isolation, and to related activities in its safety analysis report. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied.

DOE shall include information pertaining to the managerial and administrative controls to be used ^{en} to assure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) Organization. DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points, that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(l) Test control. DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components ^{important to safety} will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

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This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site. For the purposes of demonstrating compliance with this subpart, to the extent there may be any conflict with the requirements specified in this subpart and the requirements contained in subparts A-J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.202 Definitions for subpart K.

Annual committed effective dose equivalent means the effective dose equivalent received by an individual in one year from radiation sources external to the individual plus the committed effective dose equivalent.

Committed effective dose equivalent means the effective dose equivalent received over a period of time (e.g., ³⁰30 years), as determined by NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides. ✓

Effective dose equivalent means the sum of the products of the dose equivalent received by specified tissues following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

High-level radioactive waste means:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and

(2) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

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(c) does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence;

(d) focuses performance assessments and analyses ~~on~~ on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 63.305 Required characteristics of the reference biosphere.

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

(b) DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at the time of submission of the license application.

(c) DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions ^{consistent with present knowledge of} ~~of the changes in these~~ factors that could affect the Yucca Mountain disposal system over the next 10,000 years.

(d) Biosphere pathways must be consistent with arid or semi-arid conditions.

POSTCLOSURE INDIVIDUAL PROTECTION STANDARD

§ 63.311 Individual protection standard after permanent closure.

DOE must demonstrate, using performance assessment, that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed