

A F F I R M A T I O N V O T E

R E S P O N S E S H E E T

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

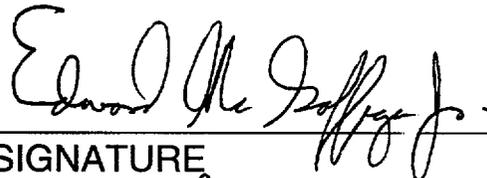
SUBJECT: **SECY-01-0127 - DRAFT FINAL RULE - 10 CFR PART 63,  
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A  
PROPOSED GEOLOGIC REPOSITORY AT YUCCA  
MOUNTAIN, NEVADA**

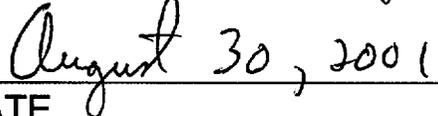
Approved   X   <sup>w/comments & edits</sup> Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

Please see attached comments and edits to the Federal Register.

  
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SIGNATURE

  
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DATE

Entered on "STARS" Yes   X   No \_\_\_\_\_

## Commissioner McGaffigan's Comments on SECY-01-0127

I join my fellow Commissioners in commending the staff for their diligent efforts throughout the long process of completing the Part 63 rulemaking. I also join them in approving this final rule subject to some minor comments and edits which are discussed below.

My approval does not mean that I believe this is a good rule. By law, Section 801(b) of the Energy Policy Act of 1992, the Commission must amend its technical requirements and criteria to be consistent with the Environmental Protection Agency's (EPA's) standards promulgated under Section 801(a) of that Act. Therefore, we must by law incorporate a nonsensical ground water protection standard into our rule and we have done so in §§63.331 and 63.332.

Why is this EPA groundwater standard nonsensical? The standard calls for a limit of 4 millirem per year to the whole body or any organ for beta and photon emitting radionuclides from the groundwater pathway, based on drinking 2 liters of water per day from the representative volume of water. This is a standard rooted in outdated science which EPA had proposed to change in a 1991 proposed rule to 4 millirem effective dose equivalent<sup>1</sup>. Effective dose equivalent is the modern internationally accepted approach to compute the overall effect of a dose on an individual. It takes into account the latest scientific understanding of the variable effect of radiation on different organs. It results in a consistent approach to risk. Unfortunately, in its December 7, 2000 final rule EPA decided against good science, abandoned its 1991 proposal, and instead maintained the existing rule. EPA vaguely promised a "near future review of the beta particle and photon radioactivity maximum contaminant level (MCL)," but implied that it believes that Section 1412(b)(9) of the Safe Drinking Water Act may constrain it from adopting a uniform risk MCL based on current science.

The sad result is that under the EPA Yucca Mountain groundwater standard, the de facto standard for the potential repository is the most broken MCL for a long-lived radionuclide, namely the 1 picocurie per liter MCL for iodine-129 which was chosen based on the radio sensitivity of the thyroid gland. This MCL corresponds to 200 microrem per year effective dose equivalent.<sup>2</sup> EPA's Federal Guidance Report 13, published in September 1999, places the annual risk of a cancer fatality as a result of the iodine-129 MCL at about one chance in 100,000,000<sup>3</sup>. This is an absurd place to be regulating. What other activities in which we engage on a daily basis expose us to this sort of dose? I live in a brick home. I have measured

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<sup>1</sup>The World Health Organization in its 1993 guidelines for drinking water quality had recommended a reference level of 10 millirem per year effective dose equivalent for beta and photon emitters and stated "Below this reference level of dose, the drinking water is acceptable for human consumption and action to reduce the radioactivity is not necessary."

<sup>2</sup>EPA proposed an iodine-129 MCL of 21 picocuries per liter in its 1991 proposed rule.

<sup>3</sup>It should be noted that this is based on the linear no-threshold hypothesis for extrapolating risk. When we extrapolate to 200 microrem per year effective dose equivalent, we are many orders of magnitude away from where there is real data on cancer risks (largely from the Hiroshima and Nagasaki bomb follow-up studies) and it is quite possible there is no adverse health effect at all at these low doses and low dose rates.

the gamma radiation in my home at 8 - 15 microrem per hour. In less than 24 hours in my home I will receive more than 200 microrem. My son worked as a U.S. Senate page this past spring. I have measured the gamma radiation in the Senate side of the Capitol in the 15 - 30 microrem per hour range. Each working day he received about the Yucca Mountain standard. A one-way non-stop flight from Washington to Los Angeles at 35,000 feet results in an effective dose from cosmic radiation of 1720<sup>4</sup> microrem, eight and a half times the EPA standard. If I eat a banana a day (which as a long distance runner I do), I will get about 2,000 microrem per year from the naturally occurring radioactive isotope potassium-40 in the banana, about 10 times the EPA standard. The EPA standard for radon in homes, 4 picocuries per liter of air<sup>5</sup>, translates to doses as high as 600,000 microrem per year, 3,000 times the EPA Yucca Mountain groundwater standard. A typical abdominal Computerized Tomography scan for medical diagnostic purposes results in a dose on the order of 2,500,000 microrem, 12,500 times the EPA Yucca Mountain groundwater standard. I could go on and on.

Both the Nuclear Regulatory Commission (NRC) and the National Academy of Sciences have strongly argued against the EPA groundwater standard. Section 801(a) of the Energy Policy Act of 1992 gave EPA authority to set generally applicable standards for the Yucca Mountain site. In doing so it states: "Such standards shall prescribe the maximum annual effective dose equivalent (underline added) to individual members of the public from releases to the accessible environment from radioactive material stored or disposed of in the repository." EPA met the law when it prescribed the 15 millirem per year effective dose equivalent all-pathways individual protection standard. It went beyond the law in prescribing an outdated and nonsensical groundwater standard. It did so as a matter of policy, a policy that has never gone through rulemaking, that EPA will protect potential sources of groundwater the same way it protects water at the tap. NRC questioned the cost/benefit of this policy applied to the Yucca Mountain standard. Yet nowhere in the EPA rulemaking file can I find a cost/benefit justification for this groundwater standard. EPA also argued for the standard based on consistency with its regulations for the Waste Isolation Pilot Plant (WIPP) in New Mexico. But as NRC pointed out in its comments, the groundwater issue simply doesn't arise at WIPP because the groundwater there is not potable.

EPA wisely made its individual protection standard and its groundwater standard severable in its final rule. We are doing the same as we incorporate EPA's standards. I hope that the Courts will strike down the groundwater standard. While I would have preferred a 25 millirem per year effective dose equivalent individual protection standard and believe that it would have been fully protective of public health and safety, the EPA's 15 millirem per year effective dose equivalent individual protection standard is not unreasonable. Its 200 microrem per year groundwater standard can not be defended.

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<sup>4</sup>Nuclear News, January 2000 edition, page 36.

<sup>5</sup>This is the level above which EPA recommends that mitigative action be taken. It is not enforced and is up to individual homeowners to take the initiative to test and, if necessary, remediate their homes. I tested my home in the mid-1980s and happily it was well below the EPA action level.

**Other Comments:*****Total Effective Dose Equivalent:***

After consideration of the calculational differences between the terms "total effective dose equivalent (TEDE)" used routinely by NRC and "annual committed effective dose equivalent (Annual CEDE)" used by EPA in 40 CFR Part 197, I agree with my fellow Commissioners to support the use of TEDE in Part 63. In this application, the two terms are essentially equivalent and it is my understanding EPA agrees. The staff should add a brief discussion in the FRN describing the essential equivalence of the two terms and the basis for the Commission's decision to use TEDE, and make conforming changes throughout the FRN.

***Human Intrusion:***

Since issuance of the Part 63 proposed rule for comment, my thinking has significantly evolved on this issue based on public comment and the approach used by EPA in its final rule. The proposed rule contained a "stylized" calculation that prescribed the timing of the intrusion (i.e., 100 years after permanent closure), the repository barriers affected by the intrusion and the relevant exposure pathway. I agree with the public comments that there is no reason to believe that human intrusion could occur at Yucca Mountain as early as 100 years after closure. Active institutional controls, which by law (Section 801(c) of the Energy Policy Act of 1992 incorporated in our rule at § 63.51(a)(3)(iii)) must be maintained indefinitely, will likely be in place much longer than 100 years. Moreover, the likelihood of drilling into Yucca Mountain for water or other resources, should these active institutional controls somehow fail, presumably because of an unforeseen catastrophe that ends our civilization, is very small. In contrast, the draft final amendments to § 63.321 (human intrusion standard) and § 63.322 (human intrusion scenario), which incorporate EPA's approach, are an improvement over the proposed rule since they are more performance-based, providing DOE flexibility to determine and justify (subject to NRC review) its selection of the time of the intrusion event based on the condition of the waste package subject to an annual individual dose limit of 15 millirem per year effective dose equivalent.

***Multiple Barriers and Defense in Depth:***

I fully support the final rule's approach to multiple barriers and defense in depth and believe that § 63.115 is entirely consistent with the statutory mandate in Section 121(b)(1)(B) of the Nuclear Waste Policy Act that our rule "shall provide for the use of a system of multiple barriers in the design of the repository."

***Reasonable Expectation versus Reasonable Assurance***

This is an area where EPA made a contribution to the overall standard setting effort. Our proposed rule used the term "reasonable assurance," partly because we had always used it, but the proposed § 63.101 really was describing "reasonable expectation." The final rule is an improvement.

***Severability of Standards***

Another issue which has arisen during the review of the final rule is the severability of certain provisions in the EPA and NRC rules, i.e., individual and ground water protection standards. Based on the information before us, I agree with the staff that the plain English of the EPA rule applies the severability provision to the individual and ground water protection standards only and does not include the human intrusion standard.

***Separate Rulemaking on Probability of Unlikely Events or Processes***

I agree with my fellow Commissioners that a separate rulemaking should be initiated on an expedited basis to establish the annual level of probability of occurrence constitutes an unlikely event or process.

***Consistency in Definitions***

I agree with Chairman Meserve that the definitions of "high-level waste" and "ground water" are problematic, in that the definition of HLW needs to be consistent with the definition in the Nuclear Waste Policy Act of 1982, as amended, and the definitions of ground water are internally inconsistent. These definitions need to be corrected as suggested by the Chairman.

***Additional General Comments:***

I fully agree with my fellow Commissioners regarding their concerns on § 63.16(d) and firmly believe that the Commission is in a position to make an informed decision on the sufficiency of the Department of Energy's site characterization efforts to date without additional input from stakeholders. Therefore, I would not support a decision to solicit additional stakeholder input on the Commission's sufficiency comments to DOE.

Also, after promulgation of the Part 63 final rule, I encourage the staff to promptly publish a Federal Register notice to close out action on the petition for rulemaking originally submitted in 1985 by the States of Nevada and Minnesota and inform the affected States of this action.

Finally, suggested edits to the Federal Register notice are indicated on the attached pages.



However, the EPA standards do not <sup>specify</sup> ~~specific~~ 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. 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

deposited nuclides may deposit radiation non-uniformly in the body over long and variable time frames. External exposure results from an individual's proximity to a radiation source present outside the body and does not require consideration of radionuclides retained in the body. The total dose is represented as an "annual CEDE" that is the summation of the internal and the external exposures.

The NRC and EPA approaches for estimating a total exposure to an individual are based on the summation of the internal exposure (determined using a CEDE approach) and the external exposure. However, EPA and NRC use different terminology in regulations and standards to describe this total exposure. EPA uses the term "annual CEDE" whereas NRC uses "total effective dose equivalent in a year" (TEDE in a year) to define the same concept. Specifically, NRC defines terms for dose extensively in 10 CFR Part 20, and uses terms consistent with traditional health physics definitions. By those definitions, Total Effective Dose Equivalent, or TEDE, is the sum of the dose from external exposure and the CEDE (for internal exposures).

Part 63 has adopted EPA's term "annual CEDE" for purposes of compliance with Subparts K and L. However, the Commission is aware that adopting CEDE in one portion of Part 63 and TEDE in another part of the Commission's regulations could be a source of confusion. Further, the dose estimation will be the same regardless of which agency's terminology is used. Therefore, the Commission would be inclined to accept a DOE demonstration in terms of either TEDE in a year or annual CEDE to meet the dose limits of Subparts K and L. [note: separate requirements for ground-water protection are still required to evaluate dose to the whole body and the organs for beta and photon emitting radionuclides].

## REQUIREMENTS FOR ENVIRONMENTAL IMPACT STATEMENT

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

#### **IMPORTANT TO WASTE ISOLATION**

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

### **III. Public Comments and Responses**

Staff Paper says "160"

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In preparing the final rule, the NRC staff carefully reviewed and considered more than 700 discrete comments enclosed in about 100 individual letters received during the public comment period. The staff also identified and evaluated an additional 193 comments made at public meetings. To simplify the analysis, the NRC staff grouped all written and oral comments on the rule into the following six major topic areas:

- 1) Regulatory Process and Licensing Process;
- 2) Requirements for the Pre-closure Period;
- 3) Requirements for the Post-closure Period;
- 4) General Requirements;
- 5) Selected Topics; and
- 6) Beyond the Scope of This Rulemaking.

## **1 Regulatory Process and Licensing Process**

### **1.1 Promulgation in Advance of EPA Standards**

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

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

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

Commenters correctly pointed out that there are significant differences between Part 60 and Part 63. In the Commission's view, the Part 63 regulations do not lessen DOE's responsibility in any way to safely site, design, and operate the proposed repository. Much has been learned regarding the expected performance of geologic repositories in general (Nuclear Energy Agency, *Lessons Learnt from Ten Performance Assessment Studies*, Paris, France, NEA/OECD Working Group on Integrated Performance Assessments for Geologic Repositories, 1997), and a potential Yucca Mountain repository in particular over the nearly two decades since Part 60 was written. Part 63 reflects and incorporates much of this new information. The risk-informed, performance-based approach used to develop the rule (see SECY-97-300, "Proposed

Strategy for Development of Regulations Governing Disposal of High-Level Radioactive Wastes in a Proposed Repository at Yucca Mountain, U.S. NRC, December 24, 1997) eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives. That being said, however, Part 63 still requires DOE to demonstrate reliance on multiple barriers and defense in depth, preservation of the retrieval option, implementation of a performance confirmation program, transparency in decision making, and application of rigorous quality assurance (QA). Moreover, as a result of public comments, other provisions have been added to Part 63 to ensure the adequacy and sufficiency of DOE's compliance demonstrations. (See Multiple Barriers and Defense in Depth for additional discussion on quantitative subsystem requirements.)

## **1.2 Differences Between Part 63 and EPA Standards for WIPP**

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

Comment. Many commenters expressed concern that NRC's proposed regulations for Yucca Mountain provided less protection than EPA's standards for WIPP. They regarded NRC's proposed regulations as less stringent than the standards for WIPP. Many cited the absence of separate criteria for protection of ground water in NRC's proposed regulation as evidence that the WIPP standards, which include separate requirements for protection of ground water, are more restrictive. Commenters also cited the differences in the individual protection limits [0.15 mSv/year (15 mrem/year) for WIPP compared to 0.25 mSv/year (25 mrem/year) limit for Yucca Mountain], and the compliance location (5 km for WIPP compared to

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

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

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

**Comment.** DOE asked for clarification about the role of precedents in other regulatory guides (e.g., consideration of earthquakes, aircraft crashes, tornadoes, and flooding) in

determining what should be considered in the development of DBEs [event sequences] (especially for Category 2). DOE also commented that development of credible natural events, for Category 2 DBEs [event sequences], would require only following applicable regulatory precedents and considering severe natural phenomena that have been historically reported for the site and geologic setting.

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

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

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

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

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

performance confirmation plan that focuses on those natural and engineered systems and components important to repository performance and operation. The requirements allow DOE the flexibility to develop a focused and effective performance confirmation program. An alternative approach would be to prescribe in detail the specifics and limits of that program. The Commission does not want to limit DOE's options regarding testing methodologies and has chosen not to follow that approach. Note, however, that NRC will evaluate the adequacy of the performance confirmation program in the course of its review of the license application.

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

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

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

## **2.4 Pre-closure Operations Activities**

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

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

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

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

## **2.5 Emergency Planning Criteria**

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

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

Response. Part 63 (Subpart I) requires DOE to submit an emergency plan for coping with radiological accidents. NRC's review of DOE's emergency plan will evaluate the adequacy of the plan including such things as the capability to respond to accidents and medical assistance for treatment of radiological injuries. Where DOE's emergency plan is found to be inadequate, the NRC, if necessary, can impose license conditions that require DOE to correct any deficiencies. (See also response to Issue 3 below.)

Additionally, U.S. Federal Emergency Management Agency (FEMA) regulations, as well as DOE orders, require that DOE have an emergency response capability that is adequate to meet anticipated accidents, including potential radiological accidents. DOE is responsible for ensuring that the emergency treatment capability exists and is documented in its emergency plan, which is subject to NRC review in accordance with § 63.161.

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

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

Response. The rule requires DOE to have plans to cope with radiological accidents (emergency planning at § 63.161) and provide for physical protection [§ 63.21(b)(3)]. These plans are required to address a number of criteria to ensure that DOE is prepared to respond, both on site and off site, to accidents, and that DOE has the capability to detect and respond to unauthorized access and activities that could threaten the physical protection of HLW. As noted in the response above, NRC and FEMA regulations, as well as DOE orders, require that DOE have adequate plans and procedures in place to address any potential accidents and incidents. DOE's emergency plan and physical protection plan are subject to NRC review. The Commission believes that the requirements for DOE's plans for emergencies and physical protection expressed in the proposed Part 63 are appropriate and <sup>has</sup> ~~will~~ <sup>ed</sup> retain them in the final rule.

Section 63.161 requires DOE to develop an emergency plan based on the criteria of § 72.32 [i.e., criteria provided for an Emergency Plan for an Independent Spent Fuel Storage Installation (ISFSI)]. The required Emergency Plan includes: identification of each type of accident, description of the means of mitigating the consequences of each type of accident; prompt notification of offsite response organizations; and adequate methods, systems, and equipment for assessing and monitoring actual or potential consequences of a radiological emergency condition. If particular types of accidents require evacuation procedures to ensure the protection of public health and safety, they will be included in the Emergency Plan.

Section 63.21(b)(3) requires DOE to submit a detailed plan to provide physical protection of HLW in accordance with § 73.51 (requirements for physical protection of stored spent nuclear fuel and HLW). The requirements for physical protection include: (1) capabilities to detect and

assess unauthorized access or activities and protect against loss of control of the facility; (2) limiting access to HLW by means of two physical barriers; (3) providing continual surveillance of the protected area in addition to protection by an active intrusion alarm; and (4) providing a primary alarm station located within the protected area and have bullet-resisting walls, doors, ceiling, and floor. These requirements provide high assurance that physical protection of the repository includes appropriate measures to prevent and respond to unauthorized access and activities, including the potential for armed intruders (e.g., terrorist activity).

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

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

Response. Section 180(c) of the NWPA requires DOE to provide technical assistance and funding for training State and local governments and Tribes for safe routine transportation and emergency response. However, NRC's responsibility for oversight and review of DOE's emergency plans (see discussion under Issues 1 and 2) does not include responsibility for how DOE provides for technical assistance and funding. Additionally, under NEPA, the potential for (environmental) impacts due to transportation, including accidents, is the responsibility of DOE to assess and mitigate.

### **3 Requirements for the Post-closure Period**

### 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, 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

final rule. However, requirements for QA, multiple barriers, and performance confirmation have been revised to clarify the Commission's intent for these requirements (see discussion under Quality Assurance, Multiple Barriers and Defense in Depth, and Performance Confirmation for more details).

The Commission believes that there have been significant advances in, and experience with, risk assessment in the past 20 years (see Commission's white paper on Risk-Informed and Performance-Based Regulation, March 1999). The Commission continues to believe that a performance assessment, developed with sufficient credibility, is the best means to provide useful information to the Commission for making an informed, reasonable licensing decision. The Commission recognizes, however, the uncertainties inherent in evaluating a first-of-a-kind facility like the repository and in estimating system performance over very long time periods (i.e., 10,000 years). Thus, proposed Part 63 contained requirements to ensure: <sup>that</sup> (1) uncertainties inherent in any performance assessment are thoroughly articulated and analyzed or addressed; (2) DOE's performance assessment is tested (corroborated) to the extent practicable; and (3) there are additional bases, beyond the performance assessment, that provide confidence that the post-closure performance objectives will be met. For example:

1. Requirements for addressing uncertainty in performance assessment.

Section 63.114 provides a number of requirements for DOE's performance assessment to thoroughly address uncertainty. Part 63 requires consideration of uncertainties in DOE's representation of the repository [uncertainty and variability in parameter values must be taken into account - § 63.114(b)] and the events that can happen during the compliance period [consideration of potentially disruptive events with a probability of occurrence as low as one chance in 10,000 of occurring over 10,000 years - § 63.114(d)] to be directly included in the

quantitative estimate of performance. Additionally, DOE is required to provide additional assurances that uncertainty in the information (e.g., evaluation of site characterization data) used to develop the performance assessment have been evaluated by consideration of alternative conceptual models of features and processes that are consistent with available data and current scientific understanding [§ 63.114(c)]; and the basis for inclusion or exclusion of FEPs that would have a significant effect on performance [§ 63.114(e) and (f)]. (See discussion under Issue 2 for further details on uncertainty in performance assessment.)

2. DOE's performance assessment is tested (corroborated) to the extent practicable.

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

3. Basis for confidence that the post-closure performance objectives will be met.

As a basis for confidence that the post-closure performance objectives will be met, the Commission plans to rely on requirements in addition to that for the performance assessment. Specifically, Part 63 requires a multiple barrier approach for the repository, and a QA program. A requirement that multiple barriers make up the repository system ensures that repository

standard. The commenter recommended that plain English should be used to document the performance assessment to improve overall understanding of the risks.

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

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

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

Response. The Commission agrees with the comments and has removed this requirement from the regulations. The NRC review should focus on the safety aspects of DOE's proposed approach. DOE should only be required to propose alternatives from its proposed approach in areas where the NRC review determines DOE's approach is deficient.

When developing proposed Part 63, the staff adopted this requirement from 10 CFR Part 60, the existing generic NRC HLW disposal regulation, which contains a similar requirement in 10 CFR 60.21 (c)(1)(ii)(D). At the time of the issuance of Part 60, DOE objected to this specific requirement with basically the same argument presented for Part 63. In the Statements of Consideration<sup>(c)</sup> for Part 60 (published in Federal Register on June 21, 1983), the Commission justified the requirement by stating "If the Commission finds, on the basis of its review, that the adoption of some alternative design feature would significantly increase its confidence that the performance objectives would be satisfied, and that the costs of such an approach are commensurate with the benefits, it should not hesitate to insist that the alternative be adopted."

The decision to require DOE to submit alternatives for certain site design features was a discretionary action on the part of the Commission as nothing (in either the Atomic Energy Act of 1954, as amended, or the Nuclear Waste Policy Act of 1982, as amended) required the Commission to obtain information on alternative designs at the site level. At the time Part 60 was initially published (1983), the Commission implemented an appropriate regulatory framework for a generic program facing many uncertainties. Multiple sites with very different geological settings were under consideration. The NRC's generic HLW regulations had to address the resolution of a large number of technical issues in the relative short licensing review period established by the Nuclear Waste Policy Act of 1982. With all the uncertainties in the program, the Commission

believed it was important to require design alternatives be submitted with the application to increase the probability of NRC approval of the license application within the three year schedule mandated by Congress.

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

### **3.2 Individual Dose Limit**

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

Comment. A number of commenters expressed concern that the dose limit specified in the proposed rule provided inadequate protection for future generations. Commenters suggested that (1) selection of the dose limit should consider the unpredictability of the future, particularly

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

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission <sup>has</sup> will incorporate <sup>d</sup> a <sup>individual</sup> 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 <sup>n</sup> a <sup>individual</sup> dose limit of 0.25 mSv/year <sup>TEDE</sup> (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.

^ 100 mrem/year

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

Comment. Some commenters, while noting that the EnPA specified a dose limit for Yucca Mountain, expressed their support for a total release limit like Part 60. The commenters believed that a total release limit is more understandable, easier to implement, and a simpler way to measure compliance of the repository's performance.

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

To set a release limit, the regulatory agency would first need to establish a risk or dose goal and calculate the risk or dose per unit release (e.g., per curie). The risk/dose goal would need to be the collective risk/dose over the entire compliance time for any release into the environment based on some assumed level of waste [e.g., for 40 CFR Part 191, EPA used a risk goal of 1,000 premature cancer deaths in 10,000 years per 100,000 metric tons of heavy metal contained in spent fuel (High-Level and Transuranic Radioactive Wastes: Background Information Document for Final Rule, Office of Radiation Programs, EPA 520/1-85-023, August 1985, Page 7-13)]. To calculate the risk per unit release, a model estimating the individual dose from a release will need to be used. To develop the model and data parameters, assumptions about the type of release [e.g., for 40 CFR Part 191, a release to surface water was assumed (ibid, pg. 7-13)], which biosphere processes to include, resource usage by the local

population [e.g., for 40 CFR Part 191, 65 percent of drinking water is assumed to be from the contaminated surface water (ibid, pg. 7-7)], and individual habits and characteristics [e.g., for 40 CFR Part 191, annual individual intake of drinking water is assumed to be 600 liters (ibid, pg. 7-7)] will need to be made. In its current form, Part 63 requires all the same calculations to be done, but the defense of many of the assumptions is the responsibility of DOE and will be subject to review and approval by NRC.

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

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

Comment. A few commenters supported either the use of collective dose limits or requiring dose distributions over the population to be calculated based on a concern that a single dose limit requiring only calculation of dose to the critical group would not adequately protect the overall population. Commenters (1) suggested that the collective dose is more important than

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

Response. The Commission agrees with NAS that “a health-based individual standard will provide a reasonable standard for protection of the general public” (p. 65 of the NAS report). The final regulations, which specify characteristics of 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.

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.

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 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, <sup>although</sup> 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 <sup>the</sup> long-term performance objective is not <sup>appropriate</sup>.

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 <sup>a dose in excess of the</sup> 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, 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 <sup>has</sup> ~~will~~ incorporate, <sup>d</sup> a dose limit of 0.15 mSv/year (15 mrem/year). The Commission

~~believes that this limit is fully protective, and has, in fact,~~ <sup>its proposed</sup> long held that the slightly higher dose limit of 0.25 mSv/year (25 mrem/year) to an individual is (1) a reasonable and appropriate fraction of the annual public dose limit to protect future generations from receiving doses greater than 1 mSv/year (100 mrem/yr), (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources. However, the Commission has changed the dose limit in the final rule in order <sup>because it is required</sup> to be consistent with EPA's final standards, <sup>and</sup> ~~but not because the Commission is persuaded that its earlier proposal is unsafe in~~ <sup>inadequate, or not appropriate</sup> any way. The Commission is confident that the ~~even greater margin of safety afforded by the~~ 0.15 mSv/yr (15 mrem/yr) limit <sup>also</sup> is <sup>^</sup>amply protective. Both limits ensure that no member of the public would be exposed to more than 1 mSv/yr (100 mrem/yr) from all sources of radiation, except background radiation. Both protect future generations. During the operational phase, the repository will be required to comply with Part 20 for worker and public health and safety, except that the permitted public dose will be limited to 0.15 mSv/yr (15 mrem/yr).

Delete sent. 1 - it could be inferred that 25 mrem/yr was not low enough.  
 Delete sent 2 - redundant w/ previous P.

~~The Commission believes that the 0.15 mSv/yr (15 mrem/yr) dose established by EPA is so far below the public dose limit that no members of the public near Yucca Mountain would be expected to receive doses from all sources, excluding background radiation, in excess of 1 mSv/yr (100 mrem/yr). Therefore, the Commission believes that by adopting a 0.15 mSv/yr (15 mrem/yr) limit to the RMEI, members of the general public will be fully protected.~~

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

**Comment.** Many commenters were concerned that the proposed Part 63 would relax health and safety standards. They (1) disagreed with the comparisons with other waste-related safety standards discussed in the Statements of Consideration of the proposed rule, especially

with rules using an older dose methodology and (2) expressed concern that the use of the single limit on the TEDE did not adequately protect the organs. They pointed to regulations requiring specific organ limits. While not a dose limit, some commenters disagreed with the use of the national value for background radiation for comparison for the Nevada area because of impacts from past practices.

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

Different sources of radiation can have different constraints placed on them. The 0.25 mSv/yr (25 mrem/yr) dose limit is in a similar range as a number of other constraints for waste management facilities or decommissioning requirements (e.g. 40 CFR 191.03(a), 10 CFR 72.104, 10 CFR 61.<sup>41</sup>~~40~~, and 10 CFR 20.1402). Furthermore, during the operational and surface facility decommissioning phases, the facility will need to meet the ALARA requirements in 10 CFR 20.1101(b). This includes an 0.1 mSv/yr (10 mrem/yr) additional constraint on air emissions [10 CFR 20.1101(d)]. X

A number of the current regulations were published before the early 1990s when the NRC (and other Federal agencies) began using current knowledge about radiation risks and internal dosimetry. These older regulations generally have two or three limits associated with them.

They tend to have separate limits for the dose to the whole body, the organs, and possibly, a specific limit for the thyroid [e.g., 10 CFR 72.104 limit of 0.25 mSv/yr (25 mrem/yr) whole body, 0.75 mSv/yr (75 mrem/yr) thyroid dose, and 0.25 mSv/yr (25 mrem/yr) to any other critical organ]. At the time these older regulations were published, the Federal government was using a dosimetry system (i.e., a model that calculates the dose if a person ingests or inhales radioactive material) that did not account for the sensitivity to radiation of the various organs (also known as radiosensitivity) nor how the dose to an organ compared to a whole body dose. Because one could not add the various organ doses together, each needed its own limit. With little information on the radiosensitivity, most organs were given the same limit.

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

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

<sup>to conform to</sup>  
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. X

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”

is completely consistent with NAS recommendations that the mean value of the calculations be used for comparison to the standard. Finally, one commenter supported the use of a 25 mrem performance objective, but suggested that it be bolstered with the addition of a 100 mrem limit on the 95<sup>th</sup> percentile of the probabilistic dose distribution.

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

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

In addition, NRC performance assessment experience indicates that the mean already reflects a high degree of confidence that dose limits will not be exceeded. For example,

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

X the General Public (59FR66422; December 23, 1994). The Commission considers the RMEI approach and associated characteristics of the RMEI <sup>to be</sup> protective of the health and safety of the public and environment (see also responses under Infant and Children Dose Standard and Location of the Critical Group or RMEI).

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

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

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

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](http://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](mailto: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. 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 <sup>its</sup> 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

provide greater assurance for overall repository performance and, in general, supported keeping the quantitative limits at Part 60.

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

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

1. Consistent with the Commission's risk-informed and performance-based regulatory philosophy, DOE is provided flexibility for deciding the extent and focus of site characterization. As the repository designer, DOE may place greater or lesser reliance on individual components of the repository system when deciding how best to achieve the overall safety objective.
2. Estimates of subsystem performance are subject to many, if not all, of the same sources of uncertainty as are estimates of overall system performance. It is questionable, therefore, whether the subsystem criteria in Part 60, or any others, <sup>criteria</sup> ~~can~~ <sup>could</sup> provide truly independent assurance of total system performance. X  
X
3. The Commission recognizes that techniques of performance assessment have improved a great deal because of significant advances in knowledge and experience achieved since Part 60 was developed. These advances in performance assessment technology support the use of performance assessment

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

The Commission's goal is to protect public health and safety and to 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 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.

### Quantitative or Qualitative Assessment?

Consistent with the proposed rule, the final rule allows DOE to select from various methods to describe the capabilities of the barriers. Regardless of the method selected, DOE must describe the capability of each barrier to perform its intended function and the relationship of that barrier's role to limiting radiological exposure in the context of the overall performance assessment. The Commission has considered the comment that an evaluation of each barrier's capability should be quantitative. The Commission continues to believe a qualitative approach, as proposed, is appropriate for the following reasons:

1. It provides information to the Commission to be considered in its decisions without constraining its considerations to a specific limit for a particular barrier, which may result in less favorable overall system performance.
2. It provides flexibility to the Commission to consider the nature and extent of conservatism in the evaluations used for compliance demonstration, and for deciding whether there is a need to require DOE to reduce uncertainties in its assessment (e.g., collecting more site data) or to include further mitigative measures.
3. Quantitative evidence of the capability of individual barriers to contribute to waste isolation is an integral part of the performance assessment. Therefore, an additional quantitative limit is not necessary to show that overall performance reflects a system of multiple barriers.

The Commission understands that establishment of explicit, quantitative limits for individual barriers might be considered a desirable and more easily explained approach. That being said, however, the Commission knows of no scientific basis for setting such limits for

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

Finally, the required description of barrier capability provides information that will aid in the interpretation of the performance assessment results, while at the same time providing information that is independent from the condition of the other barriers. For example, the unsaturated and saturated zones could provide significant retardation to many radionuclides such that radionuclides will not reach the RMEI within 10,000 years regardless of when the waste package fails. This capability of geologic systems to "retard" or slow the movement of contaminants 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~~ increases 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 <sup>have been</sup> ~~will be~~ incorporated into final Part 63 and modified accordingly to address their applicability to the high-level waste repository. X

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

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

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

appropriate for changes to the QA program description included in the Safety Analysis Report. We also agree that the rule should identify change control requirements applicable to the licensee's QA Program and that those requirements should be similar to those contained in § 50.54(a)(3). The proposed rule has been revised to specifically address change control requirements for QA program descriptions.

We disagree that § 63.21(c)(11) should be relocated to § 63.21(b) because the QA program description is required to specifically describe how the requirements of § 63.142 will be satisfied. By adding specific requirements in §§ 63.44 and 63.144 for the control of changes to the QA program description, the Commission believes it has resolved the expressed concern for relocating § 63.21(c)(11). [Note: The text at § 63.21(c)(11) in the proposed rule is specified at § 63.21(c)(17) in the final rule due to reordering of § 63.21 to achieve a more consistent order with the required analyses.]

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

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

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

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

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

During fiscal year 2000 and through June 2001, the staff evaluated the implementation of DOE's QA program by: 1) continuing observation of DOE performance-based audits; 2) daily

overviews by NRC Onsite Representatives assigned to the Yucca Mountain Project office in Las Vegas, Nevada; 3) enhanced participation of NRC's technical staff in activities at the various DOE facilities; and 4) interfacing with DOE during technical exchanges and management meetings. Through these activities, we are encouraged that many of the deficiencies are being corrected by DOE. Further, we have observed that DOE is continuing to adequately identify, process, and correct new problems. NRC believes its aggressive overview activities provide the ability to adequately evaluate whether the DOE QA program will continue to be effectively implemented.

#### **4.2 Changes, Tests and Experiments**

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

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

Response. For nuclear reactors, ISFSIs, and holders of a certificate of compliance for a spent fuel storage cask, the Commission recently amended its regulations concerning the authority of these licensees and certificate holders to make changes to the facility or operating procedures, or to conduct tests or experiments, without prior NRC approval (64 FR 53582; October 4, 1999). The final rule clarified the specific types of changes, tests, and experiments conducted at a licensed facility and revised the criteria that must be used to determine when

Whether DOE is subject to State law in obtaining any water rights that may be needed for this purpose is a matter to be determined by DOE and the State. The NRC does not have the authority to require that DOE conform to State law.

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

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

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

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

facility unless there is reasonable expectation that releases of radioactivity will remain within regulatory limits.

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

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

Response. The Commission agrees with DOE that land ownership and control requirements are not sufficiently clear regarding their application to pre-closure and post-closure activities. The requirements <sup>have been</sup> will be clarified to indicate that: (1) the GROA shall be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use; (2) DOE has the flexibility to identify and establish additional controls for lands outside the GROA necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation (post-closure); and (3) DOE has the flexibility to identify and establish additional controls for lands outside the GROA to ensure the requirements at § 63.111(a) and (b) are met. These clarifications have been made in revisions to § 63.121 of the final rule.

## 5 Selected Topics

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. 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 §

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63.61(a) because this provision <sup>is consistent with</sup> ~~mimics~~ section 117(a)(1) of the NWPA which does not include EPA. However, the information provided under § 63.61(a) is available to EPA.

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

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

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

The proposed § 63.63(a) states: “State and local governments and affected Indian Tribes may participate in license reviews as provided in Subpart G of Part 2 of this chapter. The State of Nevada and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings.” This provision is modeled on, and virtually identical to, § 60.63(a). Section 60.63(a) was incorporated into NRC regulations prior to the Commission’s adoption of

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, 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.

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 we can and need to do better in our 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.ymp.gov>. With regard to the comments proposing that activities and future events be published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. ~~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>.

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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/hwm>) for several years. Important NRC documents related to the HLW program are also distributed to DOE. <sup>Since</sup> ~~Effective~~ November 1, 1999, <sup>has made</sup> 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>. <sup>NRC/ADAMS (capitals)</sup> ~~nrc/adams~~ <sup>two</sup> Documents generated prior to November 1, 1999, can currently be found at the designated library reading rooms (in Nevada) <sup>Insert - attached.</sup>

X

X

X

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,

**INSERT for page 143 of the FRN on Part 63:**

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most likely exposure scenario to radionuclides released from a potential geologic repository at Yucca Mountain would be in the ground water, down-gradient from the site. Because of this potential hazard, some commenters expressed the view that there is a need for the NRC to require that DOE implement a post-closure ground-water monitoring system. It was noted that such a system would protect citizens living near the repository by providing early-warning of the presence of radionuclides in the ground water.

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

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

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

Response. Part 63 does not alter whatever liability the Federal Government may have for damage to health or property caused by its activities. It is possible that compensation could be available for certain types of damage to health or property under Federal law, but it would be speculative to suggest that compensation would be available in any particular case.

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

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

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

As regards the potential risk of the repository ~~to~~ radiological sabotage<sup>to</sup> during the pre-closure phase of operations, the Commission's regulations for Yucca Mountain at § 63.21(b)(3) require that licensees have in place adequate physical security plans and attendant procedures to protect against radiological sabotage, consistent with § 73.21 – NRC's regulations for the physical protection of nuclear plants (facilities) and nuclear materials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Response. In general, the Commission agrees with this comment to the extent that the Commission anticipates that it will need such information because it has a bearing on understanding the lifestyles and habits of the RMEI. However, in the Commission's view, the type of information suggested by the commenter is already included in the regulations at § 63.21(c)(1). Nonetheless, the Commission expects that this subject will be addressed in the YMRP, which describes the required contents and methods for the NRC staff review of any potential DOE construction authorization application, as well as DOE's compliance demonstration

with the rule. ~~The YMRP is currently under development by the staff and will be shared with interested stakeholders, as it is developed, and will be published for public comment. After the public comment period, the Commission will determine if additional revisions to the regulations are necessary (e.g., additional information to be included in the content of the application and a requirement for DOE to address all the issues in the YMRP).~~

*At the appropriate time,*  
*Based on the public comments received, the staff*  
*YMRP or*  
*(As written, its release sounds imminent.)*

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

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

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

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

commenter strongly opposed any suggestion to depart from formal trial-type adjudicatory and evidentiary hearing rules in 10 CFR Part 2 for this potentially complex and first of a kind licensing proceeding.

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

## 6.2 Transportation

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

Comment. Commenters raised concern that the risks for transporting nuclear waste were not being addressed in proposed Part 63. Many commenters interpreted the absence of transportation criteria in proposed Part 63 as an indication that NRC has deemphasized transportation issues. One commenter raised concern over the possibility of terrorism and theft of spent fuel shipments.

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

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

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

In Volume II of the *Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High Level Radioactive Waste at Yucca Mountain, Nye*

County, Nevada, dated July 1999 (DEIS) (at J-23), DOE states that its proposed procedures for implementing Section 180 of the NHPA provide that routing for shipments to Yucca Mountain would comply with applicable regulations of the U.S. Department of Transportation (DOT) in effect at the time of such shipments. DOT regulations on route approval for transporting radioactive material by highway and State or Tribal designation of preferred routing [as an alternative to Interstate System highways] are contained in 49 CFR <sup>§§</sup> 397.101, 397.103, and 397.201. X

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

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

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

NRC require DOE contractors to be responsible for transporting waste or are third-party contractors responsible for transporting waste.

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

As noted above, DOE has stated that routing of shipments of spent nuclear fuel and high-level waste will comply with applicable DOT regulations (DEIS, Vol. II, at J-23). The DEIS (Vol. I and Vol. II, Appendix J) also contains a discussion of the impacts associated with shipments to the proposed repository. The DOT regulations (49 CFR Part 397) provide that shipments are to be on preferred routes (Interstate System highways and city bypasses) or State- or Tribal-designated preferred routes (i.e., alternate routes). These routing requirements were developed by the DOT considering the risks of transportation. Further, DOT has published guidelines (DOT/RSPA/HMS/92-02) for State or Tribal agencies to use in performing route analyses to ensure that the overall risk of the shipments to the public is considered in designating preferred routes. The degree of local participation in the State or Tribal routing agency's process may vary from State to State or from Tribe to Tribe.

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

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

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

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

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

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

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

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

Response. The NRC is not required by NWPAA to solicit and forward comments to DOE from the AULGs or anyone else during the DEIS public comment period. The NRC is expected, under the NWPA, to comment on the DEIS during the DEIS public comment period. The NRC provided comments for DOE to consider as part of the DEIS public comment process. In preparing these comments, the NRC staff observed DOE's DEIS public meetings to better understand what DEIS issues were of concern to the public. In addition, the NRC staff conducted its own meetings with AULG officials and conducted a public meeting in Caliente (Nevada) to discuss the NRC role with respect to the EIS, as it was formulating its comments. For its part, the Commission invited AULGs, stakeholders, and other interested parties to express their views on the DEIS during a public meeting on January 21, 2000. The Commission has considered these views before forwarding its comments to DOE.

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

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

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

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

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

#### Section 63.73 Reports of deficiencies.

The phrase “[b]e a substantial safety hazard,” found at § 63.73(a)(1), was replaced with the phrase “[a]dversely affect safety at any future time,” to be consistent with terminology used at § 63.32(b)(3) and to avoid confusion with reporting requirements under 10 CFR Part 21, which includes a very precise definition for what constitutes a “substantial safety hazard.” Specific requirements regarding DOE’s implementation of a program for evaluating and reporting deficiencies have been included to clarify the reporting requirements.

#### Subpart E - Technical Criteria

##### Section 63.101 Purpose and nature of findings.

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

##### Section 63.102 Concepts.

This section has been changed to clarify NRC’s expectations for the demonstration of compliance with the requirements for multiple barriers, performance confirmation, and preclosure safety analysis. The discussion of multiple barriers has been modified to clarify the intent of the

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

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

Section 63.111(a)(2) has been modified to conform with the individual protection standard now specified in subpart L.

X [Describe revisions to §§ 63.111(b) 1 and 2. — see response to issue 3 on p. 37]

Section 63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

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

impact statement and any supplements, must be signed by the Secretary of Energy or the Secretary's authorized representative and must be filed in triplicate with the Director.

(b) DOE shall submit 30 additional copies of each portion of the application and any amendments, and each environmental impact statement and any supplements. DOE shall retain another 120 copies for distribution in accordance with written instructions from the Director or the Director's designee.

(c) On notification of the appointment of an Atomic Safety and Licensing Board, DOE shall update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement must be served in the same manner.

(d) When an application, and any amendment to it is filed, copies must be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site for inspection by the public. These copies must be updated as amendments to the application are made. The environmental impact statement and any supplements to it must be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, must be produced at any public hearing held by the Commission on the application for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of these documents submitted as required by this part.

**§ 63.23 Elimination of repetition.**

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, if the references are clear and specific and that copies of the information incorporated are made available to the public locations near the site of the proposed geologic repository, as specified in § 63.22(d).

**§ 63.24 Updating of application and environmental impact statement.**

X (a) The application must be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license --

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction;

(2) Conformance of construction of structures, systems, and components with the design;

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

CONSTRUCTION AUTHORIZATION

## PERMANENT CLOSURE

### § 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission must consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required <sup>by</sup> ~~under~~ Subpart F, and pertinent to compliance with § 63.113. x

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed — such as land use controls, construction of monuments, and preservation of records — to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, these measures must include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed, fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders — such records to identify the location of the geologic

repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, drip shields, waste packages, interactions between natural and engineered systems, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of permanent closure, DOE shall also supplement its environmental impact statement and submit this statement, as supplemented, with the application for license amendment.

#### **§ 63.52 Termination of license.**

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

(b) In addition, a State, or an affected unit of local government, or an affected Indian Tribe may submit a proposal to the Director to facilitate its participation in the review of the license application. The proposal may be submitted at any time and must contain a description and schedule of how the State, or affected unit of local government, or affected Indian Tribe wishes to participate in the review, or what services or activities the State, or affected unit of local government, or affected Indian Tribe wishes the NRC to carry out, and how the services or activities proposed to be carried out by the NRC would contribute to this participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as establishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State, or affected unit of local government, or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State, or affected unit of local government, or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described in paragraph (c) of this section, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State, or affected unit of local government, or affected Indian Tribe may bear;

(2) The proposed activities --

(i) Will enhance communications between NRC and the State, or affected unit of local government, or affected Indian Tribe;

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

(iii) Are authorized by law.

X (e) The Director shall advise the State, or affected unit of local government, or affected Indian Tribe whether its proposal has been accepted or denied. If all or any part of proposal is denied, the Director shall state the reason for the denial. <sup>a</sup>

(f) Proposals submitted under this section, and responses to them must be made available at the Public Document Room.

#### **§ 63.64 Notice to State.**

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide the notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

#### **§ 63.65 Representation.**

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature of Nevada), for an affected unit of local government, or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in this capacity.

#### **Subpart D — Records, Reports, Tests, and Inspections**

#### **§ 63.71 Records and reports.**

(a) DOE shall maintain records and make reports in connection with the licensed activity that are required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site must contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

**§ 63.72 Construction records.**

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

(b) The records required under paragraph (a) of this section must include at least the following --

- (1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;
- (2) A description of the materials encountered;
- (3) Geologic maps and geologic cross-sections;
- (4) Locations and amount of seepage;
- (5) Details of equipment, methods, progress, and sequence of work;
- (6) Construction problems;
- (7) Anomalous conditions encountered;
- (8) Instrument locations, readings, and analysis;

- (9) Location and description of structural support systems;
- (10) Location and description of dewatering systems;
- (11) Details, methods of emplacement, and location of seals used; and
- (12) Facility design records (e.g, design specifications and "as built" drawings).

### §63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design, and construction of the geologic repository operations area that, were it to remain uncorrected, could --

- (1) Adversely affect safety at any future time;
- (2) Represent a significant deviation from the design criteria and design basis stated in the design application; or

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

(b) DOE shall implement a program for evaluating and reporting deviations and failures to comply, to identify defects and failures to comply associated with substantial safety hazards, based on the applicable requirements in 10 CFR 50.55(e) as it applies to the construction authorization and design of the geologic repository operations area at the Yucca Mountain site.

(c) DOE shall implement a program of reporting specific events and conditions that is the same as that specified in 10 CFR 72.75.

(d) The requisite notification must be as specified in the applicable regulation. Copies of the written report must be sent to the NRC Operations Center, Document Control Desk, U.S. NRC, the Director of NMSS, U.S. NRC, and to the NRC onsite representative.

(a)(1) Subpart B prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives for postclosure performance of the geologic repository and other criteria that, if satisfied, support a finding of no unreasonable risk. Postclosure performance objectives for the geologic repository include a requirement to limit radiological exposures to the reasonably maximally exposed individual, a requirement to limit releases of radionuclides to the accessible environment to protect ground water, and a requirement to limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion (see §§ 63.113(b), (c), and (d), respectively).

(2) Although the postclosure performance objectives specified at § 63.113 are generally stated in unqualified terms, it is not expected that complete assurance that the requirements will be met can be presented. A reasonable expectation, on the basis of the record before the Commission, that the postclosure performance objectives will be met, is the general standard required. Proof that the geologic repository will conform with the objectives for postclosure performance <sup>is</sup> ~~are~~ not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable expectation, making allowance for the time period, hazards, and uncertainties involved, that the outcome will conform with the objectives for postclosure performance for the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Compliance demonstrations should

not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. The performance assessments and analyses should focus upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values. Further, in reaching a determination of reasonable expectation, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

X (b) Subpart B lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. Prior to closure, § 63.31(a)(1) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and stored in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. After permanent closure § 63.31(a)(2) requires the Commission to consider whether there is a reasonable expectation the site and design comply with the postclosure performance objectives. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to paragraph (a)(2) of § 63.31.

### **§ 63.102 Concepts.**

This section provides a functional overview of this Subpart E. In the event of any inconsistency, the definitions in § 63.2 prevail.

(a) *The HLW facility at the Yucca Mountain site.* NRC exercises licensing and related regulatory authority over those facilities described in Section 202 (3) and (4) of the Energy

operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified at §§ 63.113(b) and (c).

(n) *Ground-Water Protection.* Separate ground-water protection standards are designed to protect the ground water resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of ground water concentrations in a representative volume of water. Depending on the radionuclide, the estimated concentrations must either be below a specified concentration or result in an annual, drinking water dose to the whole body or any organ <sup>of the reasonably maximally exposed individual, of no greater</sup> less than 0.04 mSv (4 mrem). Although the estimation of radionuclide concentrations in the representative volume would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of ground-water protection specified at §§ 63.331, 63.332 and 63.342 of subpart L.

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## PRECLOSURE PERFORMANCE OBJECTIVES

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

(a) *Protection against radiation exposures and releases of radioactive material.*

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual dose to any real member of the public, located beyond the boundary of the site may not exceed the preclosure standard specified at § 63.204.

(b) *Numerical guides for design objectives.*

(1) The geologic repository operations area must be designed so that taking into consideration Category 1 event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area must be designed so that taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site, will receive, as a result of the single Category 2 event sequence, the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysis.* A preclosure safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 must be performed. This analysis must demonstrate that:

- (1) The requirements of § 63.111(a) will be met; and
- (2) The design meets the requirements of § 63.111(b).

(d) *Performance confirmation.* The geologic repository operations area must be designed so as to permit implementation of a performance confirmation program that meets the requirements of Subpart F.

(e) *Retrievability of waste.*

(1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter,

(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.

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(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.

(c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste. The technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessments used to demonstrate compliance with §§ 63.113(b) and (c).

## LAND OWNERSHIP AND CONTROL

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

(a) Ownership of land.

(1) The geologic repository operations area must be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use.

(2) These lands must be held free and clear of all encumbrances, if significant, such as:

(i) Rights arising under the general mining laws;

(ii) Easements for right-of-way; and

(iii) All other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) Additional controls for permanent closure. Appropriate controls must be established outside of the geologic repository operations area. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

**§ 63.204 Preclosure standard.**

DOE must ensure that no member of the public in the general environment receives more than an annual committed effective dose equivalent of 0.15 mSv (15 mrem) from the combination of:

- (a) management and storage (as defined in 40 CFR 191.02) of radioactive material that
  - (1) is subject to 40 CFR 191.03(a); and
  - (2) occurs outside of the Yucca Mountain repository but within the Yucca Mountain site.
- (b) storage (as defined in § 63.202) of radioactive material inside the Yucca Mountain repository.

**Subpart L – Postclosure Public Health and Environmental Standards**

**§ 63.301 Purpose and scope.**

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

**§ 63.302 Definitions for subpart L.**

All definitions in subpart K of this part and the following:

*Accessible environment* means any point outside of the controlled area, including:

(1) the atmosphere (including the atmosphere above the surface area of the controlled area);

(2) land surfaces;

(3) surface waters;

(4) oceans; and

(5) the lithosphere.

*Aquifer* means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

*Barrier* means any material, structure, or feature that, for a period to be determined by NRC, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

*Controlled area* means:

(1) the surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(a) south than 36° 40' 13.6661" north latitude, in the predominant direction of ground-water flow; and

(b) than five kilometers from the repository footprint in any other direction; and

(2) the subsurface underlying the surface area.