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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Rulemakings and Adjudication Staff

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(64FR8640)

U.S. DEPARTMENT OF ENERGY COMMENTS ON PROPOSED REGULATIONS AT 10 CFR PART 63

On February 22, 1999, the U. S. Nuclear Regulatory Commission (NRC) published in the *Federal Register* its proposed licensing criteria, 10 CFR Part 63, for the disposal of spent nuclear fuel and high-level radioactive wastes in a proposed geologic repository at Yucca Mountain, Nevada. This letter and its attachments transmit the U.S. Department of Energy's (DOE) comments on the proposed 10 CFR Part 63 as well as DOE's responses to the five specific questions posed by the NRC as part of this rulemaking.

DOE strongly endorses NRC's use of risk-informed, performance-based licensing criteria. This approach is consistent with NRC's ongoing emphasis on regulations that give the highest attention to the issues of most importance to protection of public health and safety. The elimination of subsystem performance objectives and siting criteria found in the generic regulations at 10 CFR Part 60 in favor of overall performance objectives allows both DOE as applicant and NRC as regulator to place emphasis on the key technical issues related to health and safety aspects of repository performance.

The proposed site-specific rule is a major improvement from the generic rule in terms of providing appropriate flexibility for DOE to determine how to best satisfy the established performance criteria and allowing NRC to focus on the results as the primary basis for regulatory decision-making. Consistent with this observation, DOE is providing comments that would improve several risk-informed, performance-based aspects of the proposed rule.

One issue of concern to DOE is the treatment of human intrusion. The proposed rule for human intrusion requires the repository to meet the same performance objectives in the event of human intrusion as are applied to the unintruded repository. DOE believes that the human intrusion analysis should focus on a qualitative understanding of the resiliency of the repository. A national decision on a repository should not rest on quantitative compliance using an unrealistic drilling scenario. Further, a quantitative standard effectively becomes a subsystem requirement, potentially leading to a suboptimal design to meet that requirement. DOE recommends that the intrusion case be used only to inform a qualitative judgment on the resilience of the repository.

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A second concern is with prescribing requirements for the performance confirmation program and the preclosure integrated safety analysis. DOE believes that prescribing requirements is inconsistent with the overall performance-based approach in the proposed rule.

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

In conclusion, we would like to reiterate that DOE fully supports the overall intent and philosophy of the proposed 10 CFR Part 63. DOE believes that the proposed rule would be effective in protecting the health and safety of the public from potential risks associated with a high-level radioactive waste repository at Yucca Mountain, Nevada.

If you have any questions regarding these comments, please contact April Gil of the Yucca Mountain Site Characterization Office staff at (702) 794-1335 or Nancy Slater of the Office of Civilian Radioactive Waste Management at (202) 586-9322.

Lake Barrett, Acting Director
Office of Civilian Radioactive
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Attachments (2)

Distribution List for Letter to, Secretary, NRC, dated: June 30, 1999

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ENCLOSURE 1

DEPARTMENT OF ENERGY (DOE) RESPONSES TO SPECIFIC QUESTIONS FOR PUBLIC COMMENT ON PROPOSED 10 CFR PART 63

The DOE responses to the NRC's five specific questions for public comment are as follows:

1. Approach to Defining the Critical Group

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

DOE Response:
Overall, the DOE believes the critical group chosen is appropriately conservative, consistent with the recommendations of the National Academy of Sciences, and protective of public health and safety.

2. Human Intrusion Scenario

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

DOE Response:
While the DOE agrees with the concept of a stylized human intrusion scenario, we believe that application of a quantitative dose limit to such a scenario is inappropriate, for reasons detailed in our specific comments (see comment #1).

3. Quality Assurance Program

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

DOE Response:
The DOE believes the proposed wording invoking Appendix B to 10 CFR Part 50 is appropriate. The DOE has developed its NRC-approved quality assurance program based on Appendix B and believes that Appendix B is protective of public health and safety.

4. Changes, Tests, and Experiments

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

DOE Response:
The DOE believes that the proposed alternative criteria for § 63.44, Changes, Tests, and Experiments (found in the supplementary Information Section XVI pages 8653 and 8654) provide a reasonable approach to addressing facility modifications and are preferable to the proposed § 63.44 presented in the body of the proposed rule. The DOE supports the NRC's intent to clarify what activities would require a license or construction authorization amendment. The DOE also supports the intent of the proposed alternative criteria in Section XVI of the Supplementary Information to more clearly define when an unreviewed safety question exists. Finally, we recommend that lessons learned from similar issues regarding 10 CFR 50.59 be applied to the repository regulations. In addition, Attachment 2 contains specific DOE recommendations for changes to the language of the proposed alternative criteria.

5. Applicability of § 63.44

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

DOE Response:
The DOE recommends that the NRC state that § 63.44 applies to activities described in the Safety Analysis Report and not to the general information. Consistent with practice the NRC applies to its licensees who operate nuclear reactors, the Safety Analysis Report is a living document, changes to which are appropriately controlled through § 63.44. The physical protection, material control and accounting, and safeguards plans are controlled by separate requirements in 10 CFR Parts 72 and 73 invoked by the proposed 10 CFR Part 63. Changes to these plans are appropriately addressed in the governing regulations. The remaining parts of the general information required by § 63.21(b) are summaries and general descriptions. Where the descriptions are related to safety, they are provided in detail in the Safety Analysis Report and merely summarized in the general information. Invoking § 63.44 for changes to the descriptions in the general information is not

appropriate. Should the NRC believe it necessary to invoke the controls of § 63.44 for any of these descriptions, the DOE recommends the requirements for the descriptions be moved to § 63.21(c) such that they will be provided in the Safety Analysis Report.

ENCLOSURE 2

DEPARTMENT OF ENERGY (DOE) SPECIFIC COMMENTS ON PROPOSED 10 CFR PART 63

The comments are ordered to reflect the importance of policy and technical concerns.

1. HUMAN INTRUSION. The DOE recommends that the results of the human intrusion analysis be considered as a qualitative indicator of resilience of the repository rather than be compared to a quantitative limit. Specifically, we recommend that § 63.113(d) be revised to state: "The ability of the geologic repository to continue to isolate waste from the environment over the long term in the event of limited human intrusion into the engineered barrier system shall be analyzed, and the results and bases of this analysis shall be included in the license application. While no quantitative regulatory limit applies to the results, the Commission will consider the results of this analysis as a qualitative indicator of the ability of the geologic repository to continue to perform acceptably following human intrusion. The repository's post-intrusion performance is satisfactory if the dose rate returns, over a reasonable period of time, to a value close to the dose rate absent human intrusion. This analysis shall be based on a separate performance assessment..."

Additionally, the characteristics of the intrusion scenario should be clarified in the rule, as suggested below, to avoid undue speculation on the results of the human intrusion scenario.

If the NRC retains a quantitative limit, the level of the standard should be changed to be incremental to the undisturbed case.

Rationale: The NRC proposes a separate human intrusion requirement that has the same stringent quantitative limits as the individual protection standard, but would require the DOE to demonstrate compliance using a stylized scenario based on a highly improbable and inherently inconsistent set of assumptions. The DOE's position on this issue is consistent with the stated purpose of the human intrusion recommendation in the 1995 National Academy of Sciences Report (NAS), which is "to evaluate the resilience of the repository to intrusion" (NAS, p. 109) and to "inform a qualitative judgment" (NAS, p. 111). These qualitative considerations would reflect "the key performance issue [of] whether the repository ... performance would be substantially degraded" (NAS, p. 111).

The purpose of the human intrusion analysis should be to assess the resilience of the repository system in terms of its ability, after intrusion, to recover and continue to isolate waste from the accessible environment over the long term. Questions to be considered qualitatively should be: (1) Will the overall repository system be significantly compromised as a result of a single hole penetrating the system (e.g., would the drifts flood, or would

the borehole become a long-term preferential pathway through the unsaturated zone to the saturated zone?), and (2) Will the repository system "heal itself" to the extent that a single borehole does not allow a significant degradation of the barriers that comprise the repository system?

Although the NAS recommended comparing the results of the intrusion to a quantitative limit, we are instead recommending the results be used as a qualitative indicator of resilience of the repository. The repository's post-intrusion performance should be satisfactory if the dose rate returns, over a reasonable period of time, to a value close to the dose rate absent human intrusion. Our position is that, because the assumed intrusion scenario is unlikely, as discussed below, it provides a poor rationale to potentially disqualify the site. In addition, to meet a quantitative human intrusion standard, a new design requirement would be needed in the design basis, and the design could be forced into one that is suboptimal from the standpoint of total system performance. That is, instead of providing additional protection to public health and safety, protection could be reduced.

Another consideration is that the proposed regulation imposes a probability of one on a human intrusion scenario that involves an extremely unlikely sequence of events. While the DOE understands the reason this approach was taken, it is contrary to the risk-informed emphasis of the remainder of the proposed 10 CFR Part 63. This also would reasonably lead to the conclusion that the performance criterion against which the repository is measured should be different from that imposed absent human intrusion.

The unlikely nature of the proposed scenario limits its usefulness and makes quantitative comparisons inappropriate. The proposed scenario is unlikely for the following reasons. Drilling for water, an important resource in the region, is not likely to occur on the crest of Yucca Mountain, as opposed to nearby dry washes, where the depth to groundwater is significantly less. A borehole would be unlikely to intersect a waste package, because the waste packages cover only a small proportion of the repository footprint. The specification that the scenario occur at 100 years also makes the scenario very unrealistic. If a waste package is intersected 100 years after closure, current drilling techniques would likely not lead to waste package penetration without recognition by the drillers, because DOE's waste packages are not likely to degrade significantly during the 10,000 year regulatory period. Once the drillers recognize the hazard, any further drilling into or beyond the repository becomes advertent, and the NAS recommended considering only inadvertent intrusion.

Additionally, the DOE suggests clarification in the rule on the characteristics of the intrusion scenario to avoid undue speculation on the form of the already highly unlikely human intrusion scenario and to base the post-intrusion processes on reasonable assumptions. The DOE recommends that the rule specify that the effect of the drilling is no more severe than the creation of an enhanced groundwater flow path from the crest of Yucca Mountain through a waste package to the water table. That is, the drilling process itself would not force wastes down to the saturated zone. Collapse of the drill hole would

be consistent with rock properties. Only transport downward through the borehole should be considered, consistent with the preamble's discussion of not considering effects of wastes carried to the surface through drilling. Further, the assumption in the preamble that current drilling practices are used is inconsistent with being able to drill through DOE's planned waste packages; this discussion should be modified. Without these clarifications, the rule again has the potential to require the DOE to use a design that would be suboptimal.

If the NRC retains a quantitative intrusion requirement, the level of the standard should be changed to be incremental. The proposed standard requires performance with the intrusion, including all effects from the undisturbed case, to meet the same standard as that for undisturbed case . However, the NAS recommended that "the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed-repository case" (NAS, p. 113), where the conditional risk is tied to the "incremental effects from the assumed scenario" (NAS, p. 112). That is, the intrusion requirement would place a limit only on the additional dose from the intrusion compared to the results of the undisturbed case. Without allowing an additional dose for the intruded case, the intruded case becomes controlling, and the analysis of the undisturbed case becomes superfluous.

2. PERFORMANCE CONFIRMATION. The DOE recommends that § 63.131(a) reflect the Commission's risk-informed, performance-based approach to regulation by revising it to read: "The performance confirmation program shall provide data important to parameters and conceptual models used in the performance assessment prepared pursuant to § 63.114, that indicate, where practicable..." Similarly, the proposed § 63.132(a) should be revised to state: "...geotechnical and design parameters used in the performance assessment are confirmed..." Finally, the DOE recommends that the proposed § 63.132(c) be revised to state that the DOE will determine the parameters, measurements, and observations appropriate for inclusion in the program based on their importance to confirming repository performance and will describe monitoring plans in the license application.

Rationale: The risk-informed, performance based approach to regulation is embodied in the proposed Part 63. For example, the performance assessment requirements permit the DOE to exercise flexibility in selecting the approach to demonstrate how it meets the established performance criteria. However, the performance confirmation requirements in 10 CFR Part 63 are essentially the same as those in 10 CFR Part 60, and they do not explicitly focus the performance confirmation program on data linked to the performance assessment. The performance confirmation program, when tied to a performance-based approach, should focus on the verification of the performance assessment. This approach would allow the DOE and the NRC to focus attention and resources on those parameters and processes that are significant contributors to repository performance and to uncertainties in that performance. Using such an approach, the overly prescriptive minimum list of geotechnical parameters to be measured as part of performance confirmation is not needed or appropriate. Prescriptive requirements potentially address

issues that are not important to the health and safety of the public. The DOE believes that some of the specific parameters listed in the regulation may not be relevant to performance confirmation. The parameters to be measured should be proposed by the license applicant and approved by the NRC.

3. CONTENT OF APPLICATION. The DOE recommends that the proposed § 63.21(c)(7) be revised to delete the requirement to specifically include in the license application a comparative evaluation of alternatives to major design features. Specifically, the DOE believes that the second sentence of § 63.21(c)(7) should be deleted so that a revised § 63.21(c)(7) would read as follows: "An assessment of the performance of the proposed geologic repository for the period after permanent closure, as required by § 63.113(c)."

Rationale: The DOE believes that the proposed § 63.21(c)(7) is not consistent with and goes beyond typical licensing practice by implying the need to justify an applicant's choice of one design over another. As an example, 10 CFR 50.109(a)(7) states, in part, that "if there are two or more ways to achieve compliance with a license or the rules or orders of the Commission or with written license commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant is free to choose the way which best suits its purposes." Consistent with existing licensing processes, the applicant should be required to demonstrate that its design meets the performance requirements established by applicable regulations.

4. CHANGES, TESTS, AND EXPERIMENTS. The DOE believes that the proposed alternative criteria for § 63.44, Changes, Tests, and Experiments (found in the supplementary Information Section XVI pages 8653 and 8654) provide a reasonable approach to addressing facility modifications and are preferable to the proposed § 63.44 presented in the body of the proposed rule. The following are specific comments regarding the change criteria:

- Should the proposed alternative criteria be implemented, the DOE recommends three specific revisions: (1) The word "final" should be deleted in all references to "Safety Analysis Report." (2) Insert the phrase "range of" into § 63.44(a)(5)(i) such that the sentence would read "Outside the controlling range of parameters..." (3) In the following item [§ 63.44(a)(5)(ii)], change "Inconsistent with" to "Invalidates." (This change will require moving the word "is" from before "either" in the first paragraph of § 63.44(a)(5) to the beginning of item (i) to retain appropriate grammatical construction of the rule.)

- The DOE recommends that the change criteria implemented in Part 63 reflect lessons learned in the planned revision to 10 CFR 50.59 as promulgated in SECY 99-054 dated February 22, 1999. SECY 99-054 presents the staff position on changes to criteria in 10 CFR 50.59 that determine when changes require evaluation by the licensee and when changes require NRC approval before they are implemented.

- The DOE intends to meet the change criteria by evaluating those structures, systems and components identified as important to safety and credited with prevention or mitigation of design basis events or credited for postclosure performance (protection of public health and safety) against screening criteria as part of a graded quality assurance classification process. In addition, quality of those structures, systems, and components identified as important to safety as a result of their importance to worker safety will be assured by compliance with 10 CFR Part 20 limits and the "As Low As Reasonably Achievable" (ALARA) principles contained therein.

Rationale: The DOE supports the Commission's intent in considering the alternative criteria of better defining the criteria for determining when an unreviewed safety question exists. We believe that the alternative wording proposed will support that intent. The DOE also supports the concept of using the design basis as a determinant of when NRC approval is needed.

With regard to the first specific comment, "Final Safety Analysis Report" is not terminology used in the proposed Part 63. The inserted phrase "range of" makes the referenced statement complete and clearer. The last part of the comment proposes wording more focused on impact to safety than the original wording. If a change is inconsistent with the Safety Analysis Report but does not invalidate the analyses in the Safety Analysis Report, it would seem to not constitute an issue of potential concern within the intent of § 63.44.

With regard to the second specific comment, the DOE recognizes that substantial revisions to rules often engender new interpretation issues. Therefore, lessons learned from the application of or rulemaking regarding comparable provisions (10 CFR 50.59) should be applied to the extent possible.

The third specific comment, as it regards worker safety, recognizes that 10 CFR 20.1101 requires procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses that are ALARA. The structures, systems, components, and procedures that provide for ALARA will be discussed in the Safety Analysis Report. The DOE is required to meet the requirements of 10 CFR Part 20 for worker protection and ALARA and is fully committed to do so. Worker radiological protection will be also included in the integrated safety analysis.

5. CHANGES, TESTS, AND EXPERIMENTS. The scope of the change criteria in § 63.44 should be limited to the geologic repository operations area, procedures, tests, and experiments as described in the Safety Analysis Report and should not include the "general information" section of the license application. The DOE supports the emphasis on the Safety Analysis Report in the alternative proposed § 63.44.

Rationale: The Supplementary Information states that the purpose of the change criteria is, in part, to allow changes and tests as long as the level of safety documented in the original licensing basis is maintained. This level of safety is described in the Safety

Analysis Report portion of the application. The Safety Analysis Report will be updated as new information becomes available, and changes to it are controlled through § 63.44. However, the "general information" section of the license application discusses the physical protection plan, safeguards contingency plan, the security organization personnel training and qualification plan, and the material control and accounting plan. The proposed Part 63 invokes separate requirements in § 73.51 and § 63.78 for controls of these plans, so there is no need to invoke § 63.44 for changes to them. The remaining parts of the general information required by § 63.21(b) are summaries and general descriptions. Where the descriptions are related to safety, they are provided in detail in the Safety Analysis Report and merely summarized in the general information. Invoking § 63.44 for changes to the descriptions in the general information is not appropriate. Should the NRC believe it necessary to invoke the controls of § 63.44 for any of these descriptions, the DOE recommends the requirements for the descriptions be moved to § 63.21(c) such that they will be provided in the Safety Analysis Report.

6. BACKFITTING PROVISIONS. Though the DOE agrees that the provisions of 10 CFR 50.109 should not apply to the repository, we recommend that a backfitting provision be added to Part 63, similar to that contained in 10 CFR 50.109.

Rationale: Backfitting provisions have been implemented by the NRC for other facilities to prevent the imposition of additional requirements without an analysis documenting the benefits in terms of performance and costs. Similar provisions should be applied to the regulatory framework of the repository.

The DOE recommends that the rule define backfitting as:

- any modification to systems, structures, components, or design
- any modification to procedures or organization required to design, construct or operate the repository
- additional site characterization or tests which result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position.

The DOE believes that the rule should require the NRC to perform a systematic and documented analysis for backfits it desires to impose to show that (1) the proposed backfit would result in a substantial increase in the overall protection of the public health and safety and (2) the direct and indirect costs of implementing the backfit are justified in view of this increased protection. The backfit provision should apply after a construction authorization is granted and should be applied to any additional tests requested of the DOE in accordance with § 63.74.

7. QUALITY ASSURANCE. The DOE recommends that a provision be added to Part 63 similar to 10 CFR 50.54(a)(3) and (a)(4). The wording should be similar to the following: "A change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report is permitted provided the change does not reduce the commitments in the program description previously accepted by the NRC." In addition, § 63.21(c)(11) should be moved to § 63.21(b).

Rationale: The NRC stated in the discussion accompanying the final rule for Part 50 concerning changes to quality assurance programs (64 FR 9029) that "use of 10 CFR 50.59 criteria for QA program changes is not appropriate." § 63.44 parallels 10 CFR 50.59, but the proposed Part 63 contains no criteria for determining what changes may be made to the QA program discussed in the Safety Analysis Report without prior NRC approval. This addition will avoid the unnecessary expenditure of resources for minor changes and the potential for different DOE and NRC regulatory interpretations related to the QA program.

Moving § 63.21(c)(11) to § 63.21(b) is consistent with the addition proposed in this comment and with the DOE's recommendation that § 63.44 apply only to the Safety Analysis Report. If the quality assurance program is described in the Safety Analysis Report as its present placement in § 63.21(c) dictates, changes to the program fall under § 63.44. As noted in this comment, the DOE recommends that changes to the program be addressed outside the § 63.44 process, so the program description should appear in the "General Information" section of the license application, as prescribed in § 63.21(b).

8. DESIGN BASIS EVENTS. The DOE recommends that the definition of "Design basis events" in § 63.2 be revised as follows:

- Part (1) should be revised to state "Those natural events and human-induced event sequences..."

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

Rationale: The proposed change addresses two issues: (1) the use of event sequences in defining design basis events, and (2) clarification of application of Category 2 design basis events to preclosure natural events to ensure consistency with practice at other NRC-licensed facilities such as nuclear power plants.

The performance objectives of proposed § 63.111 refer to doses that may result from potential releases. The definition of design basis events should encompass the sequence of events that can lead to radioactive releases from the facility, or to exposure of workers. Structures, systems and components that influence the outcome of the initiating event

would be addressed when event sequences are considered. In this way, the structures, systems, and components important to safety can be identified and design criteria defined. The DOE believes that it is important to distinguish between event and sequence because the complete event sequence and its corresponding consequences should be the determinant of the importance of a human-induced event to meeting Part 63 requirements. While the example of a Category 2 event described in Section XIII of the Supplementary Information does demonstrate a sequence of events, a similar statement that Category 1 events may also be sequences of events should be included.

Category 2 design basis events as defined in the proposed regulation (§ 63.2) are those that have one chance in 10,000 of occurring before permanent closure of the repository. Designing to this probability is a reasonable goal in general, but there are specific concerns with applying the definition to natural events, which have existing precedent for the magnitude and frequency of events to be included. For example, seismic events of an annual frequency of occurrence of 10^{-6} are excluded from consideration for nuclear power plant design. Similar regulatory guidance precedents exist for events such as aircraft crash, tornadoes, and flooding.

The DOE's *Topical Report: Preclosure Seismic Design Methodology For A Geologic Repository At Yucca Mountain*, which has been reviewed and provisionally accepted by the NRC (Letter, Stablein to Brocoum, dated 10/29/97), provides that Category 2 seismic design basis events will have a mean annual frequency of 10^{-4}. A 10^{-6} per year earthquake is far beyond normal design considerations. A radiological safety performance goal of 10^{-6} per year is assured by the 10^{-4} per year seismic design basis event combined with seismic design criteria that assure at least 10^{-2} risk reduction. These design criteria achieve safety performance conservatism equivalent to current regulatory requirements for seismic design of radiological safety significant structures, systems, or components in nuclear power generation reactors.

The DOE plans to define credible natural events by following applicable regulatory precedents, as found in Regulatory Guides or Standard Review Plans for nuclear power plants and other facilities licensed by the NRC. The process will include consideration of the most severe natural phenomena that have been historically reported for the site and geologic setting. Structures, systems, and components important to safety can be identified by using such precedents and can subsequently be designed to withstand the natural events as defined in § 63.2.

9. PRECLOSURE PERFORMANCE OBJECTIVES. The DOE would plan to implement the performance objectives of § 63.111 as follows. If this does not meet the NRC's intent, please clarify in the rule.

- Compliance with the performance objectives and numerical guides in §§ 63.111(a)(1), 63.111(a)(2) and 63.111(b)(1) relating to Category 1 design basis events will be demonstrated based on realistic or best-estimate values of doses from direct exposure.

Airborne pathways including submersion, inhalation, and ingestion will be evaluated for Category 1 design basis event sequences.

- Compliance with the numerical guides in § 63.111(b)(2) relating to Category 2 design basis events will be demonstrated based on suitably conservative values of doses from direct exposure and airborne pathways, including submersion and inhalation but not including ingestion.

- The DOE plans to perform dose analyses for Category 1 design basis events, whose limits are expressed as "annual dose" in § 63.111(a)(2), using the method specified in NUREG-0017, *Calculation of Releases of Radioactive Materials in Gaseous and Liquid Effluents from Pressurized Water Reactors*, or its equivalent, to aggregate and convert to annual dose the releases and exposures from all identified Category 1 design basis events.

- The DOE plans to perform dose analyses for Category 2 design basis events based on suitably conservative values of exposures on a "per event" basis.

Rationale: Consequences from Category 1 design basis events and for normal operations are to be applied to a "real member of the public" and limits are expressed on an annual basis. In the case of Category 1 design basis events, designs are based on limiting expected doses to a real receptor. For normal operations, activities are monitored and controlled to ensure that doses to the receptor are below the limit. In concert with the use of a "real" receptor, the calculation of consequences should be realistic. For normal operations, dose is calculated as the expected value. To be consistent, the release factors, exposures, and atmospheric transport for Category 1 design basis event sequences should be based on "realistic" or "best-estimate" values. Releases from Category 1 design basis events, if they occur, will be sporadic and stochastic. NUREG-0017 presents one method for treating the consequences from such occurrences whereby the releases or consequences from several independent, potentially occurring events, are aggregated and converted to an equivalent annual dose.

In contrast to Category 1 event sequences, Category 2 design basis event sequences are unlikely (i.e., they are not expected to occur in the period before permanent closure.) It is even more unlikely that two or more Category 2 events will occur. Therefore, it is appropriate to assess the consequences of each potential Category 2 sequence on a "per event" basis. The dose assessment will be applied to a hypothetical person who may be at a particular point on or beyond the site boundary at the precise time when a radioactive plume passes that point. To demonstrate that potential consequences are within the limits with allowance for uncertainties, it is appropriate to base the assessments on conservative parameters that represent the exposure, release, and atmospheric transport to the receptor. This approach follows the precedents at other nuclear facilities for assessments of design basis events not expected to occur.

With regard to the ingestion pathway being excluded from analyses of Category 2 events, analyses of consequences of airborne releases under accident conditions for reactors and other nuclear facilities are traditionally based on acute releases. Such conditions are analogous to the conditions applicable to a repository Category 2 design basis event. Exposure of a hypothetical individual on or beyond the boundary of the site, with doses expressed as 50-year committed doses, is assumed to occur by submersion and inhalation during passage of the radioactive plume, which occurs in a matter of minutes or hours. The intent of design basis event dose assessments is to protect the public from the immediate consequences of the design basis event. Doses due to an ingestion pathway are typically accumulated slowly over time. The ingestion pathway for a Category 2 event will be addressed as appropriate by mitigation actions taken as part of the emergency plan if post-event investigations of radiation levels and contamination indicate the need.

10. LAND OWNERSHIP AND CONTROL. The definitions in § 63.2 should be changed to retain the distinction between a "preclosure controlled area" and a "postclosure controlled area", by adding definitions similar to those in 10 CFR 60.2 for these two terms and revising the definition of "site."

A definition of preclosure controlled area should be added to § 63.2, using the definition from § 60.2, plus the description of the preclosure controlled area in § 60.136(c), for which there is no comparable section in Part 63. That is, "Preclosure controlled area means that surface area surrounding the geologic repository operations area for which the licensee exercises authority over its use, in accordance with the provisions of this part, until permanent closure has been completed. The preclosure controlled area may be traversed by a highway, railroad, or waterway, so long as appropriate and effective arrangements are made to control traffic and to protect public health and safety." "Preclosure controlled area" should replace "site" in the definition of "important-to-safety" (§ 63.2) and in the preclosure performance objectives (§ 63. 111).

A definition of postclosure controlled area should be added to § 63.2, using the definition from § 60.2, except that the generic 10 km distance limitation in the § 60.2 definition should not be included, pending issuance of the Environmental Protection Agency regulation for Yucca Mountain. That is, "Postclosure controlled area means a surface location, to be marked by suitable monuments, and the underlying subsurface, which area has been committed to use as a geologic repository and from which incompatible activities would be restricted following permanent closure." "Postclosure controlled area" should replace "site" in the description of ownership and control requirements (§ 63.121).

The definition of the site should be changed to the § 60.2 definition, that is, "Site means the location of the preclosure controlled area, or of the postclosure controlled area, or both."

Rationale: The proposed 10 CFR Part 63 does not distinguish between the site area for preclosure and for postclosure. The DOE believes that the distinctions between a

preclosure controlled area and a postclosure controlled area, as defined in the 1996 rule change to 10 CFR Part 60, would give the applicant the flexibility to use one controlled area for calculating doses from preclosure design basis events and a different controlled area for postclosure considerations. With these proposed changes, the DOE would be required to limit access to the preclosure controlled area, but this area would not have the same ownership and control requirements as for the postclosure controlled area.

By not distinguishing between preclosure and postclosure controlled areas, the proposed Part 63 is inconsistent with the approach incorporated into Part 60 in 1996. This change, which is not explained in NRC's supplementary information, limits flexibility, which is contrary to the overall approach taken in the proposed rule. The DOE proposed changes would make clear that a change from the Part 60 approach to land control and ownership at the site was not intended.

11. BIOSPHERE. The DOE recommends that the NRC move §§ 63.115(a)(3) and (4) to § 63.114 to remove any implication that climate change needs to be considered for biosphere assumptions.

Rationale: § 63.115(a)(3) calls for climate evolution to be considered, and § 63.115(a)(4) discusses evolution of the geologic setting. However, in the Supplementary Information (Section VI page 8646), the following statements are made:

> "The change from arid to semi-arid is not expected to alter the biosphere sufficiently to cause major changes in potential exposure pathways to the critical group. For a farming critical group, a semiarid farming region would be expected to support agricultural crops similar to those grown in present day Amargosa Valley. Although specific biosphere and critical group parameters may change slightly with climate, major changes in behavior and exposure pathways for the critical group are not assumed."

These statements suggest that climate change is not expected to significantly alter the biosphere assumptions and that such change need not be considered for the biosphere. In addition, changes in the geologic setting would not seem to be a biosphere issue. The statements in §§ 63.115(a)(3) and (4) therefore more properly belong in § 63.114. Climate change and evolution of the geologic setting are clearly applicable to the performance assessment, requirements for which are provided in § 63.114.

12. PERFORMANCE CONFIRMATION. The DOE recommends that the NRC revise § 63.133 to not restrict design testing to in-situ testing, but rather to allow performance of some of the design testing at other locations, such as laboratories, other test facilities, or boreholes outside of the repository block. Also, § 63.133(c) should be revised to state: "<u>If backfilling the emplacement drifts is planned</u>, a backfill test section shall be constructed..."

Rationale: This section specifically requires part of the repository to include a test section for in-situ testing to be constructed for backfill emplacement and compaction testing, and other test sections for borehole, shaft and ramp seals. These requirements should not necessarily limit the testing to in-situ locations for all of the tests. The requirement for testing should also allow for some of these tests to be accomplished by testing at other locations or facilities. In some cases testing at other locations may be more appropriate.

Backfill testing should only be required if the DOE's license application design specifies backfilling emplacement drifts.

13. LICENSES. The DOE recommends that certain changes be made to Subpart B to ensure the level of detail to be required for construction authorization and licensing is clear and appropriate to the stage of the process to which it applies. Recommended changes are:

- The first sentence of § 63.21(b)(3) should be revised as follows: "A description of the plan to provide physical protection for high-level radioactive waste in accordance with § 73.51 of this chapter."

- The proposed § 63.24(a) requirement that the application be as complete as possible at time of docketing based on reasonably available information should be moved to § 63.21(a).

- § 63.31(a)(6) should be revised as follows: "DOE's proposed plan to develop operating procedures..."

Rationale: The first proposed change makes the requirement more consistent with the construction of other provisions of § 63.21(b) and reflects what the DOE believes is an adequate level of detail for this subject. The second proposed change would place the requirement that the application be as complete as possible in § 63.21, which provides requirements for the content of the license application. It would thereby better support the Commission's apparent intent to describe the level of information required in the license application. The third proposed change recognizes that, at the time of construction authorization, details of the repository design will not in some cases be sufficient to support development of operating procedures. Also, the DOE does not believe such procedures need to be in place at this stage of the licensing process.

Consistent with these comments, it should be noted that the DOE's intent is to provide a sufficient level of information to allow the NRC to make a finding of reasonable assurance at the time of the Construction Authorization in accordance with § 63.31. Design detail will be limited (yet be sufficient for the NRC to make its safety findings). Upon issuance of the construction authorization the DOE would expect that the NRC would determine compliance with the content and commitments of the construction authorization through inspection, surveillance and audits during construction and pre-operational startup phases.

14. INTEGRATED SAFETY ANALYSIS. The DOE recommends that the NRC revise § 63.112(b) to read:

> "An identification and systematic analysis of naturally occurring and human-induced hazards at the geologic repository operations area, including a comprehensive identification of potential design basis events."

In addition, the word "accidents," which appears in § 63.112(e), should be replaced with "design basis events."

Rationale: The definition of design basis events in proposed § 63.2 makes no link with consequence, whereas § 63.112(b) implies such a link. Examination of the 1997 Design Basis Event Rulemaking (61 FR 64257) reveals no mention of a direct link between the definition of a design basis event and consequence. The word "accidents" is used in § 63.112(e) (and in § 63.161) but is not defined. Use of "design basis events" rather than "accidents" is consistent with language elsewhere in the proposed Part 63.

15. CONDITIONS OF CONSTRUCTION AUTHORIZATION. The DOE recommends that the phrase "could adversely affect safety" in proposed § 63.32(b)(3) be replaced with "could constitute a substantial safety hazard as defined in Part 21 of this chapter."

Rationale: The "substantial safety hazard" as defined in Part 21 is a well-accepted and well-defined criterion, whereas "adversely impact safety" is not well defined. The DOE does not believe it necessary to use a different criterion from that in Part 21, which is being made applicable to facilities licensed under Part 63 under this rulemaking.

16. BIOSPHERE. The DOE recommends that the NRC delete, in § 63.115(b)(1), the phrase "near Lathrop Wells, Nevada" and that it add "the junction of" before "U.S."

Rationale: The area described in the regulation is now included in the town of Amargosa Valley and is not officially referred to as Lathrop Wells. The specification of the junction between the two highways adequately defines the location intended.

17. RECORDS. The reference to § 63.51(a)(2) in § 63.71(b) and § 63.72(a) should be changed to refer to § 63.51(a)(3).

Rationale: § 63.51(a)(2) refers to a description of the program for post-permanent closure monitoring of the geologic repository and not to retention of records. Retention of records and their availability for future generations is addressed in § 63.51(a)(3).