

RULEMAKING ISSUE AFFIRMATION

July 10, 2001

SECY-01-0127

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

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

PURPOSE:

To seek Commission approval of a draft final rule that would establish licensing criteria for a proposed repository at Yucca Mountain. These criteria have been adapted consistent with final environmental standards for Yucca Mountain as published by the U.S. Environmental Protection Agency (EPA).

BACKGROUND:

On February 22, 1999 (64 FR 8640), the Commission proposed licensing criteria in a new, separate part of its regulations, at 10 CFR Part 63 (hereafter referred to as Part 63), for disposal of high-level radioactive waste (HLW) in the proposed geologic repository at Yucca Mountain, Nevada.

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After publication of the proposed Part 63, the staff sought to provide members of the public and other stakeholders¹ with multiple opportunities to participate, and to discuss the proposed requirements. In response to many requests, we extended the public comment period another 51 days, until June 30, 1999 (64 FR 24092). The staff held six facilitated public meetings in Nevada with stakeholders, five during the public comment period. The staff considered comments received at these meetings, along with written comments, in developing the draft final rule. The staff held a sixth public meeting in Nevada, a facilitated roundtable discussion, at which staff sought to clarify the proposed requirements for multiple barriers. At this meeting, we explained the relationship between the requirements contained in the proposed rule and the philosophy of defense-in-depth. The meeting was one of several steps we took in response to the Commission's direction (Staff Requirements Memorandum, April 12, 1999) to work with stakeholders to develop a better understanding of the application of defense-in-depth and of requirements for multiple barriers for the proposed repository.

In preparing the draft final rule, the staff carefully reviewed and considered more than 700 discrete comments enclosed in about 160 individual letters received during the comment period, as well as another 193 comments made at public meetings. To simplify the comment analysis, we grouped more than 900 comments into six major topic areas and then consolidated them in a single database which is available to the Commission for review. All comment letters and transcripts were placed on the U.S. Nuclear Regulatory Commission (NRC) rulemaking website, for review by all interested parties.

On June 13, 2001, EPA issued final environmental standards for Yucca Mountain, Nevada at 40 CFR Part 197 (66 FR 32073), as mandated by the Energy Policy Act of 1992. Consistent with that Act, the Commission must adapt its technical criteria to be consistent with final EPA standards.

DISCUSSION:

We received comments from the U.S. Department of Energy (DOE); the State of Nevada; Nye County and other affected units of local government (AULGs); native American organizations; EPA; electric utility licensees; citizen and environmental groups; industry groups; and individuals. The attached draft Federal Register notice addresses and provides proposed responses for all topics raised by commenters. We identified four major subject areas for which significant changes to the proposed rule text appear appropriate. These subjects include:

1. Consistency of Part 63 with final EPA standards for Yucca Mountain

The staff has imported the final 40 CFR Part 197 standards into the draft final Part 63 regulations in as transparent a manner as possible. The staff has identified three classes of changes necessary to do this. First, the 40 CFR Part 197 final standards, which contain two subparts -- Subpart A for storage and Subpart B for disposal -- have been incorporated into Part 63 as two separate Subparts, K and L, respectively. Secondly, while we were able to adopt the language exactly as it appears in the final 40 CFR Part 197 in most cases, nonsubstantive changes were needed to: conform to the

¹Stakeholders included the State of Nevada, affected units of local government, Indian Tribes, the U.S. Department of Energy, the U.S. Environmental Protection Agency, and members of citizen and industry advocacy groups.

regulatory style of the proposed Part 63, and other NRC regulations; remove unnecessary references to NRC; and adapt or remove redundant definitions. Thirdly, as the implementing authority for the EPA standards, we have provided additional specifications and requirements in the areas where it is appropriate to do so, and based on the proposed Part 63 rule and public comments we received. Indeed, EPA has acknowledged NRC's authority to add implementing requirements. A description of specific changes to the Commission's proposed rule that are necessary to achieve consistency with 40 CFR Part 197 standards appear as Attachment 1.

2. Criteria for changes, tests, and experiments

In the supplementary information published with the proposed rule, the Commission expressed its preference for a uniform policy for addressing the change process. To that end, the Commission sought comment on the suitability, for a repository at Yucca Mountain, of an approach substantially equivalent to that proposed, in October 1998, for nuclear reactors and spent-fuel storage facilities (63 FR 56098; October 21, 1998). Most who addressed the change process generally supported applying the proposed alternative criteria.

The Commission published final amendments for changes, tests, and experiments at nuclear reactors, independent spent fuel storage facilities, and holders of certificates for spent fuel storage casks (64 FR 53582; October 4, 1999). Considering comments received during the rulemaking for other NRC-licensed facilities, as well as those addressing similar requirements for the potential repository, the staff recommends final criteria at 10 CFR 63.44, which are comparable to those recently applied to reactors and spent-fuel storage facilities.

3. Basis for assigning probabilities to design basis event (DBE) sequences for preclosure operations

Several commenters suggested that the rule make clear whether event sequences or single initiating events should be used to determine the probabilities of DBEs for preclosure operations. We agree. The intent of the proposed rule was that the integrated safety analysis [now termed the preclosure safety analysis (PSA)], should consider probabilities of entire event sequences, including initiating events, in the analysis of DBEs. We did not intend that only part of an event sequence be used to determine the probability of a DBE. Therefore, we recommend a revision to the proposed regulatory text to state clearly that the probability of a DBE (now referred to as an event sequence) is based on the entire event sequence, including the initiating event and all resulting events relating to the potential release. In addition, we recommend clarifying that initiating events need only be considered for inclusion in the PSA for determining event sequences if they are reasonable (*i.e.*, based on the characteristics of

the geologic setting, the human environment, and consistent with precedents adopted for nuclear facilities with comparable or higher risks to workers and the public).

4. Criteria and change process for the required quality assurance (QA) program

Many expressed concern or confusion about the applicability of QA requirements in the proposed rule. The proposed rule requires DOE to implement a QA program based on the criteria of Appendix B to 10 CFR Part 50, as applicable. Commenters noted that Part 63 defines only the terms “important to safety” and “important to waste isolation,” whereas Appendix B to 10 CFR Part 50 refers to “safety-related.” To address this source of confusion and to express our expectations clearly, we elected to change the regulatory text of the proposed rule. First, we clarified the use of terms (*i.e.*, “important to safety” and “important to waste isolation” instead of “safety-related”). We then stated directly, instead of by reference, that DOE’s QA program must include a discussion of how applicable requirements will be satisfied. Next, we imported the applicable text from Appendix B to 10 CFR Part 50 into 10 CFR 63.143, modified the language slightly to reflect the unique characteristics of the repository, and removed references to Appendix B to 10 CFR Part 50. Lastly, we recommended adding specific change-control requirements, to the QA program description, in the draft final rule.

OTHER ISSUES

In the proposed rule, the Commission announced that a broad study of the NRC hearing process was 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, based on its broader study, the Commission concludes 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. Although the Commission explicitly stated that it was not soliciting public comment on this issue as part of the Part 63 rulemaking, many were received. Most of these comments objected to the use of informal hearings for the repository. The Commission has since issued a proposed rule on April 16, 2001, proposing revisions to its 10 CFR Part 2 hearing procedures (66 FR 19610). 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 HLW at the repository. However, amendments to the construction authorization and to the authorization to receive and possess HLW may be conducted under informal hearing procedures. The staff recommends that the supplementary information accompanying the final Part 63 regulations acknowledge publication of the proposed rule on hearing procedures, and note that 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.

A local government commenter asserted that AULGs should have the same “unquestionable legal right to participate as a party” in a repository hearing as is provided to the State and any affected Indian Tribe. The staff agrees, and recommends that reference to AULGs be added to Subpart C in the final rule. We also recommend replacement of an outdated reference to Subpart G of 10 CFR Part 2, made in 10 CFR 63.63, with a reference to Subpart J of 10 CFR Part 2. Under the Subpart J rules for intervention in the licensing proceeding, AULGs may intervene as a matter of right in the same manner as the State and an affected Indian

Tribe. The staff has consistently provided regular and timely information about its regulatory oversight activities and preclicensing decision making to the DOE-recognized AULGs and other interested parties. Accordingly, AULGs will be added to 10 CFR 63.61, which requires that the Commission provide timely and complete information to the State and affected Indian Tribes. AULGs will also be given a right, along with the State and affected Indian Tribes, to consult with NRC staff (10 CFR 63.62) and to participate in the review of the license application (10 CFR 63.63).

Representatives of the Western Shoshone Nation objected to DOE undertaking a QA program without strict oversight and review by the Western Shoshone Nation. The staff recommends that the supplementary information accompanying the final rule make clear that NRC has been assigned, by law, the licensing and oversight responsibility for the proposed repository at Yucca Mountain, and that NRC is unable to relinquish any part of that authority to other groups or individuals. However, the information should also convey NRC's interest in evaluating approaches for keeping stakeholders informed, such as opening NRC's audit process, including NRC's audit of DOE's QA program, to observation by the State, AULGs, and Indian Tribes.

Finally, we note that many commented that NRC should not allow DOE to receive and store waste at the repository until construction and licensing are complete. Others supported early receipt and storage of waste, at the repository's surface facilities, during construction, so long as no added health or safety risk result. The proposed rule did not explicitly invite comment on this issue. Once construction of the geologic repository operations area is substantially complete, DOE must update its application before receiving a license to receive and possess waste for emplacement. Construction is substantially complete, for this purpose, if, among other things, DOE has completed construction of the underground storage space necessary for initial operations. This approach provides DOE flexibility to plan for efficient operations, recognizing that complete excavation of the entire underground facility may require many years. It does not, however, allow receipt and storage of waste before the geologic repository operations area is substantially complete. If DOE proposes to use repository surface facilities to receive and store waste before the geologic repository operations area is substantially complete, an exemption from NRC's regulations would be needed. The staff is not prepared to recommend such a change to Part 63 now. If the Commission wishes to pursue another approach to the phased licensing of a repository at Yucca Mountain, the staff suggests preparation of an Advance Notice of Proposed Rulemaking that presents the issue fully, and invites broad public comment.

PETITION FOR RULEMAKING FROM THE STATES OF NEVADA AND MINNESOTA

The States of Nevada and Minnesota submitted a petition for rulemaking (PRM-60-2) in 1985, and amended this with another petition (PRM-60-2A) later in that same year. The petition requested NRC to incorporate certain requirements, such as for post-closure monitoring and multiple barriers, in 10 CFR Part 60. It also requested changes to NRC's National Environmental Policy Act (NEPA) review procedures for geologic repositories.

The portion of the petition dealing with NEPA review was denied as part of the 1989 final amendments to 10 CFR Parts 2, 51, and 60 (54 FR 27864). Action on the remaining portion of the petition has not been finalized pending completion of regulations for HLW disposal. Part 63 includes requirements that address the subject areas raised by the petitioners. The staff

intends to close out action on the petition in the next several months by publishing a Federal Register notice, and informing Nevada and Minnesota.

RESOURCES

The resources needed to complete this action are in the current budget.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

RECOMMENDATIONS:

That the Commission:

1. Approve the “Notice of Final Rulemaking” for publication (Attachment 2).
2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Note:
 - a. The rulemaking will be published in the Federal Register (Attachment 2);
 - b. A regulatory analysis will be placed in NRC’s Public Electronic Reading Room (Attachment 3);
 - c. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it, as required by the Regulatory Flexibility Act;
 - d. This rule contains a new information-collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.), and the “Notice of Final Rulemaking” will therefore be submitted to the Office of Management and Budget for clearance;
 - e. A press release will be issued;

- f. NRC has determined that this action is not a major rule, under the Small Business Regulatory Enforcement Fairness Act of 1996, and is confirming this determination with the Office of Management and Budget. This determination will be reflected in correspondence to the President of the Senate, the Speaker of the House of Representatives, and the General Counsel of the General Accounting Office (Attachment 4); and
- g. The appropriate Congressional committees will be informed.

/RA/

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Executive Director
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Attachments:

1. Implementation of the Environmental Protection Agency Final Standards
2. Federal Register Notice
3. Regulatory Analysis
4. Small Business Regulatory Enforcement Fairness Act Forms

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