

RULEMAKING ISSUE
(Affirmation)

July 17, 2002

SECY-02-0135

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations /RA/

SUBJECT: FINAL RULE: 10 CFR PART 63: SPECIFICATION OF A
PROBABILITY FOR UNLIKELY FEATURES, EVENTS, AND
PROCESSES

PURPOSE:

To request Commission approval to publish a notice of final rulemaking that would amend 10 CFR Part 63.

BACKGROUND:

In the Staff Requirements Memorandum (SRM) approving publication of final Part 63 - "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada," dated September 7, 2001, the staff was directed to initiate an expedited rulemaking to establish the annual probability of occurrence that defines an unlikely feature, event, or process (FEP). Additionally, the staff was directed to consider whether a range of values, or a single specific value, should be used, as well as the appropriate numerical value(s).

The staff transmitted the proposed rule package to the Commission in SECY-01-206. The proposed rule was published on January 25, 2002 (67 FR 3628), for a 75-day comment period. Five comment letters were received from: the State of Nevada; the U.S. Department of Energy (DOE); the U.S. Environmental Protection Agency (EPA); the Nuclear Energy Institute (NEI); and Exelon Generation. The proposed rule provided the basis for using a range of values to define an unlikely FEP. No comments were received on this aspect. The staff continues to believe there is no disadvantage associated with using a range of values.

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The radiation protection standards EPA established in 40 CFR Part 197 (66 FR 32074; June 13, 2001) include limits on what DOE must consider in performance assessments. For example, DOE's performance assessments shall not include consideration of "very unlikely" FEPs, which EPA defines to be those FEPs estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. In addition, EPA's standards direct the U.S. Nuclear Regulatory Commission (NRC) to set limits on DOE's consideration of "unlikely" FEPs, or sequences of events and processes, in the required assessments for demonstrating compliance with the human-intrusion and ground-water protection standards. EPA did not define unlikely FEPs in its standards, but, rather, left the specific probability of the unlikely FEPs for NRC to define.

In the proposed NRC rule issued on January 25, 2002 (67 FR 3628), unlikely FEPs were defined as those FEPs with less than a 10 percent chance, but greater than or equal to a 0.01 percent chance of occurring within the 10,000-year compliance period (i.e., annual probability greater than or equal to 10^{-8} and less than 10^{-5}). As a matter of reference, current understanding of FEPs relevant to Yucca Mountain indicates that this designation would allow exclusion of igneous activity as an unlikely FEP, whereas a wide range of seismic events, fault movement, and rock fall would have higher probabilities than the upper bound for unlikely FEPs and would be included in the performance assessments for human intrusion and ground-water protection.

DISCUSSION:

Commenters differed on the quantitative values NRC should use for defining unlikely FEPs. DOE, NEI, and Exelon Generation support NRC's proposed range for defining unlikely FEPs. EPA and the State of Nevada recommended more conservative probability values to define the demarcation between likely and unlikely FEPs. The staff believes that neither EPA nor the State of Nevada provided a convincing basis for rejecting NRC's proposed range and adopting a different range; therefore, the staff has prepared the draft final rule as originally proposed. The attached draft final rule addresses and provides proposed responses for all topics raised by commenters.

EPA recommended that NRC use an annual probability of 10^{-6} to define the demarcation between likely and unlikely FEPs, primarily based on its potential acceptability to particular groups. EPA believes its recommended probability value would increase public confidence in the assessments for human intrusion and ground-water protection because these assessments would need to consider a broader range of FEPs. The staff believes EPA did not provide a sound technical basis for its recommendation. The staff believes regulations should not be set based on assumptions regarding acceptance by particular groups. It understands that selection of a more conservative value (i.e., annual probability of 10^{-6}) for the demarcation between likely and unlikely FEPs could provide additional assurance by considering a broader range of FEPs. Such an approach, however, would sacrifice the intent stated in EPA's standards that the required assessments focus on likely behavior (66 FR 32114 and 32104; June 13, 2001). EPA, in describing what level of expectation will meet the standards, has pointed out negative aspects of an overly conservative approach (e.g., conservatism can bias analyses and deflect attention from questions critical to developing an adequate understanding of the FEPs) (66 FR 32102; June 13, 2001). The staff understands that EPA believes its recommendation (i.e., annual probability of 10^{-6}) is "reasonably" conservative. However, the staff views EPA's recommendation, which would identify FEPs with as little as a one-in-a-million chance of occurring in a year (i.e., 1 percent chance of occurring over 10,000 years) as likely FEPs, is overly conservative and thus not appropriate. Finally, EPA has commented that variation in

dose assessments for Yucca Mountain is sufficiently broad (e.g., two orders of magnitude - a factor of one hundred) that it is reasonable to adopt an annual probability of 10^{-6} as the demarcation between likely and unlikely FEPs because this value represents a numerically similar difference (i.e., two orders of magnitude) between it and the probability for events that EPA assumes are nearly certain to occur within the 10,000 year period (i.e., an annual probability value of 10^{-4}). The staff believes EPA's observation that the variation in estimates of repository performance and the difference between the EPA recommendation of an annual probability value of 10^{-6} and the probability of FEPs nearly certain to occur within the 10,000 year period (i.e., an annual probability of 10^{-4}) are both two orders of magnitude does not justify EPA's recommendation, nor does it imply that NRC's proposed value of 10^{-5} is inappropriate. The staff believes that 10^{-5} is acceptable, because it provides only a 10 percent chance that an event will occur.

The State of Nevada commented that the probability range for "unlikely" FEPs should be the same as is specified for "very unlikely" FEPs primarily because: (1) the ground-water resource should be protected to the same rigor as afforded individual protection, which does consider unlikely events; and (2) exclusion of igneous events, as an unlikely event, from the assessments for ground-water protection and human intrusion, is inappropriate, because igneous activity presents the largest risk to the repository.

The State of Nevada's recommendations are not consistent with EPA's standards that specify different assessments for determining compliance with the ground-water protection and individual protection standards (40 CFR 197.36) and describe the intent for "unlikely" FEPs to be defined differently from "very unlikely" FEPs (66 FR 32100; June 13, 2001). EPA's intent for the assessments for ground-water protection and human intrusion is to focus on the likely performance of the repository; thus, unlikely events are to be excluded from these two assessments. Unlikely FEPs should not be included in the assessments for ground-water protection and human intrusion because inclusion would inappropriately emphasize the contribution of these less likely FEPs when determining the likely behavior of the repository. Exclusion of low-probability FEPs ensures that the assessments for ground-water protection and human intrusion are as intended (i.e., on likely repository performance).

The State's recommendation that igneous activity be included because, as currently assessed, igneous activity is the largest contributor to risk is not consistent with EPA's standards, which specify that NRC is to determine FEPs are either "unlikely" or "very unlikely" based on the likelihood of occurrence of the FEPs and not on other considerations such as risk. However, the exclusion of igneous activity in the assessments for ground-water protection and human intrusion is not expected to have a significant effect on either assessment. The assessment for ground-water protection is not affected because the dose from an igneous event is predominately through the air pathway and not the ground-water pathway. The assessment for human intrusion is not affected because the assumed intrusion (i.e., single borehole to the water table) scenario leads to a ground-water pathway, whereas the igneous event primarily involves the air pathway. As the State has indicated, the air pathway is considered in the assessment for individual protection.

STRATEGIC PLAN GOALS:

The rule should make the licensing process for the proposed repository more effective and efficient by clarifying what assumptions DOE's performance assessments must be based on. This should also reduce unnecessary regulatory burden on the license applicant by eliminating analyses of unlikely conditions consistent with the EPA's direction that the standards address only expected conditions. The rule should contribute to maintaining high-level waste disposal safety and protection of the environment. A more efficient licensing process should enhance public confidence, and stakeholder and public input into the process should be greater.

RESOURCES:

The resources needed to complete this action are estimated to be 0.8 full-time equivalent for fiscal year 2002, which are already reflected in the budget.

COORDINATION:

The Office of the General Counsel has no legal objection to the rulemaking. To accommodate the expedited schedule for this rulemaking directed by the SRM, the normal review and concurrence process was streamlined. The Offices of the General Counsel, Chief Information Officer, and Administration were asked to review this paper. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objection.

RECOMMENDATIONS:

That the Commission:

1. Approve the amendment to specify a probability for unlikely FEPs for publication in the Federal Register (Attachment 1).
2. Certify that the rule, if promulgated, would not have a significant economic impact on a substantial number of small entities.
3. Note:
 - a. That a Regulatory Analysis has been prepared for this rulemaking (Attachment 2);
 - b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);
 - c. That 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 3);
 - d. That appropriate Congressional committees will be informed of this action;

- e. That a press release will be issued by the Office of Public Affairs when the rulemaking is filed with the Office of the Federal Register; and
- f. That resources to complete and implement this rulemaking are included in the current budget.

/RA by William F. Kane Acting For/

William D. Travers
Executive Director
for Operations

Attachments:

1. Draft Final Rule
2. Regulatory Analysis
3. SBREFA Submission

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