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} 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 <u>likely</u> 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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

RIN 3150-AG91

Specification of a Probability for Unlikely Features, Events and Processes

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) is amending its regulations governing the disposal of high-level radioactive wastes in a potential geologic repository at Yucca Mountain, Nevada, to define the term “unlikely” in quantitative terms. NRC regulations now specify a range of numerical values for use in determining whether a feature, event or process, or a sequence of events and processes, should be excluded from certain required assessments. NRC is taking this action to clarify how it plans to implement two of the environmental standards for Yucca Mountain issued by the U.S. Environmental Protection Agency (EPA). Specifically, EPA’s standards require the exclusion of “unlikely” features, events or processes, or sequences of events and processes, from the required assessments for the human-intrusion and ground-water protection standards. In accordance with the Energy Policy Act of 1992, NRC has adopted EPA’s standards in its recently published technical requirements for a potential geologic repository at Yucca Mountain.

EFFECTIVE DATE: (Insert date 30 days from the date of publication in the Federal Register).

ADDRESSES: The final rule and any related documents are available on NRC's rulemaking website at http://ruleforum.llnl.gov. For information about the interactive rulemaking website, contact Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov.

The documents may also be examined at the NRC Public Document Room (PDR), Room O-1F23, 11555 Rockville Pike, Rockville, MD.

NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/reading-rm/adams.html. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, or 301-415-4737; or by email to: pdr@nrc.gov.

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SUPPLEMENTARY INFORMATION:

I. Background

NRC published a proposed rule, "10 CFR Part 63: Specification of a Probability for Unlikely Features, Processes, and Events," on January 25, 2002 (67 FR 3628), and requested public comments. The proposed rule defined the term "unlikely" in quantitative terms. This action was taken to allow NRC to implement EPA's final standards for a potential repository at Yucca Mountain, Nevada. On November 2, 2001 (66 FR 55732), NRC published its final rule, 10 CFR Part 63, governing disposal of high-level radioactive wastes in a potential geologic repository at Yucca Mountain, Nevada. These are the regulations that the U.S. Department of Energy (DOE) must meet in any license application for construction and operation of a potential repository. As mandated by the Energy Policy Act of 1992, Pub. L. 102-486, NRC's final rule adopts the radiation protection standards established by EPA in 40 CFR Part 197 (66 FR 32074; June 13, 2001). EPA's standards for disposal include an individual-protection standard (40 CFR 197.20); a human-intrusion standard (40 CFR 197.25); and ground-water protection standards (40 CFR 197.30). These EPA standards have been incorporated into NRC's regulations at 10 CFR 63.311, 63.321, and 63.331, respectively.

DOE's performance assessments are required to consider the naturally occurring features, events, and processes (FEPs) that could affect the performance of a geologic repository (i.e., specific conditions or attributes of the geologic setting; degradation, deterioration, or alteration processes of engineered barriers; and interactions between natural and engineered barriers). EPA's standards include limits on what DOE must consider in performance assessments undertaken to determine whether the repository will perform in compliance with the standards

(40 CFR 197.36). EPA's standards state that DOE's performance assessments shall not include consideration of "very unlikely" FEPs, which EPA defines to be those FEPs that are estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. In addition, EPA's standards require NRC to exclude "unlikely" FEPs, or sequences of events and processes, from 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. The Commission explained in its rulemaking establishing Part 63 that it "...fully supports excluding unlikely FEPs from analyses for estimating compliance with the standards for human intrusion and ground-water protection...," and that it "...plan[ned] to conduct an expedited rulemaking to quantitatively define the term 'unlikely'" (66 FR 55734; November 2, 2001).

On January 25, 2002, the Commission published for comment a proposed rule to quantitatively define the term "unlikely" (67 FR 3628). Unlike the broader purposes served by the performance assessment for the all-pathway individual-protection standard, the performance assessments used to determine compliance with the human-intrusion standard and the ground-water protection standards serve narrow, focused objectives. In the case of the performance assessment for human intrusion, the purpose is to evaluate the robustness of the repository system, assuming the occurrence of a prescribed human-intrusion scenario. In the case of the performance assessment for ground-water protection, the purpose is to evaluate potential degradation of the ground-water resource. Although EPA's final standards did not specify a numerical value to define unlikely FEPs in quantitative terms, the preamble to the standards stated

that the exclusion of unlikely FEPs is intended to focus these assessments on the "expected" or "likely" performance of the repository.[1]

From a probabilistic perspective, any FEP with an annual probability of 10^{-4} or higher would have a high probability of occurring within the 10,000 year compliance period.[2] As the Commission described in the proposed rule, likely FEPs should include not only FEPs very likely to occur, but also those reasonably likely to occur. Given uncertainties in estimating the occurrence of FEPs over a 10,000 year time period, the Commission believed a prudent decision was to consider FEPs with 10 percent or greater chance of occurring within the 10,000 year compliance period as likely FEPs. Thus, the Commission sought public comment on its proposal that unlikely FEPs be 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 less than 10^{-5}, but greater than or equal to 10^{-8}, which is the upper boundary for very unlikely events). As mentioned previously, the focus of the performance assessments for human intrusion and ground-water protection is to be on expected conditions. The Commission believes an upper bound for unlikely FEPs of a 10 percent chance of occurring within the

[1] For example, the preamble states: (1) "[T]he assessment of resource pollution potential is based upon the engineered design of the repository being sufficiently robust under expected conditions to prevent unacceptable degradation of the ground-water resource over time" (66 FR 32114; June 13, 2001); and (2) the term "undisturbed," which is used in connection with demonstrating compliance with the ground-water protection standards, means the "...disposal system is not disturbed by human intrusion but that other processes or events that are likely to occur could disturb the system" (66 FR 32104; June 13, 2001).

[2] Estimating a high probability of occurrence for an FEP creates an expectation that an FEP will occur; however, it does not guarantee such an occurrence. There is a chance that even high-probability FEPs will not occur. Likewise, in a probabilistic sense, having a low probability of occurrence does not mean that an FEP will not occur.

compliance period will focus the assessments for ground-water protection and human intrusion on the likely performance of the repository.

II. Public Comments and Responses

The 75-day comment period for the proposed rule closed on April 10, 2002. Comments were received from the following five organizations: EPA; State of Nevada and the Nevada Agency for Nuclear Projects; DOE; Nuclear Energy Institute (NEI); and Exelon Generation. Commenters differed on the quantitative values NRC should use for defining unlikely FEPs. Although some commenters supported the proposed values, others provided different numbers and associated rationales. In preparing the final rule, the NRC staff carefully reviewed and considered these comments. The commenters that suggested alternative values did not provide a convincing basis for rejecting NRC's proposed range and adopting a different range; therefore, the Commission has decided to finalize the rule as originally proposed. The NRC's consideration of each of the comments is provided below.

1 EPA Comments

Comment 1.1: The upper value for the probability range for unlikely FEPs should be an annual probability of 10^{-6}. An annual probability of 10^{-6} as a demarcation separating likely FEPs from unlikely FEPs is reasonable because it is the middle of the range between FEPs that are nearly certain to occur (i.e., annual probability of 10^{-4}), and FEPs that are very unlikely to occur (i.e., annual probability of 10^{-8}). Placing the demarcation closer to either end of the range could be perceived as biased, either too liberal or too conservative, whereas the middle of the range

avoids those implications. The NRC proposal, which is a factor of 10 reduction (from the 10^{-4} annual probability level), could be perceived as an arbitrary selection, whereas an annual probability of 10^{-6} is a factor of 100 reduction and is likely to be more widely accepted.

Response 1.1: The Commission stated, in the proposed rulemaking (67 FR 3629; January 25, 2002) that the specification of a value to quantitatively define the probability for unlikely FEPs is complicated because of the subjective nature of the term "unlikely." The Commission did consider the merits of using an annual probability of 10^{-6} rather than 10^{-5} for the demarcation between likely and unlikely FEPs. These two probability values represent approximately a 1 percent and 10 percent chance of occurring over the 10,000 year regulatory period. The Commission considered a 1 percent chance of occurring (i.e., annual probability of 10^{-6} over 10,000 years) neither expected nor likely and, therefore, an inappropriate value for the demarcation between likely and unlikely FEPs (67 FR 3630; January 25, 2002). The Commission continues to believe an annual probability of 1×10^{-5} (i.e., 10 percent chance of occurring within the 10,000 year compliance period) is a protective and prudent value for defining the upper limit of unlikely FEPs and is retaining the proposed range for defining unlikely FEPs.

EPA has suggested that a probability value which represents the middle of a particular range (only when displayed on a logarithmic scale) contains some inherent justification for its selection. EPA also suggests that the NRC proposal, which is a factor of 10 less than an annual probability of 10^{-4}, may be considered too high by some, whereas the EPA recommended value of 10^{-6}, which is 100 times lower than 10^{-4}, is likely to be more acceptable. The issue is not whether a particular value lies within the middle of a range (when plotted in a particular manner), or that the value is 10 rather than 100 times less than another value. The issue for NRC is to determine

an appropriate value that is protective of public health and safety and the environment, and consistent with EPA's standards. EPA's standards exclude unlikely FEPs from the required assessments for ground-water protection and human intrusion so that these assessments may focus on the likely performance of the repository. This is the context in which the definition of a specific probability value should be viewed. The Commission and other commenters consider the NRC proposal (i.e., 10 percent chance of occurring over 10,000 years defines demarcation between likely and unlikely FEPs) consistent with the intended focus of the assessments for ground-water protection and human intrusion, and protective of public health and safety and the environment (see Comments 3-5).

Comment 1.2: Given the significant uncertainty in estimating the probability for rare events (e.g., events with an annual probability of 10^{-5}), specification of an annual probability value of 10^{-6} for the demarcation between likely and unlikely FEPs will provide greater confidence that all likely FEPs are considered in the assessments for ground-water protection and human intrusion. There is no need to be restrictive about the probability limits because both standards and regulations allow for excluding FEPs that have no significant impact on performance results. Use of an annual probability of 10^{-6} assures a reasonably conservative approach is taken for screening FEPs.

Response 1.2: EPA has suggested that the Commission adopt a more conservative approach for selecting the demarcation between likely and unlikely FEPs. The Commission disagrees with this approach advocated by EPA for the following reasons: (1) the proposed value of 10^{-5} (i.e., 10 percent chance of occurrence over 10,000 years) already represents a reasonably

conservative value for the demarcation between likely and unlikely FEPs; (2) introducing additional conservatism for screening of FEPs, by selecting an annual probability of 10^{-6}, will detract from the intended purpose of the assessments to focus on likely performance; and (3) understanding and addressing uncertainties in the quantitative estimates for the probabilities of FEPs is preferred over selection of more conservative screening values.

The Commission acknowledges 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 that the required assessments focus on likely behavior. 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 Commission understands that EPA believes its recommendation (i.e., annual probability of 10^{-6}) is "reasonably" conservative. However, the Commission 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., one percent chance of occurring over 10,000 years) as likely FEPs, is overly conservative and thus not appropriate. The Commission, as well as other commenters (see Comments 4 and 5), support the annual probability of 10^{-5} (i.e., 10 percent chance of occurrence over 10,000 years) as a reasonably conservative value for the demarcation between likely and unlikely FEPs. The Commission continues to believe the specification of an annual probability of 10^{-5} is consistent with the focus on likely performance for the assessments of ground-water protection and human intrusion.

There will be uncertainty in estimating performance of any geologic repository, including the uncertainty in estimating the probabilities of FEPs. NRC's regulation for Yucca Mountain contains specific requirements for addressing uncertainty in estimating performance, which includes uncertainty for estimating probabilities for FEPs. The Commission believes it is prudent to understand and evaluate the uncertainty in the probability estimates rather than set a more conservative screening value as a means to address uncertainty in estimating probabilities of FEPs. Reasonable expectation, as specified in EPA standards (40 CFR 197.14) and NRC regulations (10 CFR 63.304), in compliance with the postclosure standards of the repository, dictates that uncertainties be understood and evaluated even when they may be difficult to precisely quantify (e.g., accounting for the inherently greater uncertainties, in making long-term projections of the performance of the Yucca Mountain disposal system, does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence). In the preamble to the final standards, EPA asserted that "[T]he reasonable expectation approach is aimed simply at focusing attention on understanding the uncertainties in projecting disposal system performance so that regulatory decision making will be done with a full understanding of the uncertainties involved" (66 FR 32102; June 13, 2001). The Commission believes its requirements for the performance assessments provide for a thorough evaluation and understanding of uncertainties in estimating repository performance. Thus, selection of a more conservative probability value for the demarcation between likely and unlikely FEPs is unnecessary. As discussed previously, the Commission continues to believe the proposed value (i.e., 10 percent chance of occurring within 10,000 years) ensures the assessments for ground-water protection and human intrusion focus, as intended, on likely performance, whereas the use of more conservative values to define unlikely FEPs would inappropriately distort the estimation of likely performance.

Comment 1.3: 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 value 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 nearly certain to occur within the 10,000 year period (i.e., an annual probability value of 10^{-4}). Whereas NRC's proposed value (i.e., an annual probability value of 10^{-5}) is only a factor of 10 (i.e., one order of magnitude) different from the probability for events nearly certain to occur.

Response 1.3: The performance assessments for evaluating individual protection for the proposed repository at Yucca Mountain evaluate performance probabilistically; therefore, the estimates of repository performance are represented by a range of values. The variation in repository performance results from including uncertainty and variability in the models and parameters of the performance assessment used to represent FEPs associated with the site conditions and the natural and engineered barriers of the repository. 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 value 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[3]. EPA has not provided information to support the relevance of this observation to the specification of a value for the demarcation of likely and unlikely FEPs. The performance assessments for Yucca Mountain involve complex models, for FEPs, that consider

[3] The staff believes that an annual probability value of 10^{-5} is acceptable, because it provides only a 10 percent chance that an event will occur.

the uncertainty and variability in natural processes and the degradation of engineered materials. Performance assessments are expected to continue to evolve over time as new information is collected and evaluated and the variation in performance assessment results is also expected to change. A logical conclusion of the EPA comment is that the demarcation between likely and unlikely FEPs should change if future assessments of Yucca Mountain cause the variation of results to deviate from the current two orders of magnitude range. The Commission believes the determination of an annual probability for the demarcation between likely and unlikely FEPs should not be tied to the performance assessment results nor any other particular assessment of site conditions (see also response to Comment 1.4).

Comment 1.4: The selection of the probability for the demarcation between likely and unlikely FEPs should be divorced from the site conditions.

Response 1.4: The Commission agrees that site conditions should not be used to determine the probability for the demarcation between likely and unlikely FEPs. NRC's proposed rulemaking did not use any site conditions to determine an appropriate probability value. In the proposed rule, the Commission did identify a few selected FEPs, as a matter of reference, to inform the public of the kinds of FEPs that might be included and excluded by the proposed probability range for unlikely FEPs (67 FR 3630; January 25, 2002).

2 State of Nevada and the Nevada Agency for Nuclear Projects Comments

Comment 2.1: Unlikely FEPs should be defined by the same quantitative value used to define very unlikely FEPs (i.e., annual probability less than 10^{-8}). The EPA standard requires the Commission to set the quantitative level for unlikely FEPs, but it does not require that it be higher than the value used to define very unlikely FEPs.

Response 2.1: The EPA standards provide that a numerical value to define unlikely FEPs is to be specified by NRC, and the preamble to the standards clearly indicates that any such value would be higher than the value used to define very unlikely events. More specifically, the preamble to the final standards states: "[W]e intended to establish another demarcation for excluding unlikely features, events, and processes with a higher probability...." (66 FR 32100; June 13, 2002). The Commission does not consider the State's proposal (i.e., unlikely FEPs be specified with the same numerical value used to define very unlikely FEPs) consistent with EPA's intent for the standards or common understanding of the two terms "unlikely" and "very unlikely," which imply a difference in likelihood. The Commission believes its proposal, which specified a numerical range for unlikely FEPS above the range for very unlikely FEPs, is consistent with the EPA standards, as required by statute, and is fully protective of public health and safety and the environment.

Comment 2.2: Preservation of ground-water quality must not be compromised. Therefore, the assessment for protection of ground water should be no less rigorous than the assessment used to evaluate individual protection, which is required to consider unlikely events.

Response 2.2: The State is correct in pointing out that the individual protection assessment is the only assessment that includes unlikely FEPs; however, the EPA standards are clear that "unlikely" FEPs are to be excluded from the performance assessments for ground-water protection and human intrusion (40 CFR 197.36). The State of Nevada's recommendation is not consistent with EPA's standards that specify different assessments for determining compliance with the ground-water protection and individual-protection standards. 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 (see Response 1.2). 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).

Ground water is an important resource, and potential contamination of ground water is evaluated in all three assessments (i.e., ground-water protection, human intrusion, and individual protection) required by regulations and standards. More specifically, the assessment for ground-water protection must demonstrate compliance with stringent safety standards [e.g., 0.04 millisievert/year (mSVyr) (4 millirem/year (mrem/yr))] for the potential contamination of drinking water. The assessment for individual protection must demonstrate compliance with a 0.15 mSv/yr (15 mrem/yr) exposure limit from all potential exposure pathways (e.g., drinking contaminated water, consuming crops that are assumed to be irrigated with contaminated water, consuming animal products that are assumed to be raised with contaminated water and feed) and include unlikely FEPs. The assessment for human intrusion must demonstrate compliance with a

0.15 mSv/yr (15 mrem/yr) exposure limit from all potential exposure pathways, and assume that a human intrusion results in a borehole that provides a direct pathway for water to transport waste to the water table (i.e., the ground-water resource). The Commission considers the multiple and overlapping assessments for ground-water protection, individual protection, and human intrusion, and the associated standards, to provide a comprehensive evaluation of potential ground-water contamination that is protective of the ground-water resource. Requiring the assessments for ground-water protection and human intrusion to include "unlikely" FEPs is not necessary for protection of the ground-water resource nor consistent with the EPA standards.

Comment 2.3: NRC's proposed value for unlikely events would, but should not, allow the exclusion of igneous activity from consideration in the performance assessments for ground-water protection and human intrusion because it could be the largest contributor to dose. The proposed definition for unlikely events is subjective to the extreme because the largest risk contributor is excluded.

Response 2.3: 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. EPA's standards 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. The Commission explained, in its proposed rule (67 FR 3629; January 25, 2002), that EPA's intent for the assessments for ground-water protection and human intrusion was 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 such low-probability FEPs ensures that the assessments for ground-water protection and human intrusion are as intended (i.e., on likely repository performance), and are not considered "subjective to the extreme," because of this exclusion.

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.

Comment 2.4: The performance assessments for human intrusion and individual protection should consider similar FEPs, to provide a meaningful comparison of repository resilience.

Response 2.4: As discussed in the previous responses (under Comments 2.2 and 2.3), each of the three performance assessments (i.e., those conducted to demonstrate compliance with the standards for individual protection, ground-water protection, and resiliency to an assumed human intrusion) has its own specific purpose, assumptions, and standards. The EPA standards

and NRC's regulations do not require that direct comparisons be made between any of these assessments. The performance assessment for human intrusion demonstrates the resilience of the repository by assuming a specified intrusion occurs and by requiring potential exposures to comply with the same overall exposure limit [i.e., 0.15 mSv/yr (15 mrem/yr) from all pathways] used for individual protection. Although the EPA standards clearly state "unlikely" FEPs are not to be included in the assessment for human intrusion and ground-water protection (40 CFR 197.36), the performance assessments for individual protection, ground-water protection, and human intrusion provide a comprehensive evaluation of FEPs to inform the licensing decision. Regardless of which aspect of repository performance is the largest risk contributor, the regulatory requirements for all assessments must be met.

Comment 2.5: The possibility of multiple intrusions into the repository should be considered as a likely event and included in the evaluation of human intrusion rather than the "single" intrusion prescribed in the EPA standards and adopted in NRC's regulations.

Response 2.5: The State raised a similar concern (i.e., consideration for multiple intrusions) during the public comment period for Part 63. The Commission addressed this issue when it finalized Part 63, stating:

> Another related issue is whether the stylized calculation should consider multiple intrusions. The final EPA standards resolve this issue in favor of a single intrusion. Moreover, in its findings and recommendations, NAS [National Academy of Sciences] argued against analyses of whether and how often exploratory drilling would occur at

Yucca Mountain because of the complexities associated in such assessments. Simply stated, the NAS felt that no one can accurately predict the characteristics of future human society and their technology. In the context of human intrusion, estimating the probability of exploratory drilling for a given resource relies on an ability to predict certain economic and technical factors that influence supply of, and demand for, that resource. In fact, NAS noted that the continued advances in noninvasive geophysical techniques may, in fact, reduce the number and frequency of exploratory boreholes... Consequently, any consideration for the drilling of multiple exploratory boreholes or later drilling of more boreholes further increases the speculative nature of the intrusion scenario with potentially little increase in understanding repository resilience.

The EPA standards provide for consideration of a single borehole at the earliest time that human intrusion into the waste package can occur without recognition by the drillers. The Commission believes this is an appropriate test for evaluating repository resilience. Moreover, the suggested alternative to evaluate multiple intrusions for the human intrusion calculation fails to reflect the purpose of the human intrusion calculation, that is to test the resilience of the repository, not to evaluate the speculative issue of frequency of the intrusion (66 FR 55761; November 2, 2001).

3 DOE Comments

DOE supports NRC's proposed probability range for defining unlikely FEPs as a reasonable and conservative choice.

Comment 3.1: For assessing operational safety of the repository, NRC's regulations specify that operational events that occur one or more times during the operational period are considered reasonably likely to occur. Applying this definition (i.e., one or more times) to the specification of a value to define unlikely FEPs results in an upper bound of one chance of occurrence within 10,000 years (i.e., approximately 10^{-4} annual probability). Thus, NRC's proposal of an upper bound of one chance in ten of occurring within 10,000 years (i.e., 10^{-5} annual probability) for unlikely FEPs is a reasonable and conservative approach.

Response 3.1: In the proposed rulemaking, NRC considered an annual probability of 10^{-4} for the demarcation between likely and unlikely FEPs, but ultimately decided on a probability of one chance in ten of occurring within 10,000 years (i.e., annual probability of 10^{-5}) as a prudent value, given the uncertainties in estimating the occurrence of FEPs over the very long compliance period. The Commission was careful to point out that its specification for unlikely events was in the context of very specific assessments (i.e., those made to assess compliance with ground-water protection and human-intrusion standards) over a long time frame, and this specification was not intended to suggest or imply precedent for other significantly different applications that used the term "unlikely" (67 FR 3630; January 25, 2002). Similarly, significantly different applications such as requirements for the safety assessment of the operational period (e.g., significantly shorter time period, inclusion of worker activities) should not imply a precedent for specifying a value for unlikely FEPs.

4 NEI Comments

NEI supports NRC's proposed probability range for defining unlikely FEPs. NEI stated that the proposed definition of unlikely FEPs will facilitate a reasonable and prudently conservative analysis of these aspects of repository performance (i.e., ground-water protection and human intrusion).

5 Exelon Generation Comments

Exelon Generation supports NRC's proposed probability range for defining unlikely FEPs.

III. Section-by-Section Analysis

Section 63.342 Limits on performance assessments

This section specifies how DOE will determine which features, events, and processes will be considered in the performance assessments described in Subpart L of Part 63.

IV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this rule, NRC is establishing probability limits for unlikely FEPs at a potential geologic repository for high-level radioactive waste at Yucca Mountain, Nevada. This action does not constitute the establishment of a standard that contains generally applicable requirements.

V. Finding of No Significant Environmental Impact: Availability

Pursuant to Section 121(c) of the Nuclear Waste Policy Act, this rule does not require the preparation of an environmental impact statement under Section 102(2)(c) of the National Environmental Policy Act of 1969 or any environmental review under subparagraph (E) or (F) of Section 102(2) of such act.

VI. Paperwork Reduction Act Statement

This rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995. (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0199.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct nor sponsor, and a person is not required to respond to, the information collection.

VII. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. It is available for inspection in the NRC Public Document Room, One White Flint North, 11555 Rockville Pike,

Rockville, MD 20852. Single copies of the analysis may be obtained from Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6203, e-mail: cwp@ nrc.gov.

VIII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule relates to the licensing of only one entity, DOE, which does not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810)

IX. Backfit Analysis

NRC has determined that the backfit rule does not apply to this rule and, therefore, that a backfit analysis is not required, because this rule does not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1.

X. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

XI. List of Subjects in 10 CFR Part 63

Criminal penalties, High-level waste, Nuclear power plants and reactors, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 63.

PART 63 - DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A GEOLOGIC REPOSITORY AT YUCCA MOUNTAIN, NEVADA

1. The authority citation for Part 63 continues to read as follows:

Authority: Secs. 51, 53, 62, 63, 65, 81, 161, 182, 183, 68 Stat. 929, 930, 932, 933, 935, 948, 953, 954, as amended (42 U.S.C. 2071, 2073, 2092, 2093, 2095, 2111, 2201, 2232, 2233); secs. 202, 206, 88 Stat.1244, 1246 (42 U.S.C. 5842, 5846); secs. 10 and 14, Pub. L. 95-601, 92 Stat. 2951 (42 U.S.C. 2021a and 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 114, 121, Pub. L. 97-425, 96 Stat. 2213g, 2238, as amended (42 U.S.C. 10134, 10141); and Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851).

2. Section 63.342 is revised to read as follows:

§ 63.342 Limits on performance assessments.

DOE's performance assessments should not include consideration of very unlikely features, events, or processes, i.e., those that are estimated to have less than one chance in 10,000 of occurring within 10,000 years of disposal. DOE's assessments for the human-intrusion and ground-water protection standards should not include consideration of unlikely features, events, and processes, or sequences of events and processes, i.e., those that are estimated to have less than one chance in 10 and at least one chance in 10,000 of occurring within 10,000 years of disposal. In addition, DOE's performance assessments need not evaluate the impacts resulting from any features, events, and processes or sequences of events and processes with a higher chance of occurrence if the results of the performance assessments would not be changed significantly.

Dated at Rockville, Maryland, this _____ day of _____, 2002.

For the Nuclear Regulatory Commission,

_____

Annette Vietti-Cook,
Secretary of the Commission.

REGULATORY ANALYSIS

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

AMENDMENT TO SPECIFY A PROBABILITY FOR UNLIKELY FEATURES,
EVENTS, AND PROCESSES

Issue:

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations on the disposal of high-level radioactive wastes (HLW) in a proposed geologic repository at Yucca Mountain, Nevada (10 CFR Part 63) to define a probability range for use in determining whether a feature, event, or process (FEP) or sequence of events and processes is considered to be "unlikely" and thus excluded from certain required assessments. This amendment is being made to provide clarification of how NRC is implementing the final environmental standards for Yucca Mountain issued by the U.S. Environmental Protection Agency (EPA). Specifically, EPA's final standards require the exclusion of "unlikely" FEPs, or sequences of events and processes from the assessments for human intrusion and ground-water protection, and NRC is to determine the probability of the unlikely FEPs (66 FR 32135; June 13, 2001).

A proposed rule, "10 CFR Part 63 --Specification of a Probability for Unlikely Features, Events, and Processes" was published in the Federal Register on January 25, 2002 (67 FR 3628). Five comment letters were received, from the State of Nevada, EPA, DOE, Exelon, and the Nuclear Energy Institute. These comments have been considered in the development of this final rule.

Background:

NRC is establishing a regulatory framework to prepare for a possible application by the U.S. Department of Energy (DOE) for a license to construct and operate a geologic repository for HLW at a potential site at Yucca Mountain, Nevada. The Energy Policy Act of 1992 (EnPA) made changes to the U. S. HLW repository program, originally established in the Nuclear Waste Policy

Act of 1982. It directed EPA to issue public health and safety standards for HLW disposal at a potential geologic repository at Yucca Mountain, Nevada, to be based on and consistent with a National Academy of Sciences (NAS) study of the technical bases for public health and safety standards governing the Yucca Mountain repository.[1] NRC was directed to modify its technical requirements and criteria for geologic repository disposal to be consistent with the new EPA standards. The EnPA directed NRC to do so within 1 year of promulgation of the final EPA standards. NRC published proposed Part 63, "Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada", on February 22, 1999. (64 FR 8640) EPA published its proposed standards for Yucca Mountain, 40 CFR Part 197, on August 27, 1999 (64 FR 46976), and its final standards on June 13, 2001 (66 FR 32073). NRC published final Part 63, revised to conform to the final EPA standards, on November 2, 2001 (63 FR 55731). These are the regulations that DOE must meet in any potential license application for construction and operation of the repository. EPA's standards for disposal include an individual protection standard (40 CFR 197.20); a human intrusion standard (40 CFR 197.25); and ground-water protection standards (40 CFR 197.30). These EPA standards have been incorporated into NRC's regulations at 10 CFR 63.311, 63.321, and 63.331, respectively.

FEPs are features, events, and processes used to characterize the repository system. Probabilities for FEPs in the context of the potential geologic repository at Yucca Mountain primarily have focused on igneous activity, seismic events, fault movements, and rock fall. An issue in postclosure performance assessments of the repository is what FEPs should be considered in performance assessments. For the purposes of analyses for estimating compliance with the standards for human intrusion and ground-water protection, Part 63 does not specify a quantitative probability limit for unlikely FEPs that should not be considered.[2] However, in the "statement of considerations" for the final rule, the Commission noted that it considered the approach of specifying a value in the regulations " ... to be consistent with the intent of EPA's final

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[1] National Academy of Sciences, Technical Bases for Yucca Mountain Standards, National Academy Press, Washington, DC, 1995.

[2] Section 63.342, "Limits on performance assessments," does specify a quantitative limit for very unlikely FEPs -- less than one chance in 10,000 of occurring within 10,000 years of disposal -- that should not be included in DOE's performance assessments.

standards and may revisit the question of specifying a numerical value by rulemaking in the future" (63 FR 55734). EPA supports the approach of establishing a numerical value for unlikely FEPs that should be excluded from the assessments for the human intrusion standard and ground-water protection standards.

Applicable Current NRC Regulations

Under 10 CFR 63.321(b)(1), DOE must demonstrate the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion could occur without recognition by the drillers and ".... demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) as a result of a human intrusion, at or before 10,000 years after disposal." The elements of the stylized human intrusion scenario are specified by 10 CFR 63.322 and specifically mandate that DOE must assume that no releases are included which are caused by unlikely natural processes and events.

With respect to the ground-water protection standards (10 CFR 63.331) DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of "undisturbed" performance after disposal, releases of radionuclides from waste in the Yucca Mountain disposal system into the accessible environment will not cause the level of radioactivity in the representative volume of ground water to exceed the limits specified in a table attached to 10 CFR 63.33. NRC adopted a definition of "undisturbed" performance that excludes the need to consider "unlikely" events.

In assessing compliance with both the human intrusion standard and the ground-water protection standards, 10 CFR 63.342 provides that unlikely FEPs, or sequences of events and processes, shall be excluded "upon prior Commission approval for the probability limit used for unlikely features, events, and processes."

Objective of the Rulemaking:

NRC is making these amendments to Part 63 to clarify how NRC is implementing EPA's final environmental standards for Yucca Mountain. Although the Commission could review and approve a probability limit for unlikely FEPs in the context of its review of DOE's license application, it prefers to set this limit in advance, through the rulemaking process, so that it will have the advantage of public views on this question, and so that DOE, interested participants, and the public will have knowledge, before the license application, of what probability the Commission would find acceptable.

Alternatives Considered:

(1) No action. Make no change to Part 63. Leave the delineation of what constitutes unlikely FEPs to be resolved in the course of the review of DOE's license application. The determination of what unlikely FEPs should be excluded from the analysis of the consequences of human intrusion and ground-water protection would not occur until the license application review stage of the licensing process.

This alternative would require no current resources to conduct a rulemaking, or otherwise revise NRC's regulatory guidance. However, this issue could be subject to contention in the licensing review. Resolving this issue could require a significant amount of future staff time from both NRC and the other parties involved in the licensing review.

(2) Amend 10 CFR 63.342 to include a probability limit for unlikely FEPs that should not be included in DOE's performance assessments for human intrusion and ground-water protection. The probability limit proposed would classify unlikely FEPs as those that are estimated to have less than one chance in 10 of occurring within 10,000 years of disposal, but at least one chance in 10,000 of occurring within 10,000 years of disposal (the upper limit of very unlikely FEPs).

This alternative would clearly delineate those FEPs that DOE must include in its evaluation of the effects of human intrusion and its evaluation of ground-water protection. This would provide clearer requirements for the content of the license application. This would allow DOE's license application to concentrate on these effects rather than to speculate on what constitutes unlikely FEPs, some of which might not be determined to be relevant as a result of the licensing review. It would also allow other parties to the review to know in advance what unlikely

FEPs would be excluded, allowing them to more sharply focus their resources. The end result would be a more efficient licensing process.

Adequate public input would be assured because this rulemaking will follow the normal notice and comment process required by the Administrative Procedure Act. A proposed rule has been published, and public comments have been received and considered before publication of a final rule.

This alternative -- development of a rulemaking -- would be more costly in current staff resources than alternatives (1) and (3). It is estimated that the NRC staff resources needed for development of this rulemaking are 0.8 full-time equivalent staff years.

(3) Provide guidance on what constitutes unlikely FEPs in regulatory guidance -- the Yucca Mountain Review Plan -- rather than in the regulations in Part 63. The Yucca Mountain Review Plan, Revision 2 is being developed by NRC to provide guidance on how DOE's license application will be reviewed and evaluated. This alternative would take less time to develop, and require fewer staff resources, than alternative (2).

However, this alternative would not achieve the objective of delineation of what constitutes unlikely FEPs in DOE's assessments of human intrusion and ground-water protection. Unlike a rulemaking, which is codified in NRC's regulations, regulatory guidance is not legally binding. This issue of what constitutes unlikely features, processes, and events would not be resolved, and would still be subject to contention in the licensing review. DOE and other parties could not be certain about the assumptions that must be made in the analysis of human intrusion and ground-water protection until the review stage of the licensing process.

Also, the opportunity for public input is generally not as great in development of regulatory guidance as it is in development of a notice and comment rulemaking, which requires publication of the proposed rule in the Federal Register, followed by consideration of and response to public comments received thereon.

Decision Rationale

Alternative (2) -- conducting a rulemaking -- has been chosen as the preferred alternative. NRC believes that it would be in the interest of an efficient licensing process that the issue of what constitutes unlikely FEPs be resolved in advance of the licensing review. A rulemaking, with appropriate stakeholder and public input, can delineate what FEPs should be considered "unlikely" and therefore should be excluded from DOE's assessments concerning human intrusion and ground-water protection. This would help NRC in reviewing a DOE license application, by keeping the focus of the application on effects of FEPs on performance assessment that are likely to occur. It would also benefit other parties to the licensing review by allowing them to know in advance what FEPs will be considered in performance assessments of human intrusion and ground-water protection.

Implementation:

NRC's schedule for completion of a final rule to amend Part 63 calls for publication in 2002. Necessary guidance material for implementation -- the Yucca Mountain Review Plan, Revision 2-- would be revised accordingly.

Implications for Other NRC Regulatory Programs:

Promulgation of this rule would have no negative implications for other NRC regulatory programs.

Implications for Other Federal Agencies:

Promulgation of the rule will have no adverse impact on DOE's program for geologic repository development. The schedules described here will allow DOE to proceed with its currently stated schedule for a license application.

References:

(1) National Academy of Sciences, Technical Bases for Yucca Mountain Standards, National Academy Press, Washington, DC, 1995.

(2) U.S. Congress, Energy Policy Act of 1992, Public Law 102-486.

(3) Code of Federal Regulations, 40 CFR Part 197, "Public Health and Environmental Radiation Standards for Yucca Mountain, NV; Final Rule" (66 FR 32100; June 13, 2001).

(4) Code of Federal Regulations, 10 CFR Part 63, "Disposal of High-Level Radioactive Waste in a Proposed Geologic Repository at Yucca Mountain, Nevada, Final Rule" (63 FR 55731; November 2, 2001).

(5) "10 CFR Part 63 --Specification of a Probability for Unlikely Features, Events, and Processes" (67 FR 3628) January 25, 2002.

24722

Submission of Federal Rules Under the Congressional Review Act

☐ **President of the Senate** ☐ **Speaker of the House of Representatives** ☐ **GAO**

Please fill the circles electronically or with black pen or #2 pencil.

1. Name of Department or Agency
U.S. Nuclear Regulatory Commission

2. Subdivision or Office
Office of Nuclear Material Safety and Safeguards

3. Rule Title
10 CFR Part 63 - Specification of a Probability for Unlikely Features, Events, and Processes

4. Regulation Identifier Number (RIN) or Other Unique Identifier (if applicable)
RIN 3150-AG91

5. Major Rule ○ Non-major Rule ◉

6. Final Rule ◉ Other ○ _____

7. With respect to this rule, did your agency solicit public comments? Yes ◉ No ○ N/A ○

8. Priority of Regulation (fill in one)
◉ Economically Significant; or Significant; or Substantive, Non Significant
○ Routine and Frequent or Informational/Administrative/Other (Do not complete the other side of this form if filled in above.)

9. Effective Date (if applicable)

10. Concise Summary of Rule (fill in one or both) attached ○ stated in rule ◉

Submitted by: _____ (signature)

Name: **Dennis K. Rathbun**

Title: **Director, Office of Congressional Affairs**

For Congressional Use Only:

Date Received: _____

Committee of Jurisdiction: _____

3/23/99

	Yes	No	N/A
A. With respect to this rule, did your agency prepare an analysis of costs and benefits?	◉	○	○
B. With respect to this rule, by the final rulemaking stage, did your agency			
1. certify that the rule would not have a significant economic impact on a substantial number of small entities under 5 U.S.C.§ 605(b)?	◉	○	○
2. prepare a final Regulatory Flexibility Analysis under 5 U.S.C. § 604(a)?	○	◉	○
C. With respect to this rule, did your agency prepare a written statement under § 202 of the Unfunded Mandates Reform Act of 1995?	○	○	◉
D. With respect to this rule, did your agency prepare an Environmental Assessment or an Environmental Impact Statement under the National Environmental Policy Actg (NEPA)?	○	○	◉
E. Does this rule contain a collection of information requiring OMB approval under the Paperwork Reduction Act of 1995?	○	◉	○
F. Did you discuss any of the following in the preamble to the rule?	○	◉	○
• E.O. 12612, Federalism	○	◉	○
• E.O. 126630, Government Actions and Interference with Constitutionally Protected Property Rights	○	◉	○
• E.O. 12866, Regulatory Planning and Review	○	◉	○
• E.O. 12875, Enhancing the Intergovernmental Partnership	○	◉	○
• E.O. 12988, Civil Justice Reform	○	◉	○
• E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks	○	◉	○

- Other statutes or executive orders discussed in the preamble concerning the rulemaking process (please specify)
  Plain Language in Government Writing (63 FR 31883)
  National Technology Transfer and Advancement Act of 1995
  Paperwork Reduction Act of 1995