

January 10, 2002

MEMORANDUM TO: William D. Travers  
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary /RA/

SUBJECT: STAFF REQUIREMENTS - SECY-01-0206 - PROPOSED RULE:  
10 CFR PART 63: SPECIFICATION OF A PROBABILITY FOR  
UNLIKELY FEATURES, EVENTS, AND PROCESSES

The Commission has approved publication of a proposed amendment to 10 CFR Part 63 to define the term "unlikely" in quantitative terms, i.e., a range of numerical values for use in determining whether a feature, event, or process (FEP) or sequence of events and processes should be excluded from certain required assessments. The Federal Register notice and the Regulatory Analysis should be edited as shown in the attachments.

In addition, several places in the package discuss the fact that a FEP with a probability of occurring once in 10,000 years has only a 0.63 chance that it will actually occur. Reference to this value should be deleted from the paper and replaced with a more general statement that the paper is dealing with probabilities and even if a probability value is calculated that something will occur once in a lifetime there is a chance that it will not occur.

(EDO)

(SECY Suspense:

2/7/02)

Attachments as stated.

cc: Chairman Meserve  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
Commissioner Merrifield  
OGC  
CFO  
OCA  
OIG  
OPA  
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)  
PDR

[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:** Proposed rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the disposal of high-level radioactive wastes in a ~~proposed~~ **potential** geologic repository at Yucca Mountain, Nevada, to ~~quantitatively~~ define the term “unlikely” **as in quantitative terms. That is, it would be defined as** a range of numerical values for use in determining whether a feature, event, or process (FEP) or sequence of events and processes should be excluded from certain required assessments. The NRC is proposing this amendment to clarify how it plans to implement two of 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 required assessments for the human intrusion and ground-water protection standards. In

accordance with the Energy Policy Act of 1992, the NRC has adopted EPA's final standards in its recently published technical requirements for a ~~proposed~~ **potential** geologic repository at Yucca Mountain.

**DATES:** The comment period expires (insert 75 days from date of publication). Comments received after this date will be considered if it is practical to do so, but NRC is able to assure consideration only for comments received on or before this date.

**ADDRESSES:** Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via NRC's interactive rulemaking website <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415-5905; e-mail [cag@nrc.gov](mailto:cag@nrc.gov).

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room (PDR), Room O-1F23, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website.

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/NRC/ADAMS/index.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](mailto:pdr@nrc.gov).

**FOR FURTHER INFORMATION CONTACT:** Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7285, e-mail: [tjm3@nrc.gov](mailto:tjm3@nrc.gov); or 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](mailto:cwp@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On November 2, 2001 (66 FR 55732), the U.S. Nuclear Regulatory Commission (NRC) published its final rule, 10 CFR Part 63, governing disposal of high-level radioactive wastes in a ~~proposed~~ **potential** geologic repository at Yucca Mountain, Nevada. These are the regulations that the U.S. Department of Energy (DOE) must meet in any ~~potential~~ license application for construction and operation of ~~the~~ **a potential** repository. As mandated by the Energy Policy Act of 1992, Pub. L. 102-486 (EnPA), NRC's final rule adopts the radiation protection standards established by the U.S. Environmental Protection Agency (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). DOE's performance assessments shall not include consideration of "very unlikely" features, events or processes (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 "...considers a frequency for unlikely FEPs would fall somewhere between  $10^{-8}$  to  $10^{-4}$  per year...", but that it had decided not to provide a specific quantitative value for defining unlikely FEPs in the final rule (66 FR 55734; November 2, 2001). Instead, the Commission stated that it "...plan[ned] to conduct an expedited rulemaking to quantitatively define the term 'unlikely.' Consideration will be given to whether a range of values or a single specific value should be used as well as the appropriate numerical value(s). The expedited rulemaking will provide an opportunity for public comment to assist the

Commission in determining an appropriate approach” (66 FR 55734; November 2, 2001). This proposed rule initiates the rulemaking to quantitatively define the term “unlikely” promised by the Commission.

## II. Discussion

EPA’s standards for disposal include an individual protection standard; a human intrusion standard; and ground-water protection standards. EPA’s standards also prescribe that DOE should exclude “very unlikely” FEPs from the performance assessments used to determine compliance with the three postclosure standards (i.e., individual protection, human intrusion, and ground-water protection). 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 to the consequences of human intrusion. In the case of the performance assessment for ground-water protection, the purpose is to evaluate the degradation of the ground-water resource. Consistent with the specific purposes of these two standards, EPA prescribed specific conditions to be used in determining compliance with the human intrusion standard and the ground-water protection standards. **For these two standards, EPA prescribed including the exclusion of not only “very unlikely” FEPs, but also “unlikely” FEPs.** Although EPA’s final standards did not specify a numerical value to quantitatively 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.<sup>1</sup> This intent is consistent with the NRC approach of requiring the use of reasonable and prudently conservative assumptions in modeling exposure scenarios.

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 direct DOE to assume that no releases are included which are caused by unlikely natural processes and events. With respect to the ground-water standards (10 CFR 63.331), DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of undisturbed performance (i.e., 10,000 years during which the occurrence of unlikely FEPs do not disturb the repository) 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 63.331.

In assessing compliance with both the human intrusion standard and ground-water protection standards, 10 CFR 63.342 provides that unlikely FEPs, or sequences of events and

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<sup>1</sup> 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).

processes, shall be excluded “...upon prior Commission approval for the probability limit used for unlikely FEPs.” Although the Commission could review and approve a probability limit in the context of its review of a potential DOE license application, it is proposing 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.

The Commission has considered whether the probability for unlikely FEPs should be defined as a single value or a range of values. A single value would be used as a probability limit such that each FEP with a probability less than the specified limit should be considered unlikely. A probability range would be used to define the spread of probability (i.e., upper and lower values) that represents unlikely FEPs. Although both approaches specify an upper value for probability, a probability range provides a more complete description of the spread of probability that is identified with unlikely FEPs. The Commission is not aware of any disadvantages to using a range and therefore is specifying a probability range because it provides a better characterization of the range of probabilities associated with FEPs than what would be provided by a single number.

Assigning specific numerical values to a qualitative term such as “unlikely” is complicated by the subjective nature of this term. As a first step, the Commission found it useful to describe three broad categories to represent the entire probability range for what could occur at the Yucca Mountain repository site. These three categories are: (1) very unlikely; (2) unlikely; and (3) likely. As a practical matter, the rationale for the quantitative range defining unlikely FEPs is easier to describe in terms of the categories of likely and very unlikely,

because unlikely is bounded by these two categories. Very unlikely FEPs have been described in the EPA standards as FEPs with such low probability of occurrence that they need not be considered in any performance assessments for Yucca Mountain. As mentioned previously, the EPA standards quantitatively define very unlikely FEPs as those FEPs with less than a 0.01 percent chance of occurring within the 10,000 year compliance period (i.e., annual probability less than  $10^{-8}$ ). In a qualitative sense, likely FEPs are those FEPs that can be reasonably expected to occur during the 10,000 year compliance period. From a probabilistic perspective, any FEP with an annual probability of  $10^{-4}$  or higher would have a high probability of occurring (i.e., approximately a 60 percent or higher chance of occurring within the 10,000 year compliance period)<sup>2</sup>. However, 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 believes a prudent decision is to consider FEPs, with 10 percent or greater chance of occurring within the 10,000 year compliance period, as likely FEPs. Thus, unlikely FEPs are 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 and less than  $10^{-5}$ ).

Therefore, in light of the foregoing discussion, the Commission seeks comment on the appropriateness of using an annual probability range of greater than or equal to  $10^{-8}$  and

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<sup>2</sup> Any FEP with an annual probability of  $10^{-4}$  would be expected to occur once over a 10,000 year period. An expectation that an FEP would occur does not guarantee such an occurrence. Thus, the probability of an occurrence would necessarily be less than one. In fact, using the laws of probability, the probability of one or more such occurrences is 0.63.

less than  $10^{-5}$  to define unlikely FEPs. 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.

In arriving at this decision, the Commission considered the merits of using a lower value for the demarcation between likely and unlikely FEPs. For example, a 1 percent chance of occurring over the 10,000 year compliance period (i.e., annual probability of  $10^{-6}$ ) would also be considered unlikely. It is somewhat subjective whether a qualitative term such as “unlikely” should be quantitatively defined as less than a 1 or a 10 percent chance of occurring. Selection of an appropriate value needs to consider the context of the performance assessments (i.e., robustness of the repository system to the consequences of human intrusion and the degradation of the ground-water resource). As mentioned previously, the focus of the performance assessments for human intrusion and ground-water protection is to be on expected conditions. The Commission considers that an FEP having a 1 percent chance of occurring is neither expected nor likely and, therefore, an inappropriate value for the lower bound for likely events. The Commission believes a lower bound for likely FEPs of a 10 percent chance of occurring within the compliance period is consistent with the intended focus for these two standards. Although “unlikely” FEPs would not be considered in the performance assessments for human intrusion and ground-water protection, these FEPs are required to be considered in the performance assessment for the individual protection standard.

This rulemaking is proposing a probability range for unlikely FEPs as part of NRC's implementation of EPA's final standards for Yucca Mountain, in accordance with EnPA. Specification of the probability for unlikely FEPs is in the context of assessments of compliance with the human intrusion standard and ground-water protection standards, which have a regulatory compliance period of 10,000 years. The Commission made clear in its final regulations in Part 63 that the "[C]riteria set out in this final rule apply specifically and exclusively to the proposed repository at Yucca Mountain" (66 FR 55732; November 2, 2001). Similarly, the proposed definition for the term "unlikely" in this rulemaking is intended to apply specifically and exclusively to the ~~proposed~~ **potential** repository at Yucca Mountain and is not intended to suggest or imply precedent for NRC regulations in other parts of this Chapter that use the term "unlikely" in significantly different contexts (e.g., compliance periods of tens of years, higher dose limits, different facilities, and different activities).

### **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. Plain Language**

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments

on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

## **V. 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 proposed rule, the NRC is establishing probability limits for unlikely features, events, and processes at a proposed 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.

## **VI. Finding of No Significant Environmental Impact: Availability**

Pursuant to Section 121(c) of the Nuclear Waste Policy Act, this proposed 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.

## **VII. Paperwork Reduction Act Statement**

This proposed 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, 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, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

### **VIII. Regulatory Analysis**

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading. 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.

### **IX. Regulatory Flexibility Certification**

In accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], the Commission certifies that this proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed 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.

#### **X. Backfit Analysis**

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

#### **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. 553, NRC is proposing to adopt 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 \_\_\_\_\_, 2001.

For the Nuclear Regulatory Commission,

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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:

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

##### Issue:

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 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 proposed 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).

##### 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.<sup>1</sup> NRC was directed to

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<sup>1</sup> National Academy of Sciences, Technical Bases for Yucca Mountain Standards, National Academy Press, Washington, DC, 1995.

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 ~~have~~ primarily ~~been~~ **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.<sup>2</sup> 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 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

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<sup>2</sup> 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.

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 proposing 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 proposes 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 Procedures Act. A proposed rule will be published, and public comments will be 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 would be 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 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 administrative law and 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 1-- 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).