# The U.S. Environmental Protection Agency's Public Health and Safety Standards for Yucca Mountain, Nevada (40 CFR Part 197) - 9072

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## ABSTRACT

In 2001, as directed by the Energy Policy Act of 1992, the U.S. Environmental Protection Agency (EPA) issued public health and environmental radiation protection standards for the proposed repository at Yucca Mountain, Nevada. Several parties sued the Agency on a myriad of aspects of the rule. The Court ruled in EPA's favor in all aspects of the case but one, and returned the standards to the Agency in 2004. In 2005, EPA proposed amendments to the standards. Following public hearings and a public review period, the final amendments were issued in September 2008. This paper discusses the new requirements.

## INTRODUCTION

The U.S. Environmental Protection Agency (EPA) has promulgated amendments to its public health and safety standards for radioactive waste stored or disposed of in the potential repository at Yucca Mountain, Nevada. In the Energy Policy Act of 1992 (EnPA), Congress directed EPA to develop these standards and required EPA to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on reasonable standards for protection of public health and safety. In addition, the standards promulgated by EPA are to be "based upon and consistent with" the findings and recommendations of NAS. Originally, these standards were promulgated on June 13, 2001 (the 2001 standards). (1)

On July 9, 2004, the U.S. Court of Appeals for the District of Columbia Circuit vacated portions of the 2001 standards concerning the period of time for which compliance must be demonstrated (2). The Court ruled that the compliance period of 10,000 years was not "based upon and consistent with" the recommendation of NAS that standards apply to the time of peak risk within the limits imposed by the geologic stability of the site and, therefore, remanded those portions of the standards to EPA for revision. These remanded portions are the focus of the amendments.

The final rule incorporates compliance criteria for protection of individuals from both undisturbed and human-intrusion conditions. Compliance will be judged against a standard of 150 microsieverts per year (μSv/yr) (15 millirem per year (mrem/yr)) committed effective dose equivalent (CEDE) at times up to 10,000 years after disposal and against a standard of 1 millisievert per year (mSv/yr) (100 mrem/yr) CEDE at times after 10,000 years and up to 1 million years after disposal (hereafter, CEDE is not used, but is to be understood as part of the cited doses). The final rule also includes several supporting provisions affecting the projections of disposal system performance prepared by the Department of Energy (DOE).

## THE PROPOSED AMENDMENTS

The proposed amendments centered on extending the compliance period to capture the peak projected dose from the Yucca Mountain disposal system "within the limits imposed by the long-term stability of the geologic environment" (6, p. 2) and establishing dose limits that would protect public health while imposing a reasonable test upon disposal system performance. This undertaking is precedent-setting in the United States (U.S.) -- no other regulation has a compliance period longer than 10,000 years. Equally so, establishing a dose limit within that potentially significantly longer period is unprecedented in the U.S. Only a small number of countries have established standards of any kind for the geologic disposal of spent nuclear fuel (SNF) and high-level waste (HLW) with only Switzerland having established a quantitative standard applicable for as long as 1 million years ("The release of radionuclides from a sealed repository subsequent upon processes and events reasonably expected to happen, shall at no time give rise to individual doses which exceed 0,1 mSv per year." (3)).

The Agency carefully considered the language and reasoning of the Court's decision while revising the 2001 standards. As originally promulgated (in 2001), 40 CFR Part 197 contained four sets of dose standards:

(1) a storage standard of 150 μSv/yr that applies to the general public during the operational period when waste is received, prepared for emplacement, or stored on the Yucca Mountain site;
(2) a standard of 150 μSv/yr that limits the dose incurred by applies to an individual the reasonably maximally exposed individual (RMEI) as a result of disposal system evolution except for human intrusion.[1];
(3) a standard of 150 μSv/yr that applies to the RMEI in the accessible environment for the first 10,000 years after disposal as a result of human intrusion into the repository; and,
(4) a set of ground-water protection standards whose limits are the same as those developed by EPA under the Safe Drinking Water Act that apply for the first 10,000 years after disposal.

The Court's ruling affected only one aspect of 40 CFR Part 197 -- the 10,000-year compliance period that was the subject of the NAS recommendation. Therefore, since NAS made no recommendations for these provisions, the storage standard and the ground-water protection standards were not subjects of the current rulemaking and EPA proposed to revise only the individual-protection and human-intrusion standards – both of which were specifically addressed by NAS.

The Agency also proposed certain supporting provisions related to the way DOE must consider features, events, and processes (FEPs) in its compliance analyses and to adopt updated scientific factors for calculating doses. (4) Specifically, EPA proposed to:

(1) extend the compliance period for the individual-protection and human-intrusion standards to the time of peak dose up to 1 million years after disposal;
(2) retain the dose standard of 150 μSv per year for the first 10,000 years after disposal, as promulgated in 2001;
(3) establish a peak dose standard of 3.5 millisievert (mSv) per year (mSv/yr) for the period between 10,000 and 1 million years (based upon the difference of the background radiation dose rates in Colorado and Amargosa Valley, Nevada);

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[1] The RMEI is a hypothetical individual living in the accessible environment above the highest concentration of radionuclides in the plume of contamination, has a diet and living style similar to the population of Amargosa Valley, Nevada; and drinks two liters of ground water per day drawn from the aquifer at that location. In other words, the RMEI is described as a person whose location, lifestyle, and characteristics cause that person to be subject to doses at the high end of the local population. As a result, the RMEI is among the most highly exposed members of the public. The accessible environment is that area outside of the controlled area. The controlled area may be no more than 300 square kilometers around the site and no farther from the repository than the southwestern boundary of the Nevada Test Site in the direction of ground-water flow and five kilometers in any other direction) for the first 10,000 years after closure and sealing of the repository (disposal)

(4) use the arithmetic mean of the distribution of projected doses to compare to the dose standard for the initial 10,000 years, and the median of the distribution between 10,000 and 1 million years;
(5) retain the probability threshold (1 in 10,000 chance of occurring in 10,000 years, or 1 in 100 million chance of occurring per year) below which "very unlikely" FEPs may be excluded from consideration;
(6) allow features, events, and processes (FEPs) with a probability of occurring above the probability threshold to be excluded if they would not significantly affect the results of performance assessments in the initial 10,000 years;
(7) require consideration of seismic and igneous events causing direct damage to the engineered barrier system during the 1 million-year period;
(8) require consideration of the effects of increased water flow through the repository resulting from climate change, which could be represented by constant conditions between 10,000 and 1 million years;
(9) require consideration of the effects of general corrosion on the engineered barriers between 10,000 and 1 million years; and
(10) require use of updated scientific factors and dose calculation methodology, based upon Publications 60 and 72 of the International Commission on Radiation Protection (ICRP), to calculate doses for comparison with the storage, individual-protection, and human-intrusion standards.

The public comment period ended on 21 November 2005. The docket received about 2550 sets of comments; of those, about 2350 were part of mass mailings. This amounted to about 3000 pages of comments plus 1100 pages of attachments. All of the comments received, either verbal or written, were considered. Our responses to those comments are contained in our Response to Comments document ((5) at www.regulations.gov).

## THE FINAL AMENDMENTS

### Compliance Period

As noted earlier, the development of the amendments centered on extending the compliance period to the time of peak projected dose from the Yucca Mountain disposal system. The amendments define the compliance period to be 1 million years. This value was derived from an NAS recommendation ("…that compliance be with the standard be assessed at the time of peak risk, whenever it occurs, within the limits imposed by the long-term stability of the geologic environment, which is on the order of one million years." (6, p. 2)) While NAS characterized the length of the geologic stability period in loose terms ("on the order of"), EPA believes it is appropriate and necessary to fix the duration of the geologic stability period as a matter of regulatory policy because otherwise it is not sufficiently specific for regulatory purposes, i.e., to clearly implement the standards and reach a compliance decision. The Agency finds support on this point from NAS: "It is important, therefore, that the 'rules' for the compliance assessment be established in advance of the licensing process." (6, p. 73). Indeed, NAS clearly considered that the compliance period could be one of the "rules" that should be established for compliance assessments. (6, p. 56) Some commenters suggested that the period of geologic stability could be longer (one interpreted "on the order of one million years" to possibly be as long as 10 million years), and said our rule should allow consideration of longer timescales if justified by considerations of geologic stability. The actual period of geologic stability at Yucca Mountain is unknowable, and EPA disagrees that an open-ended compliance standard is justified over such time frames. The EPA believes that DOE and the Nuclear Regulatory Commission (NRC) must have definitive markers to judge when compliance is demonstrated, and that a loosely defined time frame does not provide such a marker for implementation of our standards in a licensing process.

Geologic stability. The NAS recognized that many "physical and geologic processes" are characteristic of any site and have the potential to affect performance of the disposal system. The NAS concluded that these processes could be evaluated for Yucca Mountain "within the limits imposed by the long-term stability of the geologic environment" (6, p. 2) as long as "the geologic system is relatively stable and varies in a boundable manner" (6, p. 9). Thus, the site itself could be anticipated to change over time, but in relatively narrow ways that can be defined ("bounded"). Implicit in the NAS recommendation is the idea that the maximum risk might occur outside the period of geologic stability, but assessments performed at that time would have little credibility and would not be a legitimate basis for regulatory decisions: "After the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed." (6, p. 72) As noted earlier, NAS judged this period of "long-term stability" to be "on the order of one million years." (6, p. 2)

While geologic stability may be viewed as being affected primarily by large-scale events, accumulations of small-scale changes over very long time periods also have the potential to alter the geologic setting and affect the technical basis of performance assessments. Tectonic events have such a potential at Yucca Mountain. For example, rates of displacement on the nearest potentially significant fault in the region average about 0.02 mm/yr. (7, p. 4-409) This means that in 10,000 years, there could be 20 cm (0.65 ft) of displacement, a relatively small change not likely to affect performance of the geologic system. However, in 1 million years, the same rate of movement results in 20 m (65 ft) of displacement on the fault. Such changes in the geologic setting at Yucca Mountain have the potential to erode the scientific basis for performance assessment and possibly to affect the quality of the information the assessment can provide to decisionmakers.

Effects of features, events, and processes (FEPs). As a basis for the definition of the compliance period, the Agency believes it is also appropriate to consider the geologic stability period from the perspective of a reasonable length of time for significant events to act upon the waste packages and engineered barriers, and ultimately to lead to release of radionuclides. Natural processes and events would contribute to both the package failures and the subsequent transport of radionuclides, even if such failures occur relatively late in the period. For example, a consideration of the igneous and seismic history in the area of the Yucca Mountain site supports a 1 million-year geologic stability period. Information (8) concerning basaltic igneous activity around the site shows that this type of activity has been the only activity around the site through the Pliocene (beginning roughly 5.4 million years ago), and that the volume of eruptive activity (both tuff and basaltic material) has decreased continually over the last 10 million years. (9) Further information has shown activity to have occurred in clusters of events around 1 million and 4 million years ago. (8). The occurrence of these clusters indicates that the nature and extent of past volcanic activity can be reasonably well characterized and that annual probabilities for such events can be reasonably estimated from the geologic record around the site.

The NAS also stated "we see no technical basis for limiting the period of concern to a period that is short compared to the time of peak risk or the anticipated travel time." (6, p. 56) This statement suggests that the geologic stability period must be long enough to allow FEPs that pass the probability and significance screens to demonstrate their effects on the results of the performance assessments, even from waste package failures occurring relatively late in the period. In contrast to the accumulated small-scale changes discussed above, larger-scale seismic events are more likely to contribute directly to radionuclide releases through the effects of ground motion. Strong seismic events could damage waste package integrity by causing emplacement drift collapse or vigorous shaking of the packages themselves. Earthquake recurrence intervals for the site indicate that strong events could reasonably be assumed to test waste package integrity at various times within the 1 million-year period (10 and 11). In addition, EPA notes that estimates of ground-water travel time from the repository to the DOE-selected RMEI location (i.e., in Amargosa Valley) are on the order of thousands of years (12). At these rates, the effects of disruptive volcanic and seismic effects on releases would not be delayed from reaching the RMEI location during the period of geologic stability, e.g., added releases from a low-probability seismic event at 800,000 years would have ample time to be captured by the performance assessments. Based upon these considerations, EPA believes the 1 million-year compliance period is a sufficiently long period to evaluate the potential consequences of both gradual processes and disruptive events on disposal system performance.

In summary, for regulatory policy as well as site-specific scientific considerations, the Agency believes that fixing the period of geologic stability for compliance assessments at 1 million years provides a reasonable test for disposal system performance. The Agency believes a fixed time period is necessary both to provide a definitive marker for compliance decision-making and to prevent unbounded speculation surrounding the factors affecting engineered-barrier performance and the ultimate timing of peak dose projections. Examination of site characteristics indicates that the influences of natural processes and events on release and transport of radionuclides would be demonstrated even for waste package failures occurring relatively late in the period.

**Dose Limits**

The NAS did not recommend a specific dose or risk limit for the compliance standard: "We do not directly recommend a level of acceptable risk." (6, p. 49). NAS did state that the level of protection was a matter best left to EPA to establish through rulemaking. These standards were developed through an EPA rulemaking and, so, meet the intent of the NAS recommendation.

The final rule includes an individual-protection standard for two time periods: post-10,000-years and the initial 10,000-years. The post-10,000-year standard limits the peak dose incurred by the RMEI through 1 million years from the Yucca Mountain disposal system to 1 mSv/yr. The other part of the individual-protection standard, which will apply over the initial 10,000 years, is 150 µSv/yr. These limits provide a reasonable test of disposal system performance while recognizing the relatively more difficult challenge in treating the uncertainties associated with projecting performance to such distant times, and the resulting lessened level of confidence that can be derived from such performance projections.

<u>The Peak Dose Standard Between 10,000 and 1 Million Years after Disposal</u>. The standard applicable at the time of peak dose, as required by the EnPA and recommended by NAS, is more stringent than the proposed 3.5 mSv/yr (350 mrem/yr) standard, i.e., 1 mSv/yr.

In selecting this final standard, EPA started with a range of annual fatal cancer risk ($10^{-5}$ to $10^{-6}$) that encompassed the 150 µSv/yr standard established in 2001 for the initial 10,000 years after disposal and is the "starting range" identified by NAS to be used in determining the appropriate level for the individual-protection standard. (6, p. 49 and Tables 2–3 and 2–4) As discussed elsewhere in this paper, EPA determined that it would be unreasonable to apply a standard within that starting range for the entire 1 million-year compliance period. Instead, the Agency identified a dose level that is protective of public health and safety and that reasonably accommodates our policy concerns regarding the implementation of a compliance standard for 1 million years. For the same reasons, the Agency determined that it is unreasonable to apply its traditional risk-management policies when establishing a compliance standard applicable for a period beyond 10,000 years and up to 1 million years. The EPA does not believe it is realistic to demand that projections for such complex systems over this far-future time frame be readily distinguishable at the level of incremental risk customarily addressed by the Agency in situations where results can be confirmed, modeling is utilized on a more limited scale, or institutional controls are more applicable.

While selecting 1 mSv/yr, EPA took particular note of NAS' discussion of that dose level: "Consistent with the current understanding of the related consequences, ICRP [International Commission on Radiological Protection], NCRP [National Commission on Radiological Protection and Measurements], IAEA [International Atomic Energy Agency], UNSCEAR [United Nations Scientific Committee on the Effects of Atomic Radiation], and others have recommended that radiation doses above background levels to members of the public not exceed 1 mSv/yr effective dose for continuous or frequent exposure from radiation sources other than medical exposures. Countries that have considered national radiation protection standards in this area have endorsed the ICRP recommendation of 1 mSv/yr above natural background radiation for members of the public." (6, pp. 40–41) The Agency also noted that 1 mSv/yr is included in the range of regulations offered by NAS for EPA's consideration. (6, Table 2–3) Therefore, 1 mSv/yr is well-established as protective of public health under current dose limits, and, as such, represents a robust public health protection standard in the extreme far future. (4) As noted by NAS, international organizations, such as ICRP, recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Although it had used the concept of public dose limits previously, ICRP first described its recommendations for a comprehensive system of radiation protection in Publication 60. (13)

With the selection of the peak-dose standard, EPA acknowledges and concurs in the broad consensus in the protectiveness of the 1 mSv/yr level and, furthermore, considers it especially suitable for application to the extreme far future, when planning for and projecting public exposures is much less certain. For all these reasons, EPA concluded that the 1 mSv/yr peak dose standard will protect public health and safety. By considering international guidance and examples, EPA derived a final peak-dose limit that balances the competing factors highlighted by NAS and acknowledged by us as important: the dual objectives of promulgating a standard that is protective of the health and interests of future generations, and also effectively addressing the effects of uncertainty on compliance assessment.

Although the Agency did not use background radiation in determining the final peak-dose standard, as was proposed, EPA notes that 1 mSv/yr is comparable to outdoor (unshielded) doses from cosmic and terrestrial radiation in Amargosa Valley, Nevada (the nearest population to the site and DOE's chosen location for the RMEI). In fact, when shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 1 mSv/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally. Further, within the State of Nevada, the difference in average estimates of background radiation for counties is greater than 1 mSv/yr. (14)

<u>The Dose Standard for the Initial 10,000 Years after Disposal</u>. The final rule retains the standard promulgated in 2001 in § 197.20 (1), which requires that DOE demonstrate a reasonable expectation that the RMEI will not incur annual doses greater than 150 µSv from releases of radionuclides from the Yucca Mountain disposal system for the first 10,000 years after disposal. The EPA believes this is an appropriate exercise of our policy discretion, protective of public health and safety, and consistent with our generic standards at 40 CFR Part 191 and other applications in both our regulations for hazardous materials and internationally for radioactive waste. Further, this dose level is within the range of risks identified by NAS as consistent with current national and international regulations. (6, Tables 2–3 and 2–3) Moreover, the 150 µSv/yr standard is consistent with EPA's overall risk management policies and serves as a logical foundation to incorporate concerns regarding far-future dose projections.

As was stated in the proposal, an important reason for retaining a standard applicable for the first 10,000 years is to address the possibility, however unlikely, that significant doses could occur within 10,000 years, even if the peak dose occurs significantly later, as NAS believed likely. (6, p. 2) Also, EPA believes it is important to structure our regulations to make it clear that the standard of protection at

Yucca Mountain would not be less than that provided for the Waste Isolation Pilot Plant (WIPP) or the Greater Confinement Disposal facility.

Finally, the annual risk associated with the 150 µSv/yr standard, $8.6 \times 10^{-6}$, is consistent with both the Agency's overall risk management policies and the suggested NAS "starting point" (6, p. 49) The nominal annual risk level for fatal cancer associated with 1 mSv/yr is $5.75 \times 10^{-5}$. This is comparable to the range of risks represented by national and international regulations identified by NAS for EPA to consider, and is premised on a dose level the NAS has addressed favorably as a matter of international regulatory consensus (6, pp. 40–41, Tables 2–3 and 2–4). Considering that this standard will apply for up to 1 million years, EPA believes this represents a level of risk that will protect public health and safety in the far future. However, for the reasons described above, EPA does not believe it is appropriate to view the standard through a strict risk perspective, and cautions against doing so. Further, even if the risk correlations could be assumed valid over such times, the nominal risk represented by projected doses may be a reflection of the uncertainties inherent in such projections, and therefore overstated. ICRP states, for example, that "as the time frame increases, some allowance should be made for assessed dose or risk exceeding the dose or risk constraint….This must not be misinterpreted as a reduction in the protection of future generations, and, hence, as a contradiction of the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results." (15, Paragraph 77)

## Statistical Measure of Compliance and Reasonable Expectation

The result of probabilistic performance assessments, as required by 40 CFR Part 197, is a distribution of projected doses that are produced by the myriad of combinations of parameter values that are used. It is possible that some combinations of parameter values will result in very high doses, even if such combinations have an extremely low probability of occurring. Although there may be only a few results that are very high, extreme results have the potential to exert a strong influence on the arithmetic mean, which could make the mean less representative of all performance projections. It was our desire to establish a statistical measure that would not be strongly affected by either very high- or low-end results, believing it appropriate to focus on the "central tendency" of the distribution, where the bulk of the results might be expected to be found. Therefore, for the determining compliance with the peak-dose standard, the Agency proposed the median of the distribution as being most representative of central tendency because the median is always located at the point where half the distribution is higher and half lower; the median depends only upon the relative nature of the distribution, rather than the absolute calculated values.

However, after considering public comments, the NAS Report, and the Court decision, EPA decided that the arithmetic mean, without conditions or restrictions, is the most straightforward approach, is clearly consistent with the NAS recommendation ("We recommend that the mean values of calculations be the basis for comparison with our recommended standards." (6, p. 123)), and, therefore, would be used to determine compliance with both the 150 µSv/yr and 1 mSv/yr standards. This approach is also consistent with 40 CFR Part 191 and its implementation at WIPP.

In addition, even though the primary indicator of compliance with the individual-protection standard is the arithmetic mean of the distribution of projected doses, NRC's compliance determination will consist of more than a simple comparison of that mean with the dose standards. Rather, as stated in 40 CFR 197.14, NRC will reach its determination (a "reasonable expectation") "based upon the full record before it." Regardless of whether the arithmetic mean of the projected doses is well below the dose standard or not, NRC will examine the assumptions, data, models, and other aspects of DOE's projections to ensure that it has an understanding of those projections sufficient to reach a "reasonable expectation" as to their compliance with the standards (40 CFR 197.13). While applying the principles of reasonable expectation at all times, NRC may also use its judgment as to whether it would apply the concept in exactly the same way for times as long as 1 million years as it would for much shorter times. A key element of reasonable expectation is that it "accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system" (§ 197.14(b)). In exercising its judgment, EPA considers it logical, as well as practical, for NRC to evaluate the sources and effects of uncertainties in DOE's analyses, as well as DOE's treatment of them.

**Uncertainty**

Of great concern in extending the compliance period to 1 million years is the increasing level of uncertainty in the Yucca Mountain performance assessment projections. This uncertainty affects not only the projections themselves, but also the interpretation of the results. There is general agreement in the international community that dose projections over periods as long as 1 million years cannot be viewed in the same context or with the same confidence as projections for periods as "short" as 10,000 years. As a result, the nature of regulatory decision-making fundamentally changes when faced with the prospect of compliance projections covering the next 1 million years.

Therefore, the Agency considered how the compliance standard might need to change. The EPA did not believe that extending the 10,000-year individual-protection standard of 150 μSv/yr to apply for 1 million years adequately accounted for our concern or represented a reasonable test of the disposal system. (1) This judgment reflects our view that the selected level must take into account larger, less quantifiable factors such as the uncertainties involved in projecting doses over 1 million years and the meaning that can be assigned to such projections (both in terms of their value as predictions of expected behavior of the disposal system and in their correlation with health effects), as well as the relative importance they should assume in a regulatory context. Having considered these factors, we concluded that the peak-dose standard of 1 mSv/yr standard is protective of the RMEI. It must also be emphasized that 1 mSv/yr applies to the RMEI, who is described as a person whose location, lifestyle, and characteristics cause that person to be subject to doses at the high end of the local population. As a result, the RMEI is among the most highly exposed members of the public. Therefore, most residents in the vicinity of Yucca Mountain would receive much lower doses from the disposal system than the RMEI, if any dose at all.

Taken together, the dose standards provide a reasonable test of the disposal system that appropriately combines protectiveness with recognition of the limitations of modeling in predicting the evolution of that system over hundreds of thousands of years. The 10,000-year standard is solidly grounded in the Agency's risk management framework and prior practice for geologic disposal facilities. The level of the longer-term, peak-dose, standard is widely accepted domestically and internationally as protective of public health and safety, reasonable in its recognition of the regulatory context, and fulfills our EnPA mandate by extending to the time of peak dose up to 1 million years. However, the Agency also emphasizes the site-specific nature of this rulemaking, which should not be viewed as a precedent for other regulatory situations, but as a reasoned response to unique circumstances involving issuance of a compliance standard applicable for up to 1 million years after disposal at Yucca Mountain.

**Features, Events, and Processes**

The standards require DOE to demonstrate compliance with the individual-protection standard through use of performance assessment. A performance assessment is developed by first compiling lists of features (characteristics of the disposal system, including both natural and engineered barriers), events (discrete and episodic occurrences at the site), and processes (continuing activity, gradual or more rapid, and which may occur over intervals of time) anticipated being active during the compliance period. These items are collectively referred to as "FEPs" (features, events, and processes). Once FEPs are identified, they are evaluated for their probability of occurrence (i.e., how likely they are to occur during the compliance period?) and their effect upon the results of the performance assessment (i.e., do they significantly affect projected doses from the disposal system during the first 10,000 years after disposal).

Our consideration of FEPs was affected to some extent by uncertainty. In addition, EPA took into account conclusions of the NAS. The overall probability threshold for inclusion of FEPs remained the same as in the 2001 rule, which EPA believes provides a very inclusive initial screen that captures both major and minor factors potentially affecting performance. Also, uncertainty plays a role in the sense that very gradual or infrequent processes and events may begin to influence performance only at times in the hundreds of thousands of years, when the overall uncertainty of assessments is increasing. The additional uncertainty introduced by these slow-acting FEPs led us to propose the exclusion of FEPs if they were not significant to the assessments in the initial 10,000 years. (Since FEPs have associated probabilities of occurrence that generally do not change over time, EPA believes that the database of FEPs deemed sufficiently probable would serve equally well as the basis for assessments covering 1,000, 10,000, 100,000, or 1 million years.) The Agency believes this still provides for robust assessments that would address the factors of most importance over the entire 1 million-year period. The Agency also considered whether significant FEPs might not be captured using this approach. In evaluating whether excluded FEPs might become more probable or more significant after 10,000 years, and, therefore, should not be eliminated, EPA identified general corrosion as a FEP that is certain to occur and represents a significant failure mechanism at longer times, even though it is less significant in the initial 10,000 years. The EPA also consulted the NAS Report for advice on handling long-term FEPs. The NAS identified three "modifiers" that it believed could reasonably, and should, be included in assessments: seismic events, igneous events, and climate change. (6, p. 91) We developed provisions addressing these FEPs that incorporated the views expressed by NAS. For seismic and igneous events, EPA proposed that DOE focus its attention on events causing direct damage to the engineered barriers. It took this approach because failure of the engineered barrier system, particularly the waste packages, is the predominant factor in determining the timing and magnitude of the peak dose, and is the overriding uncertainty in assessing performance of the disposal system. To address climate change, EPA requires DOE to focus on the effects of increased water flow through the repository, which is the climatic effect with the most influence on release and transport of radionuclides. We determined that such a focus would provide the basis for a reasonable test of the disposal system, and that climate change beyond 10,000 years could be represented by constant conditions reflecting precipitation levels that differ from current conditions, which eliminates irresolvable speculation regarding the timing, magnitude, and duration of climatic cycles during this time. The Agency also directed that NRC establish the exact nature of future climate characteristics to be used in performance assessments. The NRC subsequently issued a proposal to specify a range of values for deep percolation into the repository, which DOE will use as another parameter in its probabilistic performance assessments. (16)

**Probability and Significance Screening of FEPs**

Our 2001 rule set forth basic criteria for evaluating FEPs for their potential effects on disposal system performance and their incorporation into the scenarios used in the performance assessment (§ 197.36). These criteria retained the same limitations originally established in 40 CFR Part 191, which were developed to apply to any potential repository for SNF, HLW, or transuranic radioactive waste. The Agency believes that approach remains reasonable for the site-specific Yucca Mountain standards, and it believes it is desirable to maintain consistency between the two regulations for geologic repositories in the basic criteria for evaluating FEPs. The primary criteria for evaluating FEPs are:

(1) a probability threshold below which FEPs are considered "very unlikely" and need not be included in performance assessments; and
(2) a provision allowing FEPs above the probability threshold to be excluded from the analyses if they would not significantly change the results of performance assessments.

These criteria, probability and significance of the impacts on performance assessments, are of primary importance in considering how the provisions applicable to the 10,000-year period might change when the compliance period is extended to 1 million years. The screening for FEPs is done for the 10,000-year performance assessment and then used with certain additions set forth in the rule for the 1 million-year peak dose performance assessment. In the proposed rule, EPA concluded that the 10,000-year-based FEPs screening could serve as an adequate basis for the entire performance assessment because it is sufficiently inclusive to be appropriate for the entire 1 million-year compliance period, while at the same time reasonably bounding the scenarios that must be considered over the longer time frame.

Probability. In the proposed standards, the Agency kept the probability threshold for "very unlikely" FEPs to be 1 in 10,000 chance of occurrence within 10,000 years, or roughly a 1 in 100 million ($10^{-8}$) chance per year of occurring. In the final standards, the probability threshold is now stated only as an annual probability of 1 in 100 million ($10^{-8}$).

Some commenters disagreed with keeping the same probability threshold from the 2001 standards, stating that, because the compliance period is being extended by a factor of 100, the probability threshold for excluding FEPs should also be extended by a factor of 100, resulting in a threshold of 1 chance in 10 billion of occurrence per year. In our view, were there a lower, or no, probability threshold, it would be necessary to consider and describe FEPs that might have been present or occurred only in the initial years of the planet's existence. Similarly, FEPs with an annual probability of $10^{-10}$ may be only hypothetical, since the age of the Earth is generally considered to be "only" 4.6 x $10^9$ years, suggesting that these FEPs may have had less than a 50% chance of occurring within the entire history of the Earth.

Also, the volcanic rocks comprising Yucca Mountain and its surroundings are on the order of only 10-12 million years old (i.e., about $10^7$ years old). In determining the probability of particular FEPs, the geologic record at the site is necessarily the source of information to identify what FEPs have occurred at the site in the past and may occur in the future (through the period of geologic stability). Since the host rock formations at the site are only about $10^7$ years old, an annual probability cut-off of $10^{-10}$ would mean that probability estimates for some FEPs would have to be made in spite of the fact that there is no evidence for their occurrence at the site in the past. As it is, the $10^{-8}$ probability threshold presents a significant challenge to characterize FEPs with some degree of confidence, given the limits of today's science and technology. Overall, EPA believes that including events with a lower annual probability than $10^{-8}$ would introduce speculation beyond what is appropriate to define a reasonable test of disposal system performance.

Significance. The second criterion for evaluating FEPs, the evaluation of the significance of the impacts on the performance assessment, allows the exclusion of FEPs above the probability threshold from the performance assessment if they would not significantly change the results of the performance assessments. In other words, this evaluation is intended to identify those FEPs whose projected probability would otherwise make them candidates for inclusion in the performance assessment, but whose effect on repository performance (however probable) can be demonstrated not to be significant.

The Agency recognizes that setting forth the significance-screening criterion as it pertains to the 10,000-year period could be construed as creating a situation in which important long-term processes could be excluded altogether from the analysis if they were not significant in the earlier period. However, we do not believe it is reasonable to interpret the significance criterion in this way since there are provisions to ensure that significant, long-term FEPs will be considered in the assessments that are consistent with NAS, viz., EPA requires inclusion of the long-term effects of seismic, igneous, and climatic FEPs. In addition, the long-term effects of general corrosion on the engineered barrier system must be evaluated. Further, the FEPs included in the performance assessment used to demonstrate compliance with the

10,000-year dose limit must continue to be included as the performance assessment addresses compliance with the peak-dose throughout the 1 million-year compliance period.

**Dose Methodology**

The amendments require DOE to calculate annual doses for comparison to the storage, individual-protection, and human-intrusion standards. As described in the proposal, this action includes updated scientific factors necessary for the calculation, but will not change the underlying methodology. Our generic standards (40 CFR Part 191) and, by inference, the 2001 Yucca Mountain standards specified the factors associated with ICRP Publications 26 and 30 (17 and 18, respectively). Since EPA issued 40 CFR Part 191, ICRP has modified the models and associated organ-weighting factors to more accurately calculate dose. Therefore, EPA now requires DOE to use the radiation- and organ-weighting factors in ICRP Publication 60 (13), rather than those in ICRP Publication 26 (17). The Agency also used this newer method in 1999 to develop its Federal Guidance Report 13, “Cancer Risk Coefficients from Exposure to Radionuclides.” (19)

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