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Proposed Amendments to the Environmental Radiation Protection Standards for Yucca Mountain, Nevada

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ABSTRACT

The Environmental Protection Agency (EPA) proposed amendments to its radiation protection standards for the potential spent nuclear fuel and high-level radioactive waste disposal system in Yucca Mountain, Nevada on 22 August 2005. The original standards are found in Part 197 of Title 40 of the Code of Federal Regulations (40 CFR Part 197). The Energy Policy Act of 1992 directed, and gave the authority to, EPA to take this action based upon input from the National Academy of Sciences (NAS). The final original standards were published in the *Federal Register* (66 FR 32073) on 13 June 2001. In July 2004, a Federal court remanded part of the standards to EPA for reconsideration.

The 40 CFR Part 197 standards, as issued in 2001, have four major parts: (1) individual-protection during storage activities; (2) individual-protection following closure of the repository; (3) human-intrusion; and (4) ground-water protection. The storage standard is 150 microsieverts (μSv) (15 mrem) annual committed effective dose equivalent (CEDE) to any member of the general public. The disposal standards are: (1) 150 μSv (15 mrem) annual CEDE for the reasonably maximally exposed individual (RMEI) for 10,000 years after disposal; (2) 150 μSv (15 mrem) annual CEDE received by the RMEI within 10,000 years after disposal as a result of human intrusion; and (3) the levels of radionuclides in the ground water cannot cause annual individual doses to exceed: (1) 40 μSv (4 mrem) per year from beta and gamma emitters or (2) 5 picocuries per liter (pCi/L) of radium-226 and -228 or 15 pCi/L of gross alpha activity. There were also requirements related to the post-10,000-year period, the basis of compliance judgments, and performance assessments.

The Agency's proposed amendments would retain the individual-protection standard established in the 2001 standards, up to 10,000 years. In addition, the compliance period for the individual-protection and human-intrusion standards would be increased to 1 million years and the annual CEDE limit between 10,000 and 1 million years would be 3.5 mSv (350 mrem). There are also proposed requirements for the way performance assessments will be conducted. Finally, the dose calculation methodology would be updated to an ICRP 60 and 72 basis instead of ICRP 26 and 30.

The comment period on the proposed amendments ended 21 November 2005. The Agency is analyzing the comments and will publish its responses when issuing the final standards. The proposed standards and the support documents are available at http://www.epa.gov/radiation/yucca/index.html. The docket containing all of the comments is under Docket ID EPA-HQ-OAR-2005-0083 at: http://www.regulations.gov.

INTRODUCTION

The U.S. Environmental Protection Agency (EPA) first issued radiation protection standards for the potential spent nuclear fuel and high-level radioactive waste disposal system in Yucca Mountain, Nevada on 13 June 2001 (the 2001 standards [1]) under the authority of the Energy Policy Act of 1992 (EnPA [2]). (The term "repository" is used in this paper to refer to the mined facility, while the term "disposal system" is used to refer to the entirety of the mined facility, the engineered barriers, and the geologic barrier.) The EnPA also directed EPA to set the standards "based upon and consistent with" the results of a study by the National Academy of Sciences (NAS) "to provide [to EPA]...findings and recommendations on reasonable standards for protection of the public health and safety…." (The NAS Report [3]). The standards are in Part 197 of Title 40 of the Code of Federal Regulations (40 CFR Part 197).

After the standards were issued, petitions for review were filed in Federal courts by the State of Nevada, several environmental and public interest groups led by the Natural Resources Defense Council, and the Nuclear Energy Institute. The standards survived every challenge except one regarding the compliance period. The Court ruled that the 10,000-year compliance period was not based upon and consistent with a recommendation in the NAS Report [3]. The NAS recommendation was:

> "…there is no scientific reason for limiting the time period of an individual-risk standard in this way [10,000 years]. We believe that compliance assessment is feasible for most physical and geologic aspects of repository performance on the time scale of the long-term stability of the fundamental geologic regimes – a time scale that is on the order of 10^6 years at Yucca Mountain – and that at least some potentially important exposures might not occur until after several hundred thousand years. For these reasons, we recommend that compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment." [3]

Notably, NAS also said: "Nevertheless, we note that although the selection of a time period of applicability has scientific elements, it also has policy aspects that we have not addressed. For example, EPA might choose to establish consistent policies for managing risks from disposal of both long-lived hazardous nonradioactive materials and radioactive materials." The Agency's longest-term disposal standards and regulations for both nonradioactive and radioactive hazardous wastes extended only to 10,000 years. Despite EPA's explanations of those factors, the Court ruled that EPA's compliance period for Yucca Mountain was not based upon and consistent with the NAS recommendation and that EPA had not sufficiently justified its decision to set the 10,000-year compliance period on policy grounds.

On 22 August 2005, the Agency proposed amendments to address the Court ruling [4]. The parts of the standards not affecting the extension of the compliance period are not being proposed for change, with the exception of updating the dose methodology. Thus, changes were not proposed to the storage standards, the characteristics of the reasonably maximally exposed individual, and the ground-water protection standards, for example. The comment period ended 21 November 2005. Hearings were held in early October 2005 in Amargosa Valley and Las Vegas, Nevada, and Washington D.C.

In previous papers, EPA has reported the findings and recommendations in the NAS Report, public comments received from the review of the NAS Report, the considerations made while establishing the 2001 standards, and the contents of those standards. This paper discusses the proposed amendments to the 2001 standards.

OVERVIEW OF THE 2001 DISPOSAL STANDARDS

Subpart B of 40 CFR Part 197 contains the disposal standards for: (a) protection of individuals; (b) human intrusion; and (c) ground-water protection. The disposal phase is considered to start when the repository is closed. Disposal was the subject of the findings and recommendations of the NAS Report [3].

Individual-Protection Standard. - The individual-protection standard is 150 μSv (15 mrem) committed effective dose equivalent (CEDE) per year for 10,000 years after closure. The Agency uses the dose incurred by a reasonably maximally exposed individual (RMEI) to compare with the dose limits. The concept is similar to the critical group approach in that its purpose is to project doses that are among the highest but still in a reasonably expected range rather than the highest theoretical dose. The location of the RMEI must be assumed to be in the accessible environment above the point of highest concentration of radionuclides in the aquifer. The accessible environment can be no farther downgradient than the southern edge of the Nevada Test Site (NTS), or about 18 kilometers south of the repository

Ground-Water Protection Standards. - These standards provide separate protection of ground water. The overall goal is to prevent adverse effects upon human health and the environment by preventing contamination rather than relying upon later mitigation. The limits are the same as the maximum contaminant levels for radionuclides under the Safe Drinking Water Act. The compliance period for these standards is 10,000 years based upon undisturbed performance, i.e., the assumption that the repository is not affected by human intrusion or unlikely features, events, or processes (FEPs).

Human-Intrusion Standard. - The human-intrusion standard is 150 μSv (15 mrem) CEDE per year for 10,000 years after closure. The required human-intrusion scenario is a single intrusion as a result of exploratory drilling for ground water. The EPA specifies certain borehole parameters that DOE must use to assess the dose received by the RMEI as a result of releases that travel through the borehole, without including the effects of unlikely FEPs. The timing of the intrusion is to be established by NRC based upon the earliest time that current technology and practices could lead to waste package penetration without the drillers noticing it. However, it must not occur sooner than the cessation of active institutional controls. Finally, the standard requires that the human-intrusion analysis be done using the same assumptions and RMEI characteristics as those required for the individual-protection standard.

PROPOSED AMENDMENTS TO THE 2001 STANDARDS

Scope of the Rulemaking

The rulemaking is limited to those portions of the 2001 standards that were affected by the court ruling, i.e., the compliance period for the individual-protection and the human-intrusion standards and certain supporting items. Even though the ground-water protection standards also have a 10,000-year compliance period of 10,000 years, the Court did not vacate these standards since NAS made no recommendation regarding ground-water standards. Therefore, EPA did not propose changes to the ground-water standards.

The Agency also proposed to update the dose methodology and to revise certain definitions to achieve consistency with the extended compliance period.

Individual-Protection Standard

The Court's decision centered upon the NAS recommendation regarding the compliance period for the individual-protection standard. To address the Court decision, EPA proposed a compliance limit of 3.5 mSv (350 mrem) CEDE/yr to apply for projected performance between 10,000 and 1 millions years. In addition, EPA is retaining the 150 μSv (15 mrem) CEDE/yr standard applicable for the first 10,000 years as established in the 2001 standards.

The Agency believes that the most problematic aspect of extending the compliance period to peak dose is the uncertainty involved in making projections over such long time frames. Regardless of the level of rigor that can be applied to the technical calculation, it is not possible to place the same level of confidence in performance projections over 10,000 years versus 1 million years.

In addressing how to incorporate extremely long-term projections into a regulatory process and have them be sufficiently reliable to serve as a basis for regulatory decisions, EPA considered guidance and precedents from international and domestic sources. The NAS discussed some technical aspects of uncertainty. For example, NAS stated: "uncertainties in waste canister lifetimes might have a more significant effect on assessing performance in the initial 10,000 years than in performance in the range of 100,000 years." [3] On the other hand, NAS recognized that: "the timing of seismic events is unpredictable." [3] Unfortunately, NAS provided no recommendations on how to deal with such uncertainties, but noted: "No analysis of compliance will ever constitute an absolute proof; the objective instead is a reasonable level of confidence in analyses that indicates whether limits established by the standard will be exceeded." [3] For regulatory compliance within 10,000 years, EPA identified several U.S. regulatory programs as possible precedents, including those for the Waste Isolation Pilot Plant and EPA's underground injection control program, but for a compliance period extending to 1 million years, there are no precedents in U.S. regulation. In response to the Court decision, therefore, important sources for guidance and models for contemplating regulations at such long times were international programs grappling with the same issues. In general, international guidance reinforces two points. The first is that uncertainties generally increase with time. For example, the International Atomic Energy Agency [5], the Nuclear Energy Agency [6], and the Swiss National Cooperative for the Disposal of Radioactive Waste [7] have all concluded that the further into the future projections are made, the greater the uncertainty. The second point is that projections at those longer times cannot be viewed with the same level of confidence as shorter-term projections. As exemplified in statements by IAEA [5], NEA [6], and SSI [8] experts indicate that the uncertainties in quantitative performance projections become so large that the results need to be viewed more as qualitative, rather than quantitative, projections.

A number of international scientific and regulatory bodies and programs suggest natural sources of radioactivity serve as a point of comparison when uncertainties become significant. For example, IAEA has stated that, for time frames extending from about 10,000 to 1 million years, "it may be appropriate to use quantitative and qualitative assessments based on comparisons with natural radioactivity and naturally occurring toxic substances" [9]. The IAEA also suggests that "[i]n very long time frames…uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases [5]. Similarly, NEA stated that a key performance indicator could be "comparison with background radiation levels" for times up to just 100,000 years [6].

The proposed rule describes a dose limit – to apply for the period from 10,000 to 1 million years – that will not cause people living near Yucca Mountain to receive a total dose that is more than the natural background radiation which people receive routinely in other parts of the U.S. In order to assess total exposures and derive a dose limit, it is necessary to establish levels of natural background radiation

already experienced in the vicinity of Yucca Mountain. The Agency selected Amargosa Valley as the point of comparison for this analysis since that is where the RMEI will likely live. Combined with the cosmic and terrestrial exposures estimated by DOE, EPA estimated the total annual natural background radiation in Amargosa Valley to be approximately 3.5 mSv (350 mrem) CEDE/yr.

To make the comparison with total exposures, it is also necessary to consider what total exposures provide a reasonable reference point for limiting releases from Yucca Mountain. As noted above, the goal is to ensure that releases from Yucca Mountain will not cause total exposures of the RMEI to exceed natural background levels with which other populations live routinely. The Agency considered several factors in this selection. First, some incremental exposure will be allowed since the standards cannot be expected to reduce natural background exposures. Thus, the reference point would have to have a higher level of background than does the area near Yucca Mountain. Because of the complications in estimating localized background radiation (due primarily to the radon component), statewide averages, which are less uncertain, were examined. Of the States with sufficient data, 32 have average background radiation levels higher than Nevada. The States' characteristics, such as geographic location and population, were then considered. Colorado was selected as a State in the western part of the country that best fit the search criteria -- fairly well populated and with characteristics reasonably comparable to Nevada (such as radon potential, surface water/coastal features, or size of major cities). According to population data, Colorado ranks 22nd among all states in total population (Nevada is 35th) [10]. Colorado's average annual background radiation is estimated to be about 7 mSv (700 mrem)/yr [11]. Other States have comparable or higher radon potential and higher background levels with which people live routinely (e.g., background levels in North Dakota, South Dakota, and Iowa, for example, are about 8 mSv (789 mrem)/yr, 10 mSv (963 mrem)/yr, and 8 mSv (784 mrem)/yr, respectively), and might also be used for comparison, but their population and geographic characteristics are much different than Nevada's.

Finally, comparing Colorado's estimated average annual background radiation of 7 mSv (700 mrem) CEDE/yr to the estimate for Amargosa Valley, EPA derived an incremental exposure level of 3.5 mSv (350 mrem) CEDE/yr, which was proposed as the dose limit.

The Agency also considered other possible dose limits to apply out to 1 million years. The first option was 1 mSv (100 mrem) CEDE/yr. This level is based upon international guidance to limit all sources of exposure except natural, accidental, and medical. However, in view of the uncertainties in estimating performance in the very far future, EPA concluded that comparisons with natural background radiation provide a reasonable indication of safety out to 1 million years. As McCombie and Chapman have stated in their authoritative reference on radioactive waste disposal: "There is no logical or ethical reason for trying to provide more protection than the population already has from Earth's natural radiation environment, in which it lives and evolves…it must be recognized that man cannot be expected over infinite times to do much better than nature." [12] The other limit considered was 2 mSv (200 mrem) CEDE/yr. It was derived using an approach that incorporated statewide background levels in all the contiguous States in the U.S. However, EPA concluded that it was most appropriate to use site-specific information related to Amargosa Valley (and the RMEI) rather than generic points of reference. For these reasons, the 3.5 mSv (350 mrem) CEDE/yr dose limit, including consideration of natural background radiation in Amargosa Valley, was preferred over the other options considered, and was proposed as the regulatory limit.

We recognized that a standard based on variations in natural background radiation would be higher than previous, non-occupational standards in the U.S. In the 2001 rulemaking, the 150 μSv (15 mrem) CEDE/yr dose limit and the 10,000-year compliance period were justified in part because they were

consistent with other EPA policies. However, the circumstances in the proposed Yucca Mountain standards – and, in particular, the nature and degree of uncertainty in projecting performance out to 1 million years – are significantly different from the situations addressed under Superfund or any other existing U.S. regulatory program. The approach and the dose limit that EPA proposed for the Yucca Mountain standards are consistent with international guidance on the issue of radioactive waste disposal over extremely long times.

Human-Intrusion Standard

While the Court did not specifically address the human-intrusion standard, the Agency proposed revisions to it to parallel the changes proposed for the individual-protection standard. To do so is consistent with the NAS recommendation that "EPA require that the estimated risk calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case" [3].

The Agency proposed to extend the compliance period from 10,000 to 1 million years and to establish a dose limit of 3.5 mSv (350 mrem) CEDE/yr, which corresponds to the proposed individual-protection dose limit. Other aspects of the human-intrusion standard are unchanged from 2001. The intrusion scenario described in 2001 would still apply because the longer compliance period does not in any way affect the reasoning underlying the selection of this scenario. It remains fully consistent with the NAS conclusion that at Yucca Mountain "there is no scientific basis for estimating the probability of intrusion at far-future times" [3]. Instead, NAS recommended that "the result of the analysis should not be integrated into an assessment of repository performance based on risk, but rather should be considered separately. The purpose of this consequence analysis is to evaluate the resilience of the repository to intrusion" [3].

The intrusion scenario requires consideration of package degradation, premised on the assumption that drillers encountering an intact package would cease drilling and releases would be avoided. We believe that this assumption is equally valid both within and beyond a 10,000-year time frame. In the 2001 standards, DOE was not required to demonstrate compliance with a dose limit if packages did not degrade sufficiently within 10,000 years to permit intrusion (or, in any event, if the consequences of the intrusion were not calculated to occur within 10,000 years). However, the current proposal would require DOE to show compliance with a dose limit regardless of when the consequences of the intrusion occur (within 1 million years). Overall, this scenario continues to represent a reasonable test that "can provide useful insight into the degree to which the ability of a repository to protect public health would be degraded by intrusion" [3].

Dose Methodology

In 1977 and 1979, ICRP published Reports 26 [13] and 30 [14], respectively. These two reports reflected advances in the state of knowledge of radionuclide dosimetry and biological transport of radionuclides in humans that occurred over the 20 years since ICRP's 1957 dose methodology recommendation (ICRP 2) [15]. The new methodology was called the effective dose equivalent (EDE).

The 2001 standards required DOE to calculate annual doses (as CEDE) to demonstrate compliance with the storage, individual-protection, and human-intrusion standards. The Agency proposed to modify that requirement to incorporate updated scientific factors necessary for the calculation, but would not change the underlying methodology. Specifically, EPA proposed to require DOE to calculate the annual CEDE using the radiation- and organ-weighting factors in ICRP Publications 60 [16] and 72 [17], rather than those in ICRP Publications 26 [13] and 30 [14].

These ICRP factors represent the most recent science and dose calculation approaches in the area of radiation protection. The EPA believes that it is reasonable and desirable to conform the standards to the most recent method approved by the U.S. and international radiation-protection community. The Agency also proposed an updating mechanism since repository closure and license termination may be decades or even more than one hundred years into the future. Therefore, EPA would allow DOE to use, with NRC approval, further updated dose calculation factors in the future, but only if those factors have been appropriately reviewed and accepted by the scientific community and issued by independent scientific bodies (such as ICRP and its successor bodies) and incorporated by EPA into its Federal Guidance.

Judging Compliance

Under 40 CFR Part 197, EPA requires DOE to complete a probabilistic performance assessment to demonstrate compliance with the individual-protection standard. The results will be a distribution of projected doses since the analysis contains parameters with a range of values, incorporates uncertainties in the models, and uses various expert-judgment assumptions. In 2001, EPA specified the mean of the distribution as the metric to be used for comparison with the standard. In 2005, EPA proposed to retain the mean as the compliance measure for the first 10,000 years. In the unlikely event that the peak dose is found to occur within the first 10,000 years, the mean would be consistent with the statistical measure used in other applications for geologic disposal, i.e., 40 CFR parts 191 and 194 for the 10,000-year compliance period. However, for the period from 10,000 to 1 million years, the Agency believes that the compliance measure should be examined separately to determine if there is a more appropriate measure.

There are significant uncertainties in predicting when discrete events, such as seismic activity, will occur and the effects of these events. Some scenarios incorporating these uncertainties would represent unlikely behavior in that they could show extremely poor or extremely good performance. Such low-probability situations should not be ignored in compliance decisions, but they should not be given undue influence in judging compliance. The NAS stated: "The challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events."[3]. The Agency concluded that for the longer compliance period, there should be a measure that represents the "central tendency" in the distribution. Therefore, the compliance measure should represent a central measure that is not strongly affected by extreme input and results.

A difficulty with the mean is that when the bases of the calculations are excessively conservative (or non-conservative), the results suggest that the "most likely" dose is higher (or lower) than if a more reasonable and realistic approach were taken. Therefore, we believe that a regulatory performance measure should not give undue emphasis to high-end or low-end projections which the mean could do.

On the other hand, the median is less affected by the extremes of the distribution and the attendant uncertainty about how close the mean is to the center of the distribution is removed. In this respect, the median is an attractive alternative to the mean as a measure of central tendency since it is not as strongly influenced by high or low-end outliers. Therefore, EPA proposed to use the median for the post-10,000-year compliance period.

Features, Events, and Processes

The overall purpose of the performance assessment is to provide a reasonable test for compliance with the standards. A major part of providing that reasonable test is determining which features, events, and processes (FEPs) are to be included in the performance assessment. Key to this consideration is EPA's goal of setting standards that provide for a reasonable test of the disposal system under a range of conditions that represent the expected case, as well as relatively less likely (but not wholly speculative)

scenarios with potentially significant consequences. As a result, it is neither constructive nor necessary for EPA to require DOE to predict or model every conceivable scenario that could occur at Yucca Mountain.

This implies that some FEPs (or series of FEPs) need not be included in the performance assessment because their probability of occurrence is extremely low. As a means of restricting scenarios, in the 2001 standards, the Agency outlined how to screen FEPs. Without such measures, the list of FEPs would be limitless, bounded only by the imagination. The Agency determined that FEPs that could occur with a probability equal to or greater than 1 in 10,000 over a period of 10,000 years, an annual probability of occurrence of 10^{-8}, would be sufficiently likely to occur that they should be included among the FEPs available for selection in any particular scenario. Any FEPs with lower probabilities could be excluded from the performance assessment.

For the 10,000-year to 1-million-year compliance period, we considered how to address this probability cutoff. If, for example, we required consideration of events with a probability of occurrence of 10^{-4} over 1 million years, an approach that has been suggested by some stakeholders, it would equate to an annual probability of 10^{-10}, which encompasses events nearly as remote as the "Big Bang" that created the Universe. No disposal system, and perhaps not even the Earth, would survive the effects of such an event, and, therefore, EPA did not find such FEPs to be useful indicators to distinguish between safe or unsafe performance of the disposal system. In the end, the Agency proposed to retain the screening criterion without change – except as described below. However, certain scenarios merit special considerations at extremely long times (beyond 10,000 years)

The Agency also considered what scenarios should be included in the performance assessment. In formulating our approach to the extended compliance period, we began by reviewing the NAS Report. The NAS concluded that volcanism, seismic activity, and climate change have the potential to significantly modify the properties of the repository and the processes by which radionuclides are transported. The NAS also concluded that the probabilities and consequences of modifications generated by volcanism, seismic activity, and climate change are sufficiently boundable that they should be included (along with an undisturbed scenario) in performance assessments that extend over 1 million years. Thus, EPA proposed to include igneous, seismic, and climate change scenarios and have DOE assess the most likely and significant impacts, with appropriate variability incorporated, on dose projections.

Having identified particular natural FEPs, the Agency considered whether there are FEPs that could significantly affect the engineered barrier system that had not been identified for the 10,000-year compliance period. After reviewing DOE's published assessments and other relevant information, the Agency concluded that general corrosion of the waste packages could be a significant failure mechanism at times in the hundreds of thousands of years [18]. Unlike certain other corrosion processes which may be likelier or faster-acting at earlier times, general corrosion may not be a significant factor within 10,000 years and could potentially be removed from consideration at those times because of its limited consequence. This is a situation that EPA found inappropriate and proposed that DOE must project the effects of general corrosion throughout the compliance period.

STATUS AND FUTURE STEPS

The EPA published the proposed amendments to 40 CFR Part 197 in the 22 August 2005 *Federal Register* [19]. A public comment period was open from then until 21 November 2005. Public hearings

were held in Amargosa Valley, Nevada; Las Vegas, Nevada; and Washington, DC. Approximately 2500 comment messages were received.

The Agency does not have a schedule to publish its final amendments. The Agency is considering the comments and will publish its response-to-comments document and the final versions of its technical support documents when the final amendments are published.

The Yucca Mountain standards and supporting documents may be accessed on the EPA World Wide Web site at http://www.epa.gov/radiation/yucca. There is also a toll-free telephone information line: 1-800-331-9477. The official docket contains all the comments and is accessible at: www.regulations.gov under Docket ID EPA-HQ-OAR-2005-0083.

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