[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

RIN: 3150-AH68

Implementation of a Dose Standard after 10,000 Years

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the disposal of high-level radioactive wastes in a proposed geologic repository at Yucca Mountain, Nevada. The proposed rule would implement the U.S. Environmental Protection Agency's (EPA's) proposed standards for doses that could occur after 10,000 years but within the period of geologic stability. The proposed rule also specifies a value to be used to represent climate change after 10,000 years, as called for by EPA, and specifies that calculations of radiation doses for workers use the same weighting factors that

DATES: The comment period expires (insert 60 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.

EPA is proposing for calculating individual doses to members of the public.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AH68) in the subject line of your comments.

Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking website. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking website at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal at http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the

NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to 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 tim3@nrc.gov; Janet Kotra, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6674, e-mail jpk@nrc.gov; or Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2001 (66 FR 55732), NRC published its final rule, 10 CFR Part 63, governing disposal of high-level radioactive wastes in a potential geologic repository at Yucca Mountain, Nevada. The U.S. Department of Energy (DOE) must comply with these regulations for NRC to authorize construction and license operation of a potential repository at Yucca Mountain. As mandated by the Energy Policy Act of 1992, Public Law 102-486 (EnPA), NRC's final rule was consistent with the radiation protection standards issued by EPA at 40 CFR

Part 197 (66 FR 32074; June 13, 2001). EPA developed these standards under Congress' direction, in Section 801 of EnPA, to issue public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in a potential repository at the Yucca Mountain site. These standards were to be "based upon and consistent with" the findings and recommendations of the National Academy of Sciences (NAS). The NAS issued its findings and recommendations, on August 1, 1995, in a report entitled *Technical Bases for Yucca Mountain Standards*.

The State of Nevada and other petitioners challenged both the EPA standards and the NRC regulations in court. On July 9, 2004, the United States Court of Appeals for the District of Columbia Circuit upheld both EPA's standards and NRC's regulations on all but one of the issues raised by the petitioners. See *Nuclear Energy Institute, Inc. v. Environmental Protection Agency,* 373 F.3d 1251 (D.C. Cir. 2004). The court disagreed with EPA's decision to adopt a 10,000-year period for compliance with the standards and NRC's adoption of that 10,000-year compliance period in NRC's implementing regulations. The court found that EPA's 10,000-year compliance period was not "based upon and consistent with" NAS findings, as required by Section 801 of EnPA. See the aforementioned 373 F.3d at 1270. The NAS recommended that a standard be developed that would provide protection when radiation doses reach their peak within the limits imposed by long-term stability of the geologic environment. In addition, NAS found no scientific basis for limiting application of the individual-risk standard to 10,000 years. Thus, the court vacated EPA's rule at 40 CFR Part 197 to the extent that it specified a 10,000-year compliance period and remanded the matter to EPA. The court also vacated NRC's rule at 10 CFR Part 63 insofar as it incorporated EPA's 10,000-year compliance period.

In response to the remand, EPA issued its proposed revised standards on August 22, 2005 (70 FR 49014). To comply with EnPA and the court's remand, NRC must now revise

10 CFR Part 63 to be consistent with EPA's revised standards. For that purpose, NRC is proposing revisions to 10 CFR Part 63 in this notice.

II. Discussion

To address the court's decision, EPA is retaining the standards applicable to the first 10,000 years after disposal and proposes to add separate requirements for the peak dose after 10,000 years and within the period of geologic stability. EPA also proposes to revise the approach for calculating doses, based on International Commission on Radiological Protection (ICRP) recommendations, for the periods before and after 10,000 years. Specifically, EPA's proposed revisions to its standards: (1) provide a limit for the peak dose after 10,000 years; (2) specify criteria DOE must use in performance assessments for estimating doses after 10,000 years; and (3) specify "weighting factors" for DOE's use when calculating individual dose during the operational or preclosure phase as well as after the disposal or postclosure phase. Also, in its proposal, EPA states that NRC should specify a value or values that DOE must use to represent climate change after 10,000 years.

In this rulemaking, the NRC proposes to (1) adopt the limit EPA sets for the peak dose after 10,000 years; (2) adopt the criteria EPA has specified for performance assessments that estimate doses after 10,000 years; (3) adopt the "weighting factors" EPA specifies for calculating individual doses during the operational or preclosure phase, as well as after the disposal or postclosure phase; (4) require that calculations of radiation doses for workers use the same weighting factors EPA is proposing for calculating individual dose; and (5) specify a value that DOE must use to project the long-term impact of climate variation after 10,000 years, as called for by EPA. These proposals are more fully described below.

The NRC's proposal of these changes to Part 63 coincides with EPA's publication of its proposal to provide important and timely information to the public on how NRC plans to incorporate and implement EPA's standards in NRC's regulations. In general, the changes to Part 63 adopt the same or approximately the same wording as used by EPA in its proposed revisions to 40 CFR Part 197. Comments on EPA's proposal (e.g., the dose limit) should be directed to EPA and refer to EPA's proposal published on August 22, 2005. NRC's existing regulations, which are applicable for the first 10,000 years after disposal, remain in place [e.g., the 0.15 millisieverts/year (15 millirem/year) individual protection standard] consistent with the existing EPA standards, and are not affected by this rulemaking except insofar as NRC's rule adopts more up-to-date dosimetry for dose calculations.

The Commission welcomes comments on NRC's proposed implementation of EPA's proposed revisions to its standards as well as on NRC's revisions for use of specific weighting factors for calculating worker doses, and on NRC's specification of a value for climate change. NRC requests and will respond to comments only on those provisions of Part 63 that we are now proposing to change. A description of these changes follows.

1. Dose Limit

EPA's proposed standards would require DOE to estimate peak dose after 10,000 years as part of the evaluations for both individual protection and human intrusion. DOE must then compare the results of these estimates to an annual dose limit of 3.5 mSv/yr (350 mrem/yr). For this comparison, EPA proposes that DOE use the median value of the projected doses after 10,000 years and through the period of geologic stability. NRC proposes to incorporate the new EPA dose limit and statistical measure for compliance directly into NRC's regulations at § 63.311 for individual protection and at § 63.321 for human intrusion.

2. Criteria for Performance Assessments Used to Estimate Peak Dose after 10,000 Years

EPA proposes using the performance assessment for the first 10,000 years as the basis for projecting repository performance after 10,000 years. EPA asserts that its requirements for the performance assessment for the first 10,000 years (e.g., consideration for features, events, and processes with a probability of occurrence greater than 10⁻⁸ per year) provide a suitable basis for projecting performance after 10,000 years. NRC's existing regulations at 10 CFR Part 63 already include additional requirements, governing the preparation of the performance assessment, that ensure that features, events, and processes considered for inclusion in the performance assessment over the 10,000-year compliance period represent a wide range of both favorable and detrimental effects on performance.

Because of the uncertainties associated with estimating performance over very long times (e.g., hundreds of thousands of years) and to limit speculation, EPA proposes specific constraints on the consideration of features, events, and processes after 10,000 years. First, EPA asserts that data and models used to prepare the performance assessment for the first 10,000 years provide adequate support for projections used in the performance assessment after 10,000 years. For example, DOE may apply the seismic hazard curves used in the 10,000-year assessment to project seismic activity after 10,000 years. Second, EPA proposes to (1) limit the analysis of seismic activity to the effects caused by damage to the drifts and the waste package; (2) limit analysis of igneous activity to effects on the waste package that result in release of radionuclides to the atmosphere or ground water; (3) limit the effect of climate variation to those resulting from increased water flowing to the repository; and (4) require DOE to include general corrosion in its analysis of engineered barrier performance. NRC proposes to incorporate these criteria into NRC regulations at § 63.342. NRC also proposes revising requirements for the performance assessment, specified at § 63.114, to be consistent with

EPA's proposal that the performance assessment for the first 10,000 years serve as the basis for projecting repository performance assessment after 10,000 years.

3. Individual Dose Calculations

EPA proposes that DOE use specific weighting factors provided in proposed Appendix A of its standards at 40 CFR 197. These weighting factors reflect current methods of dosimetry and updated models for calculating individual exposures from radiation. EPA cites, as a basis for this proposal, recommendations and guidance from ICRP Publications 60 through 72. NRC supports the use of current dosimetry and proposes to adopt this specification.

4. Worker Dose Calculations

Consistent with EPA's specification of dosimetry for calculating individual doses to members of the public (public doses), NRC proposes to revise its Part 63 regulations to allow DOE to use the same methods for calculating doses to workers during the operational period as those required for calculating public doses. NRC believes that calculations of doses to workers and the public should rely on a single set of weighting factors, based on current dosimetry. This approach would avoid the unnecessary complication and potential confusion for stakeholders that could result from the use of two sets of weighting factors. NRC proposes to add a definition for "weighting factor" to § 63.2 that specifies the weighting factors provided in the EPA proposal, and to amend § 63.111(a)(1) to provide that calculation of doses to meet the requirements of 10 CFR Part 20 shall use the definition for "weighting factor" in § 63.2. Calculation of both worker and public doses would use the weighting factor as defined.

5. <u>Values Used to Project Climate Variation after 10,000 Years</u>

EPA proposes that DOE should assume that the effect of climate variation, after 10,000 years, is limited to the results of increased water flowing through the repository. EPA also proposes that NRC specify, in regulation, steady-state (constant-in-time) values that DOE should use to project the long-term impact of climate variation after 10,000 years. This approach focuses on "average" climate conditions over the long term rather than on time-varying aspects of climate (e.g., timing, size, and duration of short-term variations) that can be both uncertain and speculative. The NRC has considered what parameter or parameters would represent the average climate conditions. Precipitation and temperature are the most readily identified parameters, associated with climate, that directly influence the amount of water, or deep percolation, flowing to the repository horizon. It is the rate of deep percolation, however, that directly influences repository performance. Therefore, the NRC proposes to specify use of the deep percolation rate to represent the effect of future climate in performance assessments after 10,000 years.

Southern Nevada has experienced significant variation in mean annual precipitation and temperature over the past 1 to 3 million years (Forester, R. M. "Pliocene-Climate History of the Western United States Derived from Lacustrine Ostracodes," Quaternary Science Reviews, Volume 10, pages 133-146, 1991). Estimates of future climate over the next 1 million years involve many assumptions and are uncertain. One approach, discussed when NRC issued its regulations for Yucca Mountain at 10 CFR Part 63 (page 66 FR 55757; November 2, 2001), is to assume that fundamental mechanisms that will change the future climate will be the same as those that changed it in the past. Paleoclimate data suggest that, in general, over the past 1 million years, Southern Nevada has been cooler and wetter than it is today (Thompson, R. S., K. H. Anderson, and P. J. Bartlein, "Quantitative Paleoclimatic Reconstructions from Late

Pleistocene Plant Macrofossils of the Yucca Mountain Region," U.S. Geological Survey Open-File Report 99-338, U.S. Geological Survey, Denver, CO, 1999; and Reheis, M., "Highest Pluvial Lake Shorelines and Pleistocene Climate in the Western Great Basin," <u>Quaternary Research</u>, Volume 52, pages 196-205, 1999). Thus, NRC expects "average" conditions 10,000 years in the future, and later, to be cooler and wetter. Those conditions will allow more water to percolate to the repository horizon than expected during the first 10,000 years.

According to climatologists, the so-called intermediate and monsoon climate states, which occur between the warmer "interglacial" and the cooler "full glacial" climate states, are both wetter than the present climate state. Climatologists estimate a mean annual precipitation, during these climate states, at about twice that of present mean annual precipitation at Yucca Mountain. Over the past million years, these two wetter climate states were the predominate climate states (Civilian Radioactive Waste Management System, Management and Operating Contractor, "Future Climate Analysis—10,000 years to 1,000,000 Years After Present," MOD-01-001 Rev. 00, 2002). To the extent that climate is controlled by changes in solar radiation arising from variations in the Earth's orbit [op. cit.], it is reasonable to assume that climate patterns during the next 1 million years would follow a similar cycle. Deep percolation rates depend on both precipitation and temperature and their associated effects on evaporation and plant transpiration. Today, the mean precipitation, measured at Yucca Mountain, is 125 millimeters/year (mm/year) (4.9 inches/year) (Thompson, R. S., K. H. Anderson, and P. J. Bartlein, "Quantitative Paleoclimatic Reconstructions from Late Pleistocene Plant Macrofossils of the Yucca Mountain Region," U.S. Geological Survey Open-File Report 99-338, U.S. Geological Survey, Denver, CO, 1999). About 4 percent of that water reaches the repository horizon. This corresponds to an estimated deep percolation rate of 5 mm/year (0.20 inches/year) when averaged over the repository footprint (Zhu, C., J. R. Winterle, and

E. I. Love, "Late Pleistocene and Holocene Groundwater Recharge from the Chloride Mass Balance Method and Chlorine-36 Data," Water Resources Research, Vol 39, No. 7, page 1182, 2003). Examination of locations in the United States, analogous to Yucca Mountain in some future intermediate and monsoon climates, suggests potential precipitation rates of between 266 and 321 mm/year [10.5 and 12.6 inches/year] (Thompson, R. S., K. H. Anderson, and P. J. Bartlein, "Quantitative Paleoclimatic Reconstructions from Late Pleistocene Plant Macrofossils of the Yucca Mountain Region," U.S. Geological Survey Open-File Report 99-338, U.S. Geological Survey, Denver, CO, 1999).

Estimates of deep percolation rate as a fraction of precipitation have been calculated for various climate conditions. Between 5 to 20 percent of precipitation could reach the repository depth under intermediate/monsoon to "full glacial" climate conditions. The larger percentage reflects "full glacial" conditions (Mohanty, S., R. Codell, J. M. Menchaca, et al., System-Level Performance Assessment of the Proposed Repository at Yucca Mountain Using the TPA Version 4.1 Code, CNWRA 2002-05 Revision 2, Center for Nuclear Waste Regulatory Analyses, San Antonio, TX, 2004). Given that average deep percolation at Yucca Mountain is about 4 percent of precipitation, under current conditions, and assuming between 5 to 20 percent for the fraction of precipitation that remains as deep percolation under intermediate/monsoon climates, one may estimate higher average water flow to the repository than observed today. On this basis, the NRC proposes that DOE represent the effects of climate change after 10,000 years by assuming that deep percolation rates vary between 13 to 64 mm/year (0.5 to 2.5 inches/year)¹. DOE would implement this assumption in its performance

¹ The low value of the range is derived using the lower estimated fraction of precipitation that results in deep percolation and the lower precipitation rate (i.e., 5 percent of 266 is approximately 13) and the high value of the range from using the higher estimated fraction of precipitation that results in deep percolation and the higher value for precipitation rate (i.e., 20 percent of 321 is approximately 64).

assessment by sampling values of deep percolation rates within this range, and, for a given calculation, by assuming the deep percolation rate remained constant, at the sampled rate, after 10,000 years.

Thus, NRC proposes that DOE use a time-independent deep percolation rate, after 10,000 years, based on a log uniformly distributed range of deep percolation rates from 13 to 64 mm/year (0.5 to 2.5 inches/year). This "average" deep percolation rate represents the average amount of water flowing to the repository horizon. Specifying a rate that is constant over time, however, does not imply that this same rate should necessarily be held constant spatially over the entire repository horizon. To the contrary, current understanding of site behavior (e.g., NRC staff and DOE staff representations of infiltration and percolation processes at Yucca Mountain) shows significant variation in current deep percolation rates across the repository horizon. This would be expected to continue to occur into the far future. NRC expects DOE to continue such calculations of spatial variation, subject to the constraint that, across the repository footprint, the "average" overall percolation rate would remain within the range and distribution specified by NRC.

The Commission considers it appropriate to specify these constraints on how DOE must account for the effects of climate change during the period after 10,000 years because this approach: (1) is consistent with EPA's proposal for treatment of climate change after 10,000 years; (2) specifies, in a straightforward way, how DOE shall represent climate change in its performance assessment; (3) results in a mean deep percolation rate of approximately 32 mm/year² (1.3 inches/year), a rate that is approximately six times greater than the current rate, representing wetter and cooler conditions (e.g., interglacial and monsoon climate states);

 $^{^2}$ The mean value of a log-uniform distribution of deep percolation that ranges from 13 mm/year to 64 mm/yr is equal to (64 mm/year - 13 mm/year)/[log_e(64 mm/year) - log_e(13 mm/year)] = 32 mm/year.

and (4) provides information on the relative significance of the deep percolation rate (e.g., results of the performance assessment when the deep percolation rate is assumed to be at the low value of the range versus the high value of the range).

III. Discussion of Proposed Amendments by Section

Section 63.2 Definitions.

This section would be modified to revise the definition of "performance assessment" to exclude the limitation of "10,000 years after disposal," consistent with EPA's modified definition of "performance assessment." This section also would be modified to include a definition for "weighting factor" that conforms the weighting factors to be used in dose calculations to the values EPA proposes.

Section 63.111 *Performance objectives for the geologic repository operations area through permanent closure.*

This section specifies requirements for radiation exposures for the geologic repository operations area. This section would be modified to require use of the definition for "weighting factor" in § 63.2 when calculating doses to meet the requirements of part 20 of this chapter.

Section 63.114 Requirements for performance assessment.

This section specifies the requirements for the performance assessment used to demonstrate compliance with the requirements specified at § 63.113(b), (c), and (d). This section would be revised to conform to EPA's proposed standards that specify what DOE must consider in the performance assessment for the period after 10,000 years.

Section 63.302 Definitions for Subpart L.

The definition for the "period of geologic stability" would be modified to clarify that this period ends at 1 million years after disposal.

Section 63.303 Implementation of Subpart L.

This section provides a functional overview of this subpart. This section would be revised to conform to EPA's proposed standard that specifies the arithmetic mean of the projected doses to be used for determining compliance for the period within 10,000 years after disposal and the median value of the projected doses to be used for determining compliance for the period after 10,000 years and through the period of geologic stability.

Section 63.305 Required characteristics of the reference biosphere.

This section specifies characteristics of the reference biosphere to be used by DOE in its performance assessments to demonstrate compliance with the requirements specified at § 63.113. This section would be modified to conform to EPA's proposed standards, which specify the types of changes DOE shall account for in the performance assessment for the period after 10,000 years and through the period of geologic stability.

Section 63.311 Individual protection standard after permanent closure.

This section specifies the dose limit for individual protection after permanent closure for any geologic repository at the Yucca Mountain site. This section would be modified to conform with the public health and environmental radiation standards EPA proposes for the peak dose after 10,000 years and through the period of geologic stability.

Section 63.321 Individual protection standard for human intrusion.

This section directs DOE to estimate the dose resulting from a stylized human intrusion drilling scenario and specifies the dose limit that any geologic repository at the Yucca Mountain site must meet as the result of a hypothetical human intrusion. This section would be modified to conform with the public health and environmental radiation standards EPA proposes for the peak dose after 10,000 years and through the period of geologic stability.

Section 63.341 Projections of peak dose.

This section has been removed.

Section 63.342 *Limits on performance assessments.*

This section specifies how DOE will identify and consider features, events, and processes in the dose assessments described in Subpart L to Part 63. This section would be modified to conform to EPA's proposed standards, which specify the types of changes DOE shall account for in the performance assessment for the period after 10,000 years and through the period of geologic stability. A range of values has been specified that DOE shall use to represent the effects of climate change after 10,000 years and through the period of geologic stability.

IV. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State

Programs" approved by the Commission on June 30, 1997, and published in the Federal

Register on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category

"NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. An Agreement State may not adopt program elements reserved to NRC.

V. 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). NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading of "ADDRESSES," above.

VI. 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 the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, NRC would implement site-specific standards proposed by EPA and developed solely for application to a proposed geologic repository for high-level radioactive waste at Yucca Mountain, Nevada. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VII. 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.

VIII. 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 (OMB), approval number 3150-0199.

Public Protection Notification

NRC may not conduct nor sponsor, and a person is not required to respond to, a request for information nor an information collection requirement, unless the requesting document displays a currently valid OMB control number.

IX. 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, consistent with the options that are open to NRC in carrying out the statutory

directive of EnPA. The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to NRC, as indicated under the "ADDRESSES," heading. The analysis is available for inspection in the NRC PDR, 11555 Rockville Pike, Rockville, MD 20852. Single copies of the regulatory analysis may be obtained from Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

X. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 [5 U.S.C. 605(b)], NRC certifies that this proposed rule will not, if issued, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing of one entity, DOE, which does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act nor the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

XI. Backfit Analysis

NRC has determined that the backfit rule (§§50.109, 70.76, 72.62, or 76.76) does not apply to this proposed rule because this amendment would not involve any provisions that would impose backfits, as defined in the backfit rule. Therefore, a backfit analysis is not required.

XII. List of Subjects in 10 CFR Part 63

Criminal penalties, High-level waste, Nuclear power plants and reactors, 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, the 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); sec. 1704, 112 stat. 2750 (44 U.S.C. 3504 note).

2. Section 63.2 is amended by revising paragraph (1) of the definition of "performance assessment" and by adding a new definition for "weighting factor," in alphabetical order, to read as follows:

§ 63.2 Definitions.

* * * * * *

Performance assessment means an analysis that:

(1) Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring;

* * * * * *

Weighting factor for an organ or tissue is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values in Appendix A of 40 CFR Part 197 are to be used.

3. In § 63.111, paragraph (a)(1) is revised to read as follows:

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) * * *

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter. Calculation of doses to meet the requirements of part 20 of this chapter shall use the definition for "weighting factor" in § 63.2.

* * * * * *

4. Section 63.114 is revised to read as follows:

§ 63.114 Requirements for performance assessment.

- (a) Any performance assessment used to demonstrate compliance with § 63.113 for 10,000 years after disposal must:
- (1) Include data related to the geology, hydrology, and geochemistry (including disruptive processes and events) of the Yucca Mountain site, and the surrounding region to the extent necessary, and information on the design of the engineered barrier system used to define, for 10,000 years after disposal, parameters and conceptual models used in the assessment.
- (2) Account for uncertainties and variabilities in parameter values, for 10,000 years after disposal, and provide for the technical basis for parameter ranges, probability distributions, or bounding values used in the performance assessment.
- (3) Consider alternative conceptual models of features and processes, for 10,000 years after disposal, that are consistent with available data and current scientific understanding and evaluate the effects that alternative conceptual models have on the performance of the geologic repository.
- (4) Consider only features, events, and processes consistent with the limits on performance assessment specified at § 63.342.

- (5) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, for 10,000 years after disposal, would be significantly changed by their omission.
- (6) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers.

 Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, for 10,000 years after disposal, would be significantly changed by their omission.
- (7) Provide the technical basis for models used to represent the 10,000 years after disposal in the performance assessment, such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).
- (b) Any performance assessment used to demonstrate compliance with § 63.113 for the period of time after 10,000 years through the period of geologic stability must be based on the performance assessment specified in paragraph (a) of this section.
- 5. In Section 63.302, the definition of "period of geologic stability" is revised to read as follows:

§ 63.302 Definitions for Subpart L.

* * * * *

Period of geologic stability means the time during which the variability of geologic characteristics and their future behavior in and around the Yucca Mountain site can be bounded, that is, they can be projected within a reasonable range of possibilities. This period is defined to end at 1 million years after disposal.

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6. Section 63.303 is revised to read as follows:

§ 63.303 Implementation of Subpart L.

- (a) Compliance is based upon the arithmetic mean of the projected doses from DOE's performance assessments for the period within 10,000 years after disposal for:
 - (1) § 63.311(a)(1); and
- (2) §§ 63.321(b)(1) and 63.331, if performance assessment is used to demonstrate compliance with either or both of these sections.
- (b) Compliance is based upon the median of the projected doses from DOE's performance assessments for the period after 10,000 years of disposal and through the period of geologic stability for:
 - (1) § 63.311(a)(2); and
 - (2) § 63.321(b)(2), if performance assessment is used to demonstrate compliance.
 - 7. Section 63.305, paragraph (c) is revised to read as follows:

§ 63.305 Required characteristics of the reference biosphere.

* * * * * *

(c) DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions consistent with present knowledge of factors that could affect the Yucca Mountain disposal system during the period of geologic stability and consistent with the requirements for performance assessments specified at § 63.342.

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8. Section 63.311 is revised to read as follows:

§ 63.311 Individual protection standard after permanent closure.

- (a) DOE must demonstrate, using performance assessment, that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than the following annual dose from releases from the undisturbed Yucca Mountain disposal system:
 - (1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and
 - (2) 3.5 mSv (350 mrem) after 10,000 years, but within the period of geologic stability.
- (b) DOE's performance assessment must include all potential environmental pathways of radionuclide transport and exposure.
 - 9. Section 63.321 is revised to read as follows:

§ 63.321 Individual protection standard for human intrusion.

- (a) DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion (see § 63.322) could occur without recognition by the drillers.
- (b) DOE must demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives, as a result of human intrusion, no more than the following annual dose:
 - (1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and
 - (2) 3.5 mSv (350 mrem) after 10,000 years, but within the period of geologic stability.
- (c) DOE's analysis must include all potential environmental pathways of radionuclide transport and exposure, subject to the requirements at § 63.322.

§ 63.341 [Remove]

- 10. Section 63.341 is removed.
- 11. Section 63.342 is revised to read as follows:

§ 63.342 Limits on performance assessments.

(a) DOE's performance assessments conducted to show compliance with §§ 63.311(a)(1), 63.321(b)(1), and 63.331 shall 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 (less than one chance in 100,000,000 per year). 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 in the initial 10,000 year period after disposal.

- (b) For performance assessments conducted to show compliance with §§ 63.321(b) and 63.331, DOE's performance assessments shall exclude the 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 (less than one chance in 100,000 per year and at least one chance in 100,000,000 per year).
- (c) For performance assessments conducted to show compliance with §§ 63.311(a)(2) and 63.321(b)(2), DOE's performance assessments shall project the continued effects of the features, events, and processes included in paragraph (a) of this section beyond the 10,000 year post-disposal period through the period of geologic stability. DOE must evaluate all of the features, events, or processes included in paragraph (a) of this section, and also:
- (1) DOE must assess the effects of seismic and igneous scenarios subject to the probability limits in paragraph (a) of this section for very unlikely features, events, and processes. Performance assessments conducted to show compliance with § 63.321(b)(2) are also subject to the probability limits in paragraph (b) of this section for unlikely features, events, and processes.
- (i) The seismic analysis may be limited to the effects caused by damage to the drifts in the repository and failure of the waste package.
- (ii) The igneous analysis may be limited to the effects of a volcanic event directly intersecting the repository. The igneous event may be limited to that causing damage to the

waste packages directly, causing releases of radionuclides to the biosphere, atmosphere, or

ground water.

(2) DOE must assess the effects of climate change. The climate change analysis may

be limited to the effects of increased water flow through the repository as a result of climate

change, and the resulting transport and release of radionuclides to the accessible environment.

The nature and degree of climate change may be represented by constant climate conditions.

The analysis may commence at 10,000 years after disposal and shall extend to the period of

geologic stability. The constant value to be used to represent climate change is to be based on

a log-uniform probability distribution for deep percolation rates from 13 to 64 mm/year (0.5 to

2.5 inches/year).

(3) DOE must assess the effects of general corrosion on the engineered barriers. DOE

may use a constant representative corrosion rate throughout the period of geologic stability or a

distribution of corrosion rates correlated to other repository parameters.

Dated at Rockville, Maryland, this 1st day of September, 2005.

For the Nuclear Regulatory Commission.

/RA/

Annette Vietti-Cook, Secretary of the Commission.

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