

**RULEMAKING ISSUE
(Affirmation)**

November 4, 2008

SECY-08-0170

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: FINAL RULE: 10 CFR PART 63, "IMPLEMENTATION OF A DOSE STANDARD AFTER 10,000 YEARS" (RIN 3150-AH68)

PURPOSE:

To request Commission approval for a final rule that amends 10 CFR Part 63 to include licensing criteria applicable after 10,000 years for a proposed repository at Yucca Mountain, and to specify the use of current methods of dosimetry for calculating radiation exposures.

SUMMARY:

On July 9, 2004, the United States Court of Appeals for the District of Columbia Circuit vacated the U.S. Environmental Protection Agency's (EPA) standard for Yucca Mountain, to the extent that it specified a 10,000-year compliance period. The court also vacated the U.S. Nuclear Regulatory Commission's (NRC) rule at Part 63, insofar as it incorporated EPA's 10,000-year compliance period. In response to the court's remand, EPA, after a public comment period, has developed final standards for doses that could occur after 10,000 years, but within the period of geologic stability. To comply with the court's remand, NRC issued proposed revisions, to Part 63, on September 8, 2005 (70 FR 53313). After careful consideration of the public comments, the NRC staff has prepared a draft final rule for Yucca Mountain, for Commission approval. This paper provides the Commission with the draft Federal Register Notice (Enclosure 1), containing the "Statement of Considerations," including response to public comments, and the draft final rule language; and the draft regulatory impact analysis (Enclosure 2).

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BACKGROUND:

On November 2, 2001 (66 FR 55732), NRC published its final rule, Part 63, governing disposal of high-level radioactive wastes (HLW) 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 (EnPA), Pub. L. 102-486, 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 pursuant to 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. Such 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 Basis 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. 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 on and consistent with NAS' findings, as required by EnPA. The NAS recommended that EPA develop standards that 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 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 Part 63, insofar as it incorporated EPA's 10,000-year compliance period.

EPA's Proposed Rule

In response to the remand, EPA issued proposed revisions to its standards on August 22, 2005 (70 FR 49014). EPA proposed to revise elements of its individual-protection and human-intrusion standards, to incorporate the time of peak dose into the determination of compliance. EPA retained its 0.15 millisievert (mSv)/year [15 millirem (mrem)/year] standard for 10,000 years following disposal and added a 3.5 mSv/year (350 mrem/year) standard for the period after 10,000 years, within the period of geologic stability. EPA defined the period of geologic stability as ending at 1 million years after disposal. Further, EPA proposed that NRC base its determination of compliance with the post-10,000-year standards on the median of the projected doses from DOE's performance assessments, rather than on the arithmetic mean of the projected doses. The arithmetic mean was retained as the compliance measure for the first 10,000 years after disposal.

EPA also proposed to further define how DOE should incorporate features, events, and processes (FEPs) in the performance assessment for the period after 10,000 years. EPA proposed that DOE's performance assessments, conducted to show compliance with the post-10,000-year individual protection and human-intrusion standards, shall project the continued

effects of the FEPs included in the initial 10,000-year analysis. EPA also proposed certain limitations for DOE's performance assessments, for the post-10,000-year period, regarding seismic analysis, igneous analysis, climate change analysis, and the effects of general corrosion on engineered barriers. With respect to climate change, EPA further proposed that NRC specify, in regulation, the values to be used to represent climate change, such as temperature, precipitation, or infiltration rate of water.

Finally, EPA proposed to specify, in the definition of "effective dose equivalent," that DOE calculate annual committed effective dose equivalents using the weighting factors incorporated into a new Appendix A to its regulations at 40 CFR Part 197. EPA believes this reflects the most recent science and dose calculation approaches in the area of radiation protection.

NRC's Proposed Rule

Under the EnPA, NRC's regulations must be consistent with EPA's standards. On September 8, 2005, NRC proposed revisions to its regulations designed to achieve consistency with EPA's proposed revised standards (70 FR 53313; September 8, 2005). NRC proposed to incorporate the new post-10,000-year dose limit of 3.5mSv/year (350 mrem/year) and statistical measure for compliance directly into its regulations for individual protection and human intrusion. NRC also proposed to adopt the specific constraints EPA had proposed on the consideration of FEPs after 10,000 years and to revise its requirements for the performance assessment 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 after 10,000 years. NRC, supporting the use of current dosimetry, proposed to adopt the specific weighting factors provided in Appendix A of 40 CFR Part 197. Overall, NRC's proposed changes to Part 63 adopted the same or approximately the same wording as used by EPA in its proposed revisions to 40 CFR Part 197. Further, consistent with EPA's specification of dosimetry for calculating individual doses to members of the public, NRC proposed to revise its Part 63 regulations to allow DOE to use the same methods for calculating doses to workers during the operational period. Finally, in response to EPA's proposal that NRC specify, in regulation, steady-state (constant-in-time) values that DOE should use to project the long-term impact of climate variation, NRC proposed that the deep percolation rate be used to represent the effects of climate change after 10,000 years, and that DOE, in its performance assessment, sample constant-in-time deep percolation rates from a log-uniform distribution, which varies between 13 and 64 millimeters(mm)/year [0.5 and 2.5 inches(in.)/year]. In response to requests from the public, NRC extended the comment period, originally ending on November 7, 2005, to December 7, 2005 (70 FR 67098; November 4, 2005).

DISCUSSION:

Content of EPA's Final Rule Promulgating its Yucca Mountain Standard

EPA submitted its draft final Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, for the period after 10,000 years, at 40 CFR Part 197, to the Office of Management and Budget (OMB) for interagency review. Following interagency review, EPA published its final standards on October 15, 2008. On October 10, 2008, the State of Nevada filed a petition for review of EPA's final standards in the United States Court of Appeals for the District of Columbia Circuit. EPA's final standards remain substantially the same as proposed

with respect to consideration of FEPs in the post-10,000 year period, and use of specific weighting factors that reflect current methods of dosimetry and updated models for calculating individual exposures from radiation. EPA's final standards differ from its proposal in two respects: the dose limit and the consideration of seismic activity.

First, EPA's final standards establish a 1.0 mSv/year (100 mrem/year) dose limit for the reasonably maximally exposed individual (RMEI) for the period after 10,000 years and within the period of geologic stability, rather than a 3.5 mSv/year (350 mrem/year) dose limit, as had been proposed. The final standards also provide that NRC base its determination of compliance with the post-10,000 year standards on the arithmetic mean of the projected doses, rather than on the median, as was proposed.

Second, EPA's final standards now require that analyses of seismic activity consider water table rise under Yucca Mountain caused by seismic activity. The final standards specify that NRC may determine the magnitude of water table rise to be used in the performance assessment for the period after 10,000 years or, if this magnitude is found to be insignificant, not require its consideration in performance assessment. Alternatively, NRC may require DOE to demonstrate the magnitude of water table rise and its significance in terms of repository performance in its license application.

Content of the NRC's Draft Final Regulation

The EnPA directs the Commission to modify its technical criteria to be consistent with EPA's standards for a geologic repository at the Yucca Mountain site. NRC's draft final rule achieves this consistency by incorporating the revised EPA standards into its draft final revised 10 CFR Part 63 regulations, as transparently as possible. A brief description of the staff's implementation of EPA's standards follows:

- a. For the period after 10,000 years and within the period of geologic stability, the draft final rule adopts EPA's 1.0 mSv/year (100 mrem/year) dose limit for the reasonably maximally exposed individual, in both the individual protection standard at 10 CFR 63.311 and the human intrusion standard at 10 CFR 63.321.
- b. The draft final rule also adopts, in 10 CFR 63.303, EPA's specification of the arithmetic mean as the basis for determining compliance with the dose limit for the post-10,000 year period.
- c. The draft final rule adopts, in 10 CFR 63.305 and 63.342, EPA's specific requirements for the performance assessment DOE must use to evaluate the behavior of the repository for the period after 10,000 years. The FEPs selected for use in the performance assessment for the first 10,000 years should also be used for projecting repository performance after 10,000 years. The draft final rule also adopts EPA's additional constraints for the inclusion of seismic activity, igneous activity, climate change, and general corrosion in the performance assessment for the period of time after 10,000 years. The seismic analysis must include the magnitude of the water table rise and its significance on the results of the performance assessment, unless NRC, through separate rulemaking, decides to specify the magnitude of the water table rise to be used in the performance assessment after 10,000 years and, if found insignificant, not to require its consideration.

- d. The draft final rule adopts, in 10 CFR 63.102(o), EPA's specification of the weighting factors to be used for estimating potential radiation exposures for members of the public, which are provided in Appendix A of 40 CFR Part 197.

In addition to the changes made for consistency with EPA's standards, NRC proposed to add a definition for "weighting factor" and to amend § 63.111(a)(1) to allow DOE to use the weighting factors in Appendix A for calculating doses to workers. After consideration of the public comments, the draft final rule does not contain the proposed definition for "weighting factor" to its regulations nor amend § 63.111(a)(1). Instead, the draft final rule provides a discussion regarding implementation of total effective dose equivalent (TEDE). The added text at § 63.102(o) clarifies that the weighting factors specified in EPA's final standards should be used for dose calculations for workers and the public. Thus, TEDE calculations of potential radiation exposures to workers and the public are implemented consistently with a single set of weighting factors based on current dosimetry. The definition for TEDE is also revised to be consistent with NRC regulations at Part 20. This approach avoids the unnecessary complication and potential confusion that could result from the use of different definitions in Parts 20 and 63 and provides a single, clear statement on the proper implementation of TEDE in Part 63 thereby eliminating any need for further changes.

EPA's rule requires DOE to assess the effects of climate change in the period after 10,000 years. This assessment is limited to the effects of increased water flow through the repository. The nature and degree of climate change may be represented by sampling within a range of constant climate conditions. EPA leaves it to NRC to specify, in regulation, the values to be used to represent climate change, such as temperature, precipitation, or infiltration of water. NRC's proposed rule sought public comment on its approach for representing the effect of future climate in performance assessments after 10,000 years. NRC proposed that the constant value to be used to represent climate change is to be sampled from a log-uniform distribution for deep percolation rates, which varies between 13 and 64 mm/year (0.5 and 2.5 in./year).

After consideration of the public comments received on its proposal, NRC's draft final rule adopts its proposed approach with some modifications. The draft final rule requires that DOE represent the effects of climate change by assuming constant-in-time climate conditions. The analysis may commence for the period beginning at 10,000 years after disposal and shall extend through the period of geologic stability (1 million years). The constant-in-time deep percolation rates to be used to represent climate change shall now be sampled from a truncated lognormal distribution, for deep percolation rates, which varies between 10 and 100 mm/year (0.39 and 3.9 in./year). The truncated lognormal distribution has an arithmetic mean of 37 mm/year (1.5 in./year) for the deep percolation rate, as compared to an arithmetic mean of 32 mm/year (1.3 inches/year) that resulted from the range and distribution in the proposed rule.

Public Comments and Responses:

NRC invited 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. Further, NRC cautioned that comments on EPA's proposal (e.g., the dose limit) should be directed to EPA, and that NRC was requesting comments only on those provisions of Part 63 that it proposed to

change. NRC received 16 individual comment submittals, many of which contained numerous specific comments. Additionally, many more submissions were received (over 3000) that had identical or nearly identical text. In preparing the final rule, the NRC staff carefully reviewed and considered the range of comments received during the public comment period. To simplify the analysis, the NRC staff grouped the comments on the rule into the following five major topic areas: (1) "NRC Adoption of EPA Standards," (2) "Clarifications on NRC's Implementation of FEPs for the Performance Assessment for the Period after 10,000 Years," (3) "Climate Change," (4) "Use of Current Dosimetry," and (5) "Comments Beyond the Scope of this Rulemaking."

The staff has developed detailed responses regarding its specification of a value for climate change and use of specific weighting factors for calculating worker doses. For those comments raising issues that were either EPA's responsibility (e.g., dose limit) or not relevant to the proposed changes (e.g., the difference between reasonable assurance and reasonable expectation), the staff has provided some perspective on the specific issue in the response to comments. The staff considers the approach taken by EPA to be reasonable and protective of public health and safety and the environment. A discussion of the staff's review and consideration of the public comments is contained in the Federal Register Notice (Enclosure 1).

STRATEGIC PLAN GOALS:

The rule amendments in the final rule will protect public health and safety and the environment at the time of peak dose. The amendments will also enhance effectiveness and efficiency to the licensing process for the proposed repository. The amendments clarify the assumptions DOE must use in assessing repository system performance after 10,000 years and provide for use of current weighting factors for calculating radiological doses.

RECOMMENDATIONS:

That the Commission:

1. Approve, for publication in the *Federal Register*, the notice of final rulemaking (found in Enclosure 1).
2. To satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605 (b), certify that this rule, if promulgated, will not have significant impact on a substantial number of small entities. This certification is included in the attached Federal Register Notice.
3. Note:
 - a. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);
 - b. That a Regulatory Analysis has been prepared for this rulemaking (Enclosure 2);

- c. That the staff has determined that this action is not a “major rule,” as defined in the Congressional Review Act of 1996 [5 U.S.C 804(2)] and has confirmed this determination with OMB. The appropriate Congressional and Government Accountability Office contacts will be informed;
- d. That the appropriate Congressional committees will be informed;
- e. That a press release will be issued by the Office of Public Affairs, when the final rulemaking is filed with the Office of the Federal Register; and
- f. That no OMB review, under the Paperwork Reduction Act, is required, because the final rule amendment does not contain new nor amended information collection requirements subject to the Paperwork Reduction Act of 1995.

RESOURCES:

To complete and implement the rulemaking, less than 1 full-time equivalent position will be required. Although this rulemaking was not planned or budgeted for FY2009 due to delays in EPA’s rulemaking, the staff will reprogram existing resources to complete the rulemaking in FY2009. This activity will be funded through the Nuclear Waste Fund.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA Martin J. Virgilio for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

- 1. Federal Register Notice
- 2. Regulatory Analysis

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