UNITED STATES COURT OF APPEALS
FOR DISTRICT OF COLUMBIA CIRCUIT

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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

STATE OF NEVADA, Petitioner, v. UNITED STATES NUCLEAR REGULATORY COMMISSION, Respondents.	)	Case No. 09- 09-1133

PETITION FOR REVIEW

1. Notice is hereby given this the 11th day of May, 2009, that petitioner State of Nevada petitions the United States Court of Appeals for the District of Columbia Circuit for review of the attached final rule of the respondent entitled "Implementation of a Dose Standard After 10,000 Years," signed by Annette L. Vietti-Cook, Secretary of the United States Nuclear Regulatory Commission (NRC), on March 9, 2009, and published in the Federal Register (74 Fed. Reg. 10811-10830) on March 13, 2009 (the "2009 NRC Yucca Mountain Rule").

2. NRC adopted the 2009 NRC Yucca Mountain Rule pursuant to its authority to adopt technical requirements and criteria under section 121(b) of the Nuclear Waste Policy Act, as amended ("NWPA"), 42 U.S.C. § 10141(b), which in turn references the NRC's authority under the Atomic Energy Act of 1953 ("AEA"), 42 U.S.C. § 2011, *et seq.*, and the Energy Reorganization Act of 1974, 42 U.S.C. § 5801, *et seq.*

3. Section 801 of the Energy Policy Act of 1992 ("EnPA," Public Law No. 102-486, Title VIII, § 801) provides further direction to NRC in its adoption of technical requirements and criteria under NWPA section 121(b) for the proposed high-level nuclear waste repository at Yucca Mountain, Nevada.

4. Section 801(b)(1) of EnPA directs the NRC to "modify its technical requirements and criteria under section 121(b)" of NWPA "as necessary, to be consistent with" the Environmental Protection Agency's (EPA's) public health and safety standards for radiation releases at Yucca Mountain adopted under EnPA section 801(a).

5. An earlier version of NRC's regulations governing Yucca Mountain, 10 C.F.R. Part 63, was published in the Federal Register

(66 Fed. Reg.55732) on November 2, 2001 ("2001 NRC Yucca Mountain Rule"). In *Nuclear Energy Institute v. Environmental Protection Agency*, 373 F.3d 1251 (D.C. Cir. 2004), this Court vacated in part both the 2001 NRC Yucca Mountain Rule and the 2001 EPA Yucca Mountain Rule (40 C.F.R. Part 197) that NRC had incorporated into its 2001 rule.

6. On October 15, 2008, EPA published in the Federal Register its final "Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada" (73 Fed. Reg. 61257), amending the standards it had earlier set under 40 C.F.R. Part 197 ("2009 EPA Yucca Mountain Rule"). Petitioner State of Nevada has petitioned this Court to review the 2009 EPA Yucca Mountain Rule in an action pending in this Court (*State of Nevada v. Environmental Protection Agency*, Case No. 08-1327).

7. Petitioner has commenced this action because the 2009 NRC Yucca Mountain Rule fails to comply with applicable laws, including the NWPA, the AEA, and EnPA, and thereby fails to protect public health and safety in connection with the proposed Yucca Mountain Repository. The 2009 NRC Yucca Mountain Rule is also arbitrary, capricious, an abuse of discretion, and not in

accordance with the law, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(A)(2).

8. Venue for this petition properly lies in this Court pursuant to NWPA section 119(a)(2), 42 U.S.C. 10139(a)(2). Pursuant to 28 U.S.C. §§ 1391, 2343, venue additionally lies in this Court, based upon the legal residence and headquarters of respondent, and the location of a substantial part of the events and omissions by respondents giving rise to the claim, within the District of Columbia.

9. Petitioner requests as relief that the Court: (a) declare that the 2009 NRC Yucca Mountain Rule is arbitrary and capricious, an abuse of discretion and otherwise inconsistent with applicable law; (b) hold unlawful and set aside the 2009 NRC Yucca Mountain Rule; (c) stay application and enforcement of the 2009 NRC Yucca Mountain Rule pending resolution of this petition; and (d) grant such other and further relief as may be appropriate.

Dated: May 11, 2009

Respectfully submitted,

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Rules and Regulations

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

RIN 3150–AH68

[NRC–2005–0011]

Implementation of a Dose Standard After 10,000 Years

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations governing the disposal of high-level radioactive wastes in a proposed geologic repository at Yucca Mountain, Nevada. The final rule implements the U.S. Environmental Protection Agency's (EPA's) revised standards for doses that could occur after 10,000 years, but within the period of geologic stability. The final rule also specifies a range of values for the deep percolation rate 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 EPA is using for calculating individual doses to members of the public.

DATES: *Effective Date:* This final rule is effective on April 13, 2009.

ADDRESSES: Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), Room O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents and information on this rulemaking can be accessed at the Federal rulemaking portal, *http://regulations.gov* by searching on rulemaking docket ID: NRC–2005–0011.

Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.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 (800) 397–4209, (301) 415–4737, or by e-mail to *pdr.resource@nrc.gov*.

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SUPPLEMENTARY INFORMATION:

I. Background
II. Implementation of the Environmental Protection Agency's Final Standards for a Compliance Period Beyond 10,000 Years and Within the Period of Geologic Stability
III. Public Comments and Responses
1. NRC Adoption of EPA Standards
2. Clarifications on NRC's Implementation of Features, Events, and Processes for the Performance Assessment for the Period After 10,000 Years
3. Climate Change
4. Use of Current Dosimetry
5. Comments Beyond the Scope of This Rulemaking
IV. Summary of Final Revisions
V. Agreement State Compatibility
VI. Voluntary Consensus Standards
VII. Finding of No Significant Environmental Impact: Availability
VIII. Paperwork Reduction Act Statement
IX. Regulatory Analysis
X. Regulatory Flexibility Certification
XI. Backfit Analysis
XII. Congressional Review Act

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 (EnPA), Public Law 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 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 (DC Cir. 2004) (*NEI* v. *EPA*). 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* 373 F.3d at 1270. The NAS recommended 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 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.

EPA's Proposed Rule

In response to the remand, EPA proposed revisions (70 FR 49014; August 22, 2005) to elements of its standards affected by the court's decision. EPA proposed to revise 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] standards for 10,000 years after disposal, and added a 3.5 mSv (350 mrem) standard for the period after 10,000 years, but 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, based 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 still retained as the compliance measure for the first 10,000 years after disposal.

EPA also proposed to define how DOE should incorporate features, events, and processes (FEPs) in the performance assessment for the period after 10,000 years. EPA explained that the goal of the performance assessment "is to design an assessment that is a reasonable test of the disposal system under a range of conditions that represents the expected case, as well as relatively less likely (but not wholly speculative) scenarios with potentially significant consequences. The challenge is to define the parameters of the assessment so that they demonstrate whether or not the disposal system is resilient and safe in response to meaningful disruptions, while avoiding extremely speculative (and in some cases, fantastical) events." (70 FR 49048; August 22, 2005). 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 constraints on DOE's performance assessments for the post-10,000 year period. These are:

(1) Seismic analysis may be limited to the effects caused by damage to the drifts in the repository and the failure of the waste packages;

(2) Igneous analysis may be limited to the effects of a volcanic activity event directly intersecting the repository, and 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;

(3) Climate change analysis may be limited to the effects of increased water flow through the repository as a result of climate change, and that the nature and degree of climate change may be represented by sampling within a range of specified constant conditions; and

(4) DOE must assess the effects of general corrosion on engineered barriers and may use a constant representative corrosion rate throughout the period of geologic stability, or a distribution of corrosion rates correlated to other repository parameters.

With respect to climate change, EPA further proposed that NRC shall specify in regulation the values to be used to represent climate change, such as temperature, precipitation, or infiltration rate of water.

Finally, in its definition of "effective dose equivalent" EPA proposed that DOE calculate annual committed effective dose equivalents using the weighting factors that would be incorporated in its regulations in a new Appendix A to 40 CFR Part 197. EPA believes this reflects the most recent application of current radiation science to the calculation of dose.

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 3.5 mSv/year (350 mrem/year) and statistical measure for compliance directly into its regulations for individual protection and human intrusion. Also, NRC proposed to adopt specific constraints EPA proposed for considering FEPs after 10,000 years. NRC proposed to revise its requirements 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, NRC proposed to specify, in its regulation, steady-state (constant-in-time) values that DOE should use to project the long-term impact of climate variation. NRC proposed that DOE represent future climate change in the performance assessment by sampling 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].

NRC's notice of proposed rulemaking invited comments on its proposal to implement 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 values for climate change. NRC requested comments only on those provisions of Part 63 that NRC proposed to change and noted that its existing regulations were not affected by this rulemaking except insofar as NRC's proposed rule adopts more up-to-date dosimetry for dose calculations. NRC notified potential commenters that comments on EPA's revised standards should be directed to EPA. 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).

II. Implementation of the Environmental Protection Agency's Final Standards for a Compliance Period Beyond 10,000 Years and Within the Period of Geologic Stability

EPA's Final Rule

EPA published final "Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada," for the period after 10,000 years at 40 CFR Part 197 on October 15, 2008 (73 FR 61256). EPA has finalized its proposals relating 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 rule differs from its proposal in two respects: the dose limit and the consideration of seismic activity.

First, the EPA 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 EPA 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 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 the 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 the water table rise and its significance in terms of repository performance in its license application.

NRC's Final Rule

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 final rule achieves this consistency by incorporating the revised standards into its final revised 10 CFR Part 63 regulations as transparently as possible. A brief description of the Commission's implementation of EPA's standards follows:

(1) For the period after 10,000 years and within the period of geologic stability (up to 1 million years), NRC adopts EPA's 1.0 mSv/year (100 mrem/year) dose limit for the RMEI in both the individual protection standard at 10 CFR 63.311 and the human intrusion standard at 10 CFR 63.321.

(2) NRC 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.

(3) NRC 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. NRC 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 rulemaking, decides to specify the magnitude of the water table rise to be used in the performance assessment after 10,000 years or to not require its consideration.

(4) NRC 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, NRC chooses not to add the proposed definition for "weighting factor" to its regulations nor to amend § 63.111(a)(1). Instead, NRC is providing a discussion regarding implementation of total effective dose equivalent (TEDE). NRC is adding text at § 63.102(o) to clarify 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. (*See* response to comments under Use of Current Dosimetry, in this document.)

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 final rule adopts its proposed approach with some modifications. NRC will require 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. The constant-in-time value to be used to represent climate change is to be the spatial average of the deep percolation rate within the area bounded by the repository footprint. The constant-in-time deep percolation rates to be used now to represent climate change shall 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). This "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 in./year) based on the range and distribution in the proposed regulations. (See response to comments under Climate Change, in this document for further details on this approach and the consideration of public comments.)

For a full description of changes NRC is incorporating into its Part 63 regulations, see Section IV of this document.

Water Table Rise From Seismic Activity

NRC currently requires DOE to demonstrate the magnitude of the water table rise from seismic activity and its significance in its license application. The National Research Council (1992) conducted a comprehensive technical evaluation of mechanisms that could raise the water table at Yucca Mountain (National Research Council, *Ground Water at Yucca Mountain: How High Can It Rise?*, National Academy Press, Washington, DC, 1992). The Council considered both the dynamic response of the water table to propagation of seismic waves, as well as the long-term hydrologic response of the ground water system to permanent changes in rock stress after the seismic waves pass. The Council concluded that transient effects are not relevant to the performance of a repository. Of potential significance, however, are permanent changes to the

fluid pore pressure or rock permeability that may bring about long-term changes in the height of the water table. The report's authors evaluated historical accounts of relevant large earthquakes that have caused long-term changes to the regional hydrologic regime of ground water systems. The authors conducted site-specific quantitative analyses of the potential change in the level of the water table. They concluded that "although the models are based on very limited data * * * [the] stress/strain changes resulting from an earthquake are inadequate to cause more than a few tens of meters rise in the water table based on the convergence of the results by a variety of models and assumptions, especially if the deep carbonate aquifer is as incompressible as the limited data suggest." Whatever approach DOE takes when determining the magnitude of the water table rise from seismic activity, NRC expects that DOE will consider the information provided by the National Research Council as referenced in the National Academy of Sciences report entitled, "Technical Bases for Yucca Mountain Standards" (1995) at page 94 (*i.e.*, "Results indicate a probable maximum transient rise on the order of 20 m or less").

Although EPA standards specify that NRC may determine the magnitude of water table rise and its significance, NRC is not planning such action. If, in the future, NRC decides to specify the magnitude of the water table rise and whether it is significant enough for consideration in DOE's performance assessment, NRC will do so in a future rulemaking.

III. Public Comments and Responses

The NRC received 16 individual comment submittals, many of which contained numerous specific comments. In addition, NRC received more than 3000 submissions objecting, in nearly identical text, to NRC's adoption of EPA's standards because the commenters believed the proposed standards are inadequate and because NRC published its proposed revision to Part 63 before EPA issued final standards. NRC carefully reviewed and considered the range of comments received during the public comment period. The NRC staff grouped the comments 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.

1. NRC Adoption of EPA Standards

Issue 1: Must NRC supplement EPA's standards because they do not adequately protect public health and safety and the environment?

Comment. Some commenters supported NRC's adoption of EPA's standards, while others opposed adoption because they believe EPA's proposed standards are inadequate to protect public health and safety and the environment. The State of Nevada recognized that EnPA requires NRC's regulations to be consistent with EPA's standards but claims this does not mean the two must be identical. Rather, the State asserts, NRC must recognize that compliance with EPA's standards is necessary but not sufficient to provide adequate protection of public health and safety and the environment. The State also asserts that NRC should promulgate supplemental standards, in its regulations, that will provide the additional protection the State believes is needed. With respect to EPA's proposed standards, the State and other commenters particularly objected to EPA's 3.5 mSv/year (350 mrem/year) post-10,000 year standard and use of the median to assess compliance. The State and other commenters also objected to many other features of the EPA standards, including limitations on the FEPs, use of a two-tier standard, and defining the period of geologic stability as ending at 1 million years. In support of its comments, the State attached a copy of the comments on the EPA proposed standards it had submitted to EPA.

Response. While EnPA does not require NRC regulations to be identical to EPA's, EnPA does direct the Commission to modify its technical criteria to be consistent with EPA's standards for a geologic repository at the Yucca Mountain site. Thus, NRC is required to adopt EPA's post 10,000 year standard, and the NRC has done so. The NRC's notice of proposed rulemaking notified potential commenters that comments such as these on EPA's revised standards should be directed to EPA for EPA's response.

Issue 2: Should NRC extend the compliance period beyond 1 million years if it is determined that the peak dose may occur beyond the 1 million-year period?

Comment. The State commented that EPA's requirement that the post-10,000 year performance assessment should end at 1 million years is unnecessarily prescriptive. The State believes that if the trends in dose projection are not clear or heading upward and geologic stability is maintained, extending the assessment beyond 1 million years may be required to establish the performance of the entire repository system. The State believes that NRC has the authority to consider not only the magnitude of the peak, but also the timing and overall trends of dose projections as it evaluates the license application.

Response. As explained in the response to the comment on Issue 1 under NRC Adoption of EPA Standards of this document, EnPA requires the Commission to modify its technical criteria to be consistent with EPA's standards for a geologic repository at the Yucca Mountain site. The NRC's notice of proposed rulemaking notified potential commenters that comments such as these on EPA's revised standards should be directed to EPA for EPA's response.

Issue 3: Has NRC illegitimately used rulemaking to resolve issues that must be resolved in an adjudicatory proceeding?

Comment. The State of Nevada commented that the proposed rule violates fundamental principles of administrative law because it fails to conform to the usual distinctions in agency administrative processes between "rulemaking" and "adjudication." This is because the rule includes what the commenter believes to be "determinations of adjudicative fact" that apply only to Yucca Mountain and that should be matters adjudicated in NRC's hearing on DOE's license application. According to the commenter, there are two critical distinctions between rulemaking and adjudication: "First, a rule addresses the future while an order [the product of adjudication] addresses the past or the present. Second, a rule is based on general policy considerations or on what are sometimes called legislative facts, generalizations about people and things, while an order is based on specific facts about things and individuals, sometimes called adjudicative facts." The commenter believes that the proposed rule violates this distinction because "[n]o agency may resolve a controversy over an adjudicative fact, relevant only to a single adjudication, by rulemaking." The State further asserts that NRC's alleged improper use of rulemaking to resolve adjudicatory factual issues constitutes an unlawful abrogation of Nevada's right, under section 189 of the Atomic Energy Act of 1954 as amended (AEA), to an NRC licensing hearing on these factual issues.

In the State's view, NRC cannot claim that it is permitted to resolve adjudicatory factual issues in its rulemaking simply because EPA did so and NRC must adopt EPA's standards. The commenter recognizes that the EnPA alters a straightforward demarcation between rulemaking and adjudication because "EnPA does contemplate Yucca 'rules' that by their nature depend on some facts relevant only to Yucca." However, the commenter contends that "EnPA authorized only those EPA findings of adjudicatory fact that (1) are based on what the [National] Academy [of Sciences] considered necessary to support an EPA rule; and (2) are essential to promulgate limits on radiation exposures, concentrations, or quantities beyond the boundary of the Yucca Mountain site." This is because the grant of authority to EPA in EnPA to issue standards applicable only to Yucca Mountain is based on the previous delegation of rulemaking authority to EPA in section 121 of the Nuclear Waste Policy Act of 1982 (NWPA), which, in turn, relies upon the delegation of authorities to EPA in Reorganization Plan Number 3 of 1970 that identifies what standards EPA may issue. The commenter believes that the EPA standards that NRC is adopting are rife with "adjudicative facts" and go well beyond the narrow limits permitted by EnPA.

The commenter cites eight "determinations of adjudicative fact" that appear in NRC's proposed rule, most of which NRC is adopting from EPA's standards:

(1) The performance assessment for the period after 10,000 years must use a time-independent log-uniform probability distribution for deep percolation rates of from 13 to 64 mm/year;

(2) Models and data used to develop FEPs ("features, events and processes") for the assessment period before 10,000 years are sufficient for the post-10,000-year assessment period;

(3) Seismic analyses for the post-10,000 year period may be based on seismic hazard curves developed for the pre-10,000-year period;

(4) Seismic effects in the post-10,000-year period may be limited to effects on the repository's drifts and waste packages;

(5) Igneous effects in the post-10,000 year period may be limited to effects on waste packages;

(6) The effects of climate change in the post-10,000-year period may be limited to increased water flux through the repository;

(7) Different types of corrosion of the waste packages must be considered in the pre-10,000-year period but only general corrosion at a constant rate may be considered in the post-10,000-year period; [1] and

(8) Effects of climate change in the post-10,000-year period may be expressed by steady state (time independent) values.

Response. The Commission disagrees with the comment. "It is a well-settled principle of administrative law that the decision whether to proceed by rulemaking or adjudication lies within the broad discretion of the agency. *See, SEC* v. *Chenery Corp., 332 U.S. 194, 202–03 (1947)*" *Wisconsin Gas Company* v. *Federal Energy Regulatory Commission,* 770 F.2d 1144, 1166 (DC Cir. 1985). The Commission has properly exercised its discretion to resolve the issues referenced by the commenter through rulemaking rather than through adjudication.

The commenter mischaracterizes as "determinations of adjudicative fact" what are in reality assumptions, derived from data, testing, and scientific analysis, that DOE is to use in its performance assessment to demonstrate compliance with regulatory standards. A performance assessment is used to take account of the considerable uncertainties inherent in projecting disposal system performance over times as long as 1 million years. The performance assessment is not intended to resolve issues arising in the past or present. Rather, it is intended to provide a reasonable test of the safety of the repository by modeling through computer simulations a large number of "alternative futures," incorporating the features, events, and processes required by the rule to be included in the assessment to determine if there is a reasonable expectation that the disposal system will meet regulatory standards. The assumptions identified by the commenter impose certain limitations on the scope of the performance assessments. These limitations are based on the application of scientific reasoning to data, testing, and analysis at hand on these issues and are for the purpose of enabling a reasonable test of repository safety.

NRC has made a policy judgment that rulemaking is the better procedural vehicle to use to determine how the performance assessments should be constructed and, in particular, what limitations are appropriate to avoid unbounded speculation and to provide a reasonable test of repository safety. How this testing should be conducted is preeminently a matter of scientific and technical analysis. To the extent that there may be disagreement in the scientific community as to the scientific soundness of the assumptions and any limitations on assumptions to be incorporated into the performance assessments, the notice and comment rulemaking process is of particular value because it allows equal access to all viewpoints and best assures achievement of the ultimate goal of making sure that the testing of the safety of the repository rests on the best science available. The determination of what assumptions and limitations on assumptions are best suited to form a reasonable test is not aimed at determining the rights or liabilities of particular individuals and thus, the adjudicatory process is not conducive to selecting the ingredients of the tests used to provide a reasonable expectation of repository safety.

Because neither EPA nor NRC have made "determinations of adjudicative fact," as explained above, the question of the extent of EPA's authority under EnPA to establish standards through rulemaking that the commenter believes would otherwise be determinations of adjudicative fact does not arise. EPA has adequately addressed its jurisdiction to issue the standards that NRC is adopting in this final rule.

The commenter may also be asserting that all the issues in this rulemaking are adjudicatory issues simply because the rule applies to only one entity, DOE, and the licensing of a repository at one site. A "rule," as defined in the Administrative Procedure Act, "means the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy" 5 U.S.C. 551(4) (emphasis added). Thus, the fact that NRC's rule applies only to DOE and only to DOE's activities at one site does not, per se, turn the issues considered in this rulemaking into adjudicative issues determining adjudicative facts (*See Attorney General's Manual on the Administrative Procedure Act,* 1947, p. 13 ("[R]ule" includes agency statements not only of general applicability but also those of particular applicability applying either to a class or to a single person"); *Anaconda Company* v. *Ruckelshaus,* 482 F.2d 1301, 1306 (10th Cir. 1973)).

The cases cited by the commenter, *Heckler* v. *Campbell,* 461 U.S. 458 (1983), *Broz* v. *Heckler,* 711 F.2d 957 (11th Cir. 1983) (*Broz II*), and *Opinion Modified on Denial of Rehearing by Broz*

[1] The rule does not, in fact, restrict consideration of corrosion in the post-10,000 year period to general corrosion; other types of corrosion, if important, will be carried over from the pre-10,000 year period and will also be considered.

v. *Heckler*, 721 F.2d 1297 (11th Cir. 1983) (*Broz III*), in support of its view that NRC may not make "determinations of adjudicatory fact" in a rulemaking are similarly not relevant because no such determinations are being made in the final rule. These cases do not establish the broad principle stated by the commenter; *i.e.*, that "[n]o agency may resolve a controversy over an adjudicative fact, relevant only to a single adjudication, by rulemaking." In *Heckler* v. *Campbell*, the Supreme Court upheld the Secretary of Health and Human Service's (HHS) reliance on rulemaking to establish guidance for the determination that jobs existed in the national economy within the capability of the disabled claimant against a claim that such a determination must be made in an individual adjudication. *Broz* considered the same guidance with respect to its application to the effect of age on disability determinations. Ultimately, in *Broz III*, the Eleventh Circuit of the U.S. Court of Appeals based its decision that this must be an individualized determination reached in an adjudication on its interpretation of Congress' intent in amending the Social Security Act (SSA) rather than on more sweeping statements about an agency's choice to use rulemaking or adjudication to achieve its mission.[2] Finally, the Commission does not agree that resolving the issues the commenter has labeled "determinations of adjudicative fact" deprives the State of its right to a hearing under section 189a. of the AEA on these issues. As the Supreme Court has stated, "the statutory requirement for a hearing * * * does not preclude the Commission from particularizing statutory standards through the rulemaking process and barring at the threshold those who neither measure up to them nor show reasons why in the public interest the rule should be waived" (*Federal Power Commission* v. *Texaco, Inc.*, 377 U.S. 33, 39 (1964)).[3]

The commenter also believes that, as explained in its comments to EPA, EPA's "findings of adjudicative fact," in its final rule, now being adopted in NRC's final rule, are without any technical basis and are contrary to sound science, and for that reason violate both EnPA and the AEA. The NRC's notice of proposed rulemaking notified potential commenters that comments such as these on EPA's revised standards should be directed to EPA for EPA's response.

Issue 4: Should NRC have waited to propose its regulations until after EPA had finalized its standards?

Comment. A number of commenters objected to the process NRC used to conduct this rulemaking, namely issuing a proposed rule adopting EPA's proposed standards before EPA issued its final standards. Commenters expressed the view that NRC conveyed the impression that EPA's proposed standards would be adopted in NRC's final rule, such that public comment on EPA's proposal would have no effect; that if NRC cared what potential commenters thought about EPA's proposal, it should have waited, considered the comments received by EPA, and developed NRC's rule based on EPA's final rule; that having the public comment period for both rules at the same time is confusing for concerned citizens and makes it difficult for them to comment on the NRC rule; and that NRC should provide an additional comment period on its rule if EPA's final rule departs substantially from its proposed rule.

Response. NRC's process for conducting this rulemaking was intended to put in place revised regulations, consistent with EPA's final revised standards, because the court had vacated NRC's rule insofar as it incorporated EPA's 10,000 year compliance period. NRC also sought to inform potential commenters on both rules, of how NRC envisioned implementing the EPA's proposed standards. It was hoped that such information would be of value in developing comments on both proposals. NRC's intention has always been, consistent with its statutory obligations, to conform its final regulations to the final standards EPA would issue after EPA duly considers the comments it received.

NRC emphasized in its notice of proposed rulemaking that comments on EPA's revised standards were to be addressed to EPA and that the scope of NRC's revised rule was limited to its adoption of EPA's revised standards, its proposal to allow DOE to use the same methods for calculating doses to workers during the operational period as those required for calculating public doses and its proposal to specify use of a deep percolation rate to represent the effect of future climate in performance assessments after 10,000 years. Thus, the narrow focus of NRC's rulemaking only required potential commenters to focus on two technical issues beyond the issues involved in EPA's proposal (*i.e.*, setting a value for the deep percolation rate and use of modern dosimetry for estimating worker exposures). NRC extended the comment period by one month in response to public comments. For these reasons, we believe the public was given a fair opportunity to comment on NRC's proposal. NRC regrets any misimpression that NRC was assuming that EPA's proposed rule would become final as proposed without modification and that comments provided to EPA would have no effect. NRC made no such assumption and EPA has in fact made changes to its proposed rule in light of the comments it received.

Finally, with respect to the request for an additional comment period if EPA's final rule is substantially different from its proposed rule, as stated above (*see* Background section of this document), EPA's final rule differs from its proposed rule in only two respects: the dose limit is set to 1.0 mSv/year (100 mrem/year) with the arithmetic mean as the statistical metric to be used to assess compliance; and its requirement that NRC either establish the magnitude of the water table rise and its significance as part of the seismic assessment, or require DOE to do this assessment. The first change responds favorably to the numerous public comments urging use of a dose limit lower than 3.5 mSv/year (350 mrem/year) and use of the arithmetic mean as the measure of compliance. Similarly, in its final regulations, NRC requires DOE to include the magnitude of the water table rise and its significance in its seismic assessment submitted with the license application. As a result, this information would also be subject to litigation, absent any future NRC rulemaking on this subject. Because of these changes, the Commission believes there is no need for an additional comment period.

[2] The Eleventh Circuit initially construed the provisions of the SSA in terms of the distinction between adjudicative facts and legislative facts and concluded that the effect of age on disability was an adjudicative fact that could not be determined in a rulemaking. *Broz* v. *Schweiker*, 677 F.2d 1351 (11th Cir. 1982) (*Broz I*) *Certiorari Granted, Judgment Vacated by Heckler* v. *Broz*, 461 U.S. 952 (1983). Upon remand for reconsideration in light of *Campbell*, the Eleventh Circuit, in *Broz II*, reaffirmed its original decision upon finding that the Supreme Court had left open the validity of the guidance with respect to its use in determining the effect of age on disability.

[3] The commenter believes that the rules which resolve these issues will be incapable of actually being applied as written because they will turn out to be based on outdated scientific evidence. If this should happen, any person can petition to amend the rules. In addition, NRC's procedural rules enable a party to an adjudicatory proceeding to petition that application of a rule be waived in circumstances when the rule would not serve the purposes for which it was adopted. See, 10 CFR 2.335(b).

2. Clarification of NRC's Implementation of FEPs for the Performance Assessment for the Period After 10,000 Years

Issue 1: Are the FEPs considered for the first 10,000 years after repository closure the *only* FEPs that need be considered for the entire post-closure period?

Comment. The Nuclear Energy Institute (NEI) agreed with NRC's adoption of EPA's requirement that the same FEPs identified and screened for inclusion in performance assessments to show compliance with the standards for the initial 10,000 years after closure be used in performance assessments to show compliance with the post-10,000 year standards. However, NEI believes NRC should clarify that FEPs that are screened-in for the first 10,000 years after repository closure are the only FEPs that need be considered for the entire post-closure period. NEI provided the example that if DOE provides an adequate basis to screen-out post-closure criticality or microbially-influenced corrosion (MIC) effects during the first 10,000 years after repository closure, the Yucca Mountain Review Plan (YMRP) should specify that no additional consideration of criticality or MIC in the post-10,000 year period is necessary.

Response. The requirements for FEPs to be included in the performance assessment for the period after 10,000 years are specified at § 63.342. DOE is required to include those FEPs that are screened into the performance assessments for the first 10,000 years after repository closure *and* the four FEPs specifically identified for inclusion, *i.e.*, seismicity, igneous activity, climate change, and general corrosion. Based on the requirements at § 63.342, the specific FEPs (criticality or MIC) identified by the commenter would only be included in the performance assessment after 10,000 years if they were also included in the performance assessment for the first 10,000 years (i.e., could not be screened out of the performance assessment for the first 10,000 years). The Commission does not believe further clarification to the regulation is necessary.

Issue 2: Do the proposed changes to § 63.114 "Requirements for performance assessment" impose additional limits on the performance assessment for the period after 10,000 years?

Comment. The State of Nevada believes that § 63.114(b) appears to include another limit beyond the limits in § 63.342(c) on the post-10,000 year performance assessment and asks for clarification. NEI believes that NRC should more clearly assert that performance assessment methods meeting existing Part 63 requirements are also adequate for the post-10,000 year period.

Response. The changes to § 63.114 impose no additional limits on the performance assessment for the period after 10,000 years. The changes ensure consistency between NRC's regulations and EPA's final standards. In particular, EPA's final standards specify that FEPs used for the first 10,000 years should be used for estimating performance after 10,000 years. Thus, § 63.114(b) specifies that the same performance assessment methods used for the first 10,000 years are to be used for the period after 10,000 years. For example, parameter ranges used in the performance assessment for the first 10,000 years would be used in the performance assessment for the period after 10,000 years. Additional technical basis for selection of FEPs, beyond that developed for the performance assessment for the first 10,000 years, is not required. Thus, the changes at § 63.114 ensure the performance assessment methods, such as the support and treatment of FEPs will be the same for the periods before and after 10,000 years, subject to the limits on performance assessments at § 63.342. Some minor revisions have been made to § 63.114(b) to further clarify the Commission's intent.

Issue 3: Does the proposed treatment of a potential igneous event during the period after 10,000 years limit consideration of the effects of magma on spent fuel?

Comment. The State of Nevada commented that the proposed regulation at § 63.342(c)(1)(ii) specifies that the effects of an igneous event are limited to the effects of damage directly to the waste package. The State is concerned that NRC will not consider the effects of magma on the radioactive waste inside the waste package. The State asserts that effects on the contents of the waste package could be important for igneous events that occur at times after waste packages are already breached because of other processes (such as corrosion) and the radioactive waste may be more vulnerable to igneous events.

Response. The regulations do not exclude consideration of the spent fuel in the treatment of a potential igneous event during the period after 10,000 years. The rule, at § 63.342(c)(1)(ii), requires the igneous analysis to include damage to the waste package directly. *Waste package* is defined in § 63.2 to mean "the waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container" and *waste form* is defined in the same section to mean "the radioactive waste materials and any encapsulating or stabilizing matrix." Thus, consideration of damage to the waste package would include consideration of damage to the radioactive waste materials inside the waste package.

Issue 4: Should the seismic analysis exclude seismic activity from magma movement?

Comment. NEI agreed with NRC's proposal to limit analysis of long-term effects of seismicity to effects on the drifts in the repository and the waste package but requested that NRC clarify that seismic activity from magma movement need not be considered in the analysis. NEI suggests such a limitation is appropriate based on an Electric Power Research Institute (EPRI) analysis that demonstrates that seismic activity induced from magma movement is very minor, compared to seismic activity caused by tectonism.

Response. Seismic activity includes activity from both tectonism and magma movement. Current methods to develop and quantify seismic ground motions, such as DOE's current Probabilistic Seismic Hazard Assessment, include consideration of seismic activity from volcanism or magma movement. Volcanic sources of seismic activity are often included as part of the background seismic source term. Therefore, the commenter's request for clarification, which would exclude seismic activity caused by magma movement from the seismic analysis, is not appropriate.

Issue 5: Should NRC's rule set a requirement for assuring the statistical significance of DOE's modeling results in its performance assessments?

Comment. The State of Nevada stated that NRC's rule should establish a requirement for DOE to prove mathematically that its modeling results are statistically significant (*i.e.*, a sufficient number of "runs" or the set of probabilistic simulations used to simulate the wide range of possible future behaviors of the repository system have been performed).

Response. The current regulations provide specific requirements at § 63.114 for the performance assessment. Among these, for example, are proper consideration of uncertainty and variability in parameter values. The Commission believes it is neither necessary nor appropriate to further specify measures of statistical significance. Fundamental to any approach for representing uncertainty and variability is demonstrating how the results accurately represent the uncertainty and variability, for example,

by performing a sufficient number of probabilistic simulations. Determining what number of "runs is sufficient" is best left for DOE to present and defend, based on the approach used in the performance assessment and an understanding of the results. NRC is confident that its regulations for performance assessment require DOE to provide sufficient information for NRC to judge if DOE has performed enough probabilistic simulations.

Issue 6: Will FEPs associated with atmospheric releases of radioactivity and exposure of residents downwind of Yucca Mountain be considered in the performance assessment for the period after 10,000 years?

Comment. Two commenters expressed concern over how FEPs associated with atmospheric releases of radioactivity and exposure of residents downwind of Yucca Mountain will be considered in the performance assessment for the period after 10,000 years, including FEPs associated with seismic and igneous FEPs.

Response. The performance assessment for the period after 10,000 years must include consideration of potential atmospheric releases of radioactivity. The NAS report, *Technical Bases for Yucca Mountain Standards* (1995), pp. 6–7, recommended that the exposure scenario be specified in the standards because of the difficulties in projecting where people may reside and how exposures might occur in the distant future (*e.g.*, thousands to hundreds of thousands of years in the future and longer). Accordingly, EPA specified characteristics of the RMEI (66–FR 32134; June 13, 2001).

Issue 7: Does the fact that the limitations on FEPs in the performance assessments are being established through rulemaking rather than adjudication, based on data available in 2005, mean that there will be no flexibility to take into account data and models used in DOE's license application or that DOE will have no incentive to further reduce uncertainties?

Comment. The State of Nevada believes that the assumptions being used to account for uncertainty in the post-10,000 year period, and which are incorporated through this rulemaking into the limitations on the FEPs to be considered in DOE's performance assessments, are premature and render the rule inflexible because they are based on data available in 2005. NRC's rules must be sufficiently flexible to take into account data and models used in DOE's license application. The State fears that because the rules are premised on uncertainties as perceived through 2005 data and models, DOE will have a disincentive to reduce these uncertainties and add realism to its post-10,000 year performance assessment because it will wish to preserve the uncertainties and conservatisms that form the basis for the rules.

Response. NRC's regulations afford DOE the flexibility to account for uncertainty in data and models. Such flexibility provides neither incentive nor disincentive to reduce uncertainties. The regulations, at § 63.114, require DOE to account for the uncertainties in data and models in the performance assessment over the initial 10,000 years, and these same uncertainties are to be included in the performance assessment beyond 10,000 years. On June 3, 2008, DOE submitted a license application to NRC for authorization to construct a repository at Yucca Mountain. The NRC will review DOE's treatment of the uncertainties. DOE has the flexibility to decide where to reduce uncertainties; however, it must demonstrate there is a reasonable expectation that the performance objectives will be met. NRC regulations afford DOE appropriate flexibility for selecting and supporting its performance assessment, including the consideration of uncertainties, given the unique and difficult task of estimating performance of a geologic repository over thousands of years.

The regulations do provide certain limitations, as specified in EPA's final standards, with respect to certain FEPs (*i.e.*, seismicity, igneous activity, climate change, and general corrosion). Uncertainties in data and models for these FEPs are limited to those aspects of the FEPs considered most important to performance and the treatment of the uncertainties used in the performance assessment for the initial 10,000 years (see also the response to Issue 2 under this topic). For example, the consideration of seismic events in the performance assessment for the period after 10,000 years would be based on the same seismic hazard curve, including its uncertainties, that was used in the performance assessment for the initial 10,000 years. However, the analysis for the period after 10,000 years would only consider the aspects of the seismic events that might be the most important to repository performance (i.e., damage to the drifts in the repository, failure of the waste package, and magnitude of the water table rise under Yucca Mountain).

Finally, the commenter believes that the rules which resolve these issues will be incapable of actually being applied as written because they will turn out to be based on outdated scientific evidence. If this should happen, any person can petition to amend the rules. In addition, NRC's procedural rules enable a party to an adjudicatory proceeding to petition that application of a rule be waived in circumstances when the rule would not serve the purposes for which it was adopted (*See*, 10 CFR 2.335(b)).

3. Climate Change

Issue 1: Can the future climatic regime be bounded by the observed range of conditions over past glacial-interglacial cycles?

Comment. One commenter indicated it is incorrect to presume that future climate conditions at Yucca Mountain can be bounded by the observed range of conditions over past glacial-interglacial cycles. To the extent this comment may refer to human-induced influences on climate, those influences are considered under a separate issue.

Response. The Commission believes the future climatic regime can be bounded by the observed range of conditions over past glacial-interglacial cycles. All climate predictions are based on and calibrated to evidence of past climates contained in the geologic record. The values specified for deep percolation rates adopted in the final regulation capture the range of temporal variability, uncertainty, and magnitude of deep percolation expected as a consequence of future climate change.

The NAS committee (1995) was familiar with the science behind predicting future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is "unlikely but not impossible," in the next 10,000 years is "probable but not assured." However, over a 1-million-year time frame, the climate is much more likely to pass through several glacial-interglacial cycles (*i.e.*, ice ages). The NAS indicated there is a reasonable data base from which to infer past changes and noted that "(a)lthough the range of climatic conditions has been wide, paleoclimate research shows that the bounding conditions, the envelope encompassing the total climatic range have been fairly stable" and that "(b)ased on this record, it seems plausible that the climate will fluctuate between glacial and interglacial stages during the period suggested for the performance assessment calculations." Further, in its 1995 findings, the NAS stated that "enough of the important aspects [of climate change] can be known within reasonable limits of uncertainty, and these properties and processes are sufficiently understood and stable over the long time scales of interest to make calculations possible

and meaningful, we believe that there is a substantial scientific basis for making such calculations, taking uncertainty and natural variability into account."

Issue 2: Should human-induced influences on climate be considered when bounding the future climatic regime?

Comment. One commenter noted that human-induced (*i.e.*, anthropogenic) influences on climate from fossil fuel combustion and the resulting persistence of greenhouse gases in the atmosphere are the main issues to consider in predicting future climatic conditions. These anthropogenic effects might cause substantial reorganization of atmospheric systems, both before and after 10,000 years, that increase the number and intensity of extreme storm events at Yucca Mountain. The commenter believed that the highly non-linear hydrologic response of an arid system like Yucca Mountain to such extreme events would affect the performance of the repository and invalidate the use of the long-term average climate proposed in the Part 63 revisions. The same commenter also noted that the predictive challenges of simulating these postulated extreme events could be met through use of existing and soon-to-be-available global circulation models (GCMs) that explicitly incorporate atmospheric composition and evolution in predicting future climate conditions. In presuming use of these models, this commenter noted that uncertainties in climate prediction do not change in the period beyond 10,000 years, at least in terms of the range of climate conditions that could occur, but rather that their detailed timing may change. Another commenter speculated that the same anthropogenic climate effects might delay the onset and reduce the magnitude of full glacial cycles, resulting in longer interglacial periods that would be warmer and drier than present-day conditions. Accordingly, this second commenter felt that the use of long-term average climate conditions represented by the values specified for deep percolation rates in the proposed Part 63 revisions was overly conservative and that less water would reach the repository horizon.

Response. NRC considered the effects of anthropogenic influences on climate change. Based on that evaluation, the NRC believes the range of values specified for deep percolation rates adopted in the final rule captures the range of temporal variability, uncertainty, and magnitude of deep percolation expected as a consequence of future climate change.

The magnitude and timing of the anthropogenic effects suggested by the commenter are likely to be more pronounced during the first 10,000 years. The final regulation addresses only the 10,000 to 1 million year time period, during which any anthropogenic effects are anticipated to diminish. Anthropogenic effects, as represented in the GCMs cited by the commenter, might persist for 100,000 year time periods, but they do not fluctuate periodically and they decrease with time after an initial peak. Therefore, NRC believes that these effects can be captured by the long-term average infiltration values adopted in the final regulation because the range of values for the sampled population bounds these effects in an appropriately conservative manner.

Atmospheric reorganization and increased frequency and magnitude of extreme events might result from natural or anthropogenic climate change. However, extreme 10-to 20-year events effectively become long-term averages that are incorporated into the range specified for deep percolation in the final regulation, when simulating a time period of 1 million years.

The Paintbrush non-welded tuff unit (PTn unit) overlying the potential repository dampens the effects of transient phenomena associated with shorter time frames (Manepally, C., *et al.*, "The Nature of Flow in the Faulted and Fractured Paintbrush Nonwelded Hydrogeologic Unit," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, April 2007) in the system's response to external hydrologic events. The NAS also recognized that long-term net infiltration averages can bound and describe Yucca Mountain hydrology adequately, stating that "the subsurface location of the repository would provide a temporal filter for climate change effects on hydrologic processes" The commenter also acknowledged this, quoting Cohen, "no evidence shows that high-frequency fluctuations (a few years or shorter) penetrate to the depth of the potential repository" (Cohen, S., "Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments," S. Cohen & Associates, prepared for U.S. Environmental Protection Agency, August 8, 2005). Flow simulations have shown that the non-welded PTn rock unit effectively damps out decadal flow transients. Also, as the first commenter notes, 'frequent events' are mitigated by evapotranspiration. If high-precipitation events occur more frequently, the concomitant increases in soil formation and vegetation likely will mitigate the potential for increased infiltration, because net infiltration correlates inversely with soil thickness and extent of vegetative cover. Given the expected ratios of infiltration to precipitation, infiltration estimates of 15 to 60 mm (0.6 to 2.4 in.) per event would result if all precipitation were to infiltrate. In reality, a substantial fraction of such high precipitation will run off or evapotranspire. Accordingly, long-term deep percolation as specified in the proposed rule captures these events in an appropriately conservative manner.

The points raised by the second commenter illustrate the divergence of scientific opinions about the nature and magnitude of natural and anthropogenically influenced climate change, particularly at the sub-regional scale necessary for net infiltration predictions at Yucca Mountain. The natural and anthropogenic effects associated with climate change are uncertain at this scale. Predictions will vary in timing, frequency, and magnitude of climatic variables such as temperature and precipitation, and therefore, net infiltration and deep percolation. The first commenter notes that climate change might result in wetter conditions resulting in insufficiently conservative predictions; the second commenter is concerned that conditions at Yucca Mountain might be drier in the future, resulting in overly conservative predictions. The first commenter refers to Cohen (2005) with respect to certain aspects of this issue; however, Cohen (2005) also notes that "(a)nthropogenic climate changes could reduce possibility of future glacial climates, lowering long-term infiltration rates and reducing dose."

In conclusion, the range of uncertainty and variability in predictions of future climate, including that associated with anthropogenic changes, and the resulting deep percolation are captured by the range of values specified in the final regulation.

Issue 3: Is the nature and extent of the future climatic regime reasonably represented by the stylized scenario where constant climate conditions take effect after 10,000 years and continue through the time of geologic stability?

Comment. Some commenters were concerned about the proposed future climate scenario, in which the future climate is represented by constant-in-time conditions that take effect after 10,000 years and continue through the time of geologic stability. The commenter's general concern is that assuming constant conditions may underestimate the hydrologic response at Yucca Mountain by failing to consider explicitly either variable dry and wet periods or changes in soils,

vegetation, and the watershed geomorphic characteristics in performance assessments over the time of geologic stability. Specifically, one commenter states that using constant-in-time infiltration rates is non-conservative because a performance assessment conducted with this assumption would underestimate doses to the RMEI. The stated basis for this conclusion is that transient changes from dry to wet conditions in the repository cause greater radionuclide releases because localized corrosion of the waste packages is more likely under drier conditions. Also the exposed waste form is more likely to be dissolved and radionuclides are more apt to be transported to the biosphere under subsequent wet conditions.

Response. The range and distribution of deep percolation rates adopted in the final regulations appropriately reflect the uncertainty in the area-averaged water flux through the footprint of the potential repository during the period after 10,000 years and are a reasonable basis for estimating and evaluating the long-term safety of the repository.

The range and distribution of deep percolation rates adopted in the final regulation are not, in fact, based on constant climate conditions. The technical bases for the deep percolation range subsume time-variant climate conditions, whose future periodicity and magnitude are based on and calibrated to the range of conditions preserved in the geologic record, which includes geomorphic changes. In addition, the hydrogeologic properties of the PTn unit overlying the repository horizon, where present, dampen the magnitude of short term fluctuations in deep percolation that might be associated with future climate change or variability in precipitation (Manepally, C., *et al.*, "The Nature of Flow in the Faulted and Fractured Paintbrush Nonwelded Hydrogeologic Unit," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, April 2007). NAS acknowledges the phenomenon by indicating that "(t)he subsurface location of the repository would provide a temporal filter for climate change affects on hydrologic responses. For this reason, climate changes lasting on the order of hundreds of years would have little, if any, effect on repository performance."

The commenter's argument that doses to the RMEI would be underestimated appears to be based on results from preliminary performance assessments conducted by DOE in which localized corrosion is the predominant mode of waste package failure. Preliminary waste package models developed by DOE indicate that the Alloy 22 outer container is susceptible to localized corrosion predominantly during the first few thousands of years, when waste package temperatures are high and concentrated solutions could develop. At times beyond 10,000 years, when waste package temperatures are lower, the relative humidity within the emplacement drift is high, and solutions are less concentrated; the waste package is less susceptible to localized corrosion. Because general corrosion appears to be the dominant mode of waste package failure after 10,000 years, precise modeling of transient changes from drier to wetter conditions is unlikely to have a pronounced effect on peak expected dose.

The commenter's argument does not appear to consider 10 CFR 63.303, which states that "compliance is based upon the mean of the distribution of projected doses of DOE's performance assessments." The 1995 NAS document at page 77 concluded that "[a]lthough the typical nature of past climate change is well known, it is obviously impossible to predict in detail either the nature or the timing of future climate change." Although the science of climatology has advanced significantly in the 15 years after the publication of the NAS report, predicting the timing of dry-to-wet transitions remains highly uncertain. Even if it were true that "[p]eak dose is likely to occur when a wet period follows a long period of unusually dry conditions" as indicated by the commenter, dry-to-wet transients in performance assessments would have less influence on the mean of the distribution of projected doses than on any single projected dose used to construct the distribution. Specifically, simulations done by the NRC using its performance assessment code (TPA Version 4.1j) exhibited similar repository performance, in terms of dose, under constant and non-constant climate scenarios ("Regulatory Perspective on Implementation of a Dose Standard for a One-Million Year Compliance Period," T. McCartin, Proceedings of the 2006 Materials Research Society Fall Meeting, Volume 985 from the Materials Research Society Proceedings Series). In these simulations, the non-constant climate scenarios were developed using cyclic variations caused by orbital parameters. Also, the constant climate scenarios used deep percolation values specified in NRC's proposed regulations. Performance assessment models and analyses continue to improve; however, dry-to-wet conditions appear to have a limited effect on the mean dose within the constraints of current performance assessment approaches.

Issue 4: What is the range of future mean annual precipitation rates used to estimate future mean annual deep percolation rates?

Comment. The State of Nevada commented that the upper bound of the future precipitation rate stated in the discussion section preceding the proposed regulation is lower than that used by DOE. DOE commented that the precipitation rates discussed in the proposed regulation do not represent the full range of expected climates. The Advisory Committee on Nuclear Waste suggested including additional documentation in the final rule for the approach used to calculate average precipitation rates over the post-10,000 year period.

Response. NRC has conducted detailed climate analyses that considered time-varying values of historic, inferred prehistoric, and potential future precipitation rates to support the range of long-term-average future deep percolation rates adopted in the final regulations. These time-varying precipitation rates were also used to estimate the range and bounds of 1-million-year-average annual precipitation. Having considered the comments and conducted further analyses, the Commission believes the time-varying precipitation rates used to estimate future mean annual deep percolation rates are appropriate.

The lowest and highest values of the 1-million-year-average future annual precipitation in any climate sequence used to estimate the 1-million-year-average future deep percolation rate are 211 and 471 mm/year (8.3 and 18.5 in./year) at a 1,524 meter (5,000 foot) reference elevation. NRC used two approaches, which are described by Stothoff and Walter, "Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2007), to estimate time-varying sequences of mean annual precipitation that vary over glacial cycles. Both approaches estimate precipitation for glacial stages, with the sequence of glacial stages determined using well-known orbital dynamics relationships. The first approach is based on the climate reconstruction by Sharpe, "Future Climate Analysis: 10,000 Years to 1,000,000 Years After Present," Reno, NV: Desert Research Institute (2003), with present-day and monsoon climatic conditions adjusted to reflect historical precipitation measurements in the vicinity of Yucca Mountain based on meteorological data in Bechtel SAIC Company (BSC),

"Simulation of Net Infiltration for Present-Day and Potential Future Climates," Las Vegas, NV: Bechtel SAIC Company, LLC (2004). The 1-million-year-average mean annual precipitation rate from the first approach ranges from 213 to 389 mm/year (8.4 to 15.3 in./year), and with a mean of 315 mm/year (12.4 in./year) and a standard deviation of 52 mm/year (2.0 in./year). The second approach is based on estimated sequences of future continental ice volumes, which respond to insolation variation caused by orbital dynamics, with changes in precipitation related to changes in atmospheric patterns occurring from changes in continental ice volume. The 1-million-year-average mean annual precipitation for the second approach ranges from 211 to 471 mm/year (8.3 to 18.5 in./year), and with a mean of 322 mm/year (12.7 in./year) and a standard deviation of 47 mm/year (1.8 in./year).

Both approaches described by Stothoff and Walter, "Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2007) subdivide the 1-million-year period into a sequence of interglacial and glacial stages that vary in duration from 500 to 40,000 years. For each stage, a range of mean annual precipitation is estimated that includes uncertainty. The smallest and largest values of estimated mean annual precipitation considered in any stage are 162 and 581 mm/year (6.4 and 22.9 in./year).

Issue 5: What is the range of future deep percolation rates?

Comment. A number of commenters endorsed the approach of specifying the rate of water flow through the Yucca Mountain repository (expressed as deep percolation rate) as an appropriate and practical approach to adopting EPA's requirement to consider the effect of climate variation after 10,000 years. Several commenters indicated that the basis for the proposed regulation was not clearly explained. Also, several commenters questioned the specific range of deep percolation rates discussed in the proposed regulation. The State of Nevada raised a number of additional concerns. First, the State questioned the validity of estimating infiltration using a constant climate state. Second, the State questioned the range of uncertainty used to represent infiltration for present-day and future climate in the long-term-average estimates. Third, the State questioned the adequacy of computer models (e.g., one-dimensional models without lateral distribution) to extrapolate net infiltration values to future climates. Fourth, the State questioned the assumption that plant and soil regimes remain stationary during future climate states. Another commenter was concerned with the assumption that spatial variability of infiltration remains constant over time. NEI commented that requiring climate to be assumed constant at present-day conditions over the post-10,000 year period would be a more appropriate implementation of a stylized approach. NEI also considered the range of 5 to 20 percent for the ratio of the deep percolation rate to precipitation rate, used to support the deep percolation rates in the proposed rule, was too large and provided an alternative range of 5 to 10 percent. DOE commented that deep percolation rates appear to be skewed to the maximum deep percolation rate rather than a rate obtained from the full range of expected climate.

Response. Having considered the comments and conducted further analyses, the final regulations specify a slightly different range for the deep percolation rate from the proposed rule. The final rule now specifies that deep percolation rates averaged over the period of 10,000 to 1 million years in the future may be reasonably described with a "truncated" lognormal distribution,[4] which varies between 10 and 100 mm/year (0.39 and 3.9 in./year). To address commenters' concerns with respect to certain simplifying assumptions used to estimate the deep percolation rates (*e.g.*, range of 5 to 20 percent for the ratio of the deep percolation rate to precipitation rate) the NRC has conducted more sophisticated analyses, which are now used to support the estimates for the deep percolation rates. The distribution of deep percolation rates is based on the analysis of Stothoff and Walter, "Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2007), who estimated deep percolation areally averaged within a rectangle overlying the repository footprint considering uncertainty in both climate and net infiltration. The analysis suggested that long-term-average deep percolation is better represented by a "truncated" lognormal distribution than the originally proposed log-uniform distribution that ranged from 13 to 64 mm/year (0.5 to 2.5 in./year). The NRC adopted a "truncated" lognormal distribution between the 5th and 95th percentiles of the lognormal distribution to represent reasonable lower and upper limits for the long-term average deep percolation rates. The revised distribution for deep percolation is consistent with available deep percolation estimates from Yucca Mountain, recharge estimates from a wide range of elevations in central and southern Nevada, and uncertainty estimates from a numerical model. 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 in./year) based on the range and distribution in the proposed regulations. Although the upper limit of the deep percolation rate [*i.e.*, 100 mm/year (3.9 in./year)] in final regulations is almost twice the upper limit in the proposed regulation [*i.e.*, 64 mm/year (2.5 in./year)], the deep percolation rates in the final regulations, on average, represent only slightly wetter conditions than what was specified in the proposed regulations [*i.e.*, arithmetic mean of 37 versus 32 mm/year (1.5 versus 1.3 in./year)]. Truncation of the lognormal distribution between 10 and 100 mm/year (0.39 and 3.9 in./year) results in reasonable lower and upper limits for the long-term average deep percolation rates. If the lower and upper limits were extended further, the resulting arithmetic mean of the distribution would change very little because of the decreasing probability of values that occur at the tails (or extremes) of a lognormal distribution.

To document more clearly the technical bases for the proposed range of long-term-average future deep percolation rates expected at Yucca Mountain during the post-10,000 year period, the NRC conducted additional detailed climate and infiltration analyses, which are reported in Stothoff and Musgrove, "Literature Review and Analysis: Climate and Infiltration," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses (2006) and Stothoff and Walter (2007). Stothoff and Musgrove (2006) provide a comprehensive review and analysis of relevant infiltration and recharge studies that have been conducted for the Yucca Mountain region, the Death Valley region, the southern and central Great Basin of Nevada, and analogous arid to semi-arid regions in the western United States and the world. Stothoff and Walter (2007) describe additional technical investigations of estimated precipitation rates and temperatures for the past 1 million years in the Yucca

[4] The truncated lognormal distribution is based on a lognormal distribution with an arithmetic mean of 41 mm/year (1.6 in./year) and a standard deviation of 33 mm/year (1.3 in./year). The 5th and 95th percentiles of this lognormal distribution are approximately 10 and 100 mm/year (0.39 and 3.9 in./year), respectively.

Mountain region based on various climate proxy data reported in the literature. Stothoff and Walter (2007) link these past precipitation and temperature estimates with a well-accepted glacial model based on orbital dynamics to estimate precipitation and temperature sequences for the next 1 million years. Finally, Stothoff and Walter (2007) use these future climate sequences with infiltration relationships supported by the data described in Stothoff and Musgrove (2006) and site observations at Yucca Mountain to estimate the range of long-term-average future deep percolation rates at Yucca Mountain during the post-10,000 year period.

Contrary to inferences made by the State of Nevada, the revised distribution for deep percolation does not use steady-state hydrology based on annual average precipitation to estimate deep percolation. Stothoff and Walter (2007) considered the time-varying response of net infiltration to precipitation at time scales ranging from individual precipitation events, to decadal-scale averages, to millennial-scale glacial stages to derive estimates of long-term-average deep percolation.

Stothoff and Walter (2007) considered the response of net infiltration to climate at approximately 16,000 locations across Yucca Mountain to derive estimates of long-term-average deep percolation averaged over the repository footprint. Uncertainty in each of the hydraulic and climatic factors affecting infiltration was considered at each of the 16,000 locations. Stothoff and Walter (2007) found that a lognormal distribution for areal-average net infiltration reasonably reflects the effect of the uncertainty in these factors. Stothoff and Walter (2007) did not use the INFIL version 2 model developed by the U.S. Geological Survey (USGS) for this analysis, nor did they neglect lateral redistribution of runoff.

The State of Nevada questioned the appropriateness of using a stationary hydrologic state to describe plant and soil characteristics in numerical modeling and another commenter was concerned with the assumptions that the spatial variability of infiltration remains constant over time. The deep percolation model described by Stothoff and Walter (2007) does not use a stationary description for plant uptake. It does use a stationary description for soil characteristics but recognizes that soil thicknesses and soil texture may change over a glacial cycle. Stothoff and Walter (2007) consider the likely influence of such changes on net infiltration to be relatively small compared to the overall uncertainty in net infiltration. Soil evolution under glacial conditions will tend to deepen soil profiles over time and make the soil texture finer than at the present time, which would tend to reduce net infiltration at the end of a long, wetter glacial interval. Soil cover tends to erode under interglacial conditions, which may promote net infiltration during dry intervals. NRC considers it reasonable to neglect soil evolution because soil evolution would tend to make net infiltration under both glacial and interglacial climatic states more like the long-term-average infiltration. Although soil properties are stationary in the deep percolation model in Stothoff and Walter (2007), plant uptake is not and therefore the spatial variability of deep percolation in the model of Stothoff and Walter (2007) is not constant over time.

NEI commented that the 1-million-year-average deep percolation rates used for performance assessments should be maintained at present-day values because this would be more conservative with respect to groundwater usage for dose calculations for the RMEI. Deep percolation rates in Yucca Mountain do not affect the groundwater usage rate of the RMEI for evaluating compliance with the post-10,000 year individual protection standard. Groundwater usage rates at the location of the RMEI as prescribed at 10 CFR 63.312(c) are fixed at an annual water demand of 3.7 million cubic meters (3,000 acre-feet). DOE commented that, considering the analyses by Sharpe "(Future Climate Analysis: 10,000 Years to 1,000,000 Years After Present," Reno, NV: Desert Research Institute, 2003), the proposed probability distribution was skewed towards maximal percolation rates because the full range of potential climates was not considered in the regulation. Stothoff and Walter (2007) compared net infiltration estimates using potential future climate sequences obtained from an independent model based on site and regional observations and a global ice volume model, and sequences obtained from a slightly modified version of the Sharpe (2003) model. The Sharpe (2003) model was modified to update the present-day climate with site-specific present-day climate observations from BSC ("Simulation of Net Infiltration for Present-Day and Potential Future Climates," Las Vegas, NV: Bechtel SAIC Company, LLC, 2004). The modified Sharpe model yields an estimate for long-term-average deep percolation with a mean value of 44 mm/year (1.7 in./year) and values of 9.9 and 103 mm/year (0.39 and 4.1 in./year) at the 5th and 95th percentiles, respectively. The independent model, which was used to specify the deep percolation distribution in the regulation, has a mean value of 41 mm/year (1.6 in./year) and values of 10 and 102 mm/year (0.39 and 4.0 in./year) at the 5th and 95th percentiles, respectively. Because the two independent climate sequences consider a wide range of potential climates yet yield similar infiltration estimates, the NRC believes the distribution of deep percolation rates adopted in the final regulation is not skewed toward maximal percolation rates.

Issue 6: Is the NRC guidance document on uncertainty and analysis of infiltration and subsurface flow and transport, intended for Site Decommissioning Management Plan (SDMP) sites, applicable to establishing an appropriate stylized climate scenario for times beyond 10,000 years at the potential high-level radioactive waste (HLW) disposal site at Yucca Mountain?

Comment. One commenter noted there is no clear indication whether or how NRC's existing guidance on accounting for uncertainty when establishing infiltration rates has been applied. Specifically, the commenter referred to NUREG/CR–6565, "Uncertainty Analysis of Infiltration and Subsurface Flow and Transport for SDMP Sites" (1997).

Response. The guidance presented in NUREG/CR–6565 is intended to be used only at SDMP sites. Therefore, NUREG/CR–6565 is not directly applicable to a potential high-level waste disposal site. However, the methods NRC uses to account for uncertainty in its independent estimate of infiltration rates (deep percolation) for both present and future climatic conditions at Yucca Mountain encompass and exceed in sophistication the methods discussed in NUREG/CR–6565. The technical methods used by the NRC to account for uncertainty are discussed in detail under Issue 5 (What is the range of estimated present-day deep percolation rates and the appropriate range of future deep percolation rates?).

The guidance in NUREG/CR–6565 applies to SDMP sites and recommends an appropriate level of modeling sophistication commensurate with the risk of such sites. This is consistent with NRC's general approach of using simple models for simple sites with low likelihood of exceeding exposure criteria, and using increasingly sophisticated models and requiring more robust data for more complex sites that pose potentially greater risks to public safety. The more detailed

requirements in Part 63 and the associated guidance in the YMRP are appropriate for the site complexity of Yucca Mountain and for the greater risk associated with HLW disposal.

For example, NUREG/CR–6565 recommends the use of generic models, such as Residual Radiation (RESRAD) and Multimedia Environmental Pollutant Assessment System (MEPAS), which simplify the physical system to reduce computational effort. Conversely, a site-specific performance assessment model with all the processes considered important at Yucca Mountain is needed to determine if Part 63 performance objectives are met. Both generic models and site-specific models are typically run in Monte Carlo mode to address uncertainty. In addition, NUREG/CR–6565 provides tables of generic hydraulic parameter distributions to use in lieu of site-specific parameters that are not typically available for SDMP sites, whereas the YMRP provides technical acceptance criteria for data sufficiency and uncertainty specific to Yucca Mountain.

Issue 7: To what degree does the stylized climate scenario depend on information provided by the USGS?

Comment. One commenter indicated NRC's proposal is unsupportable because it is based on the past work of USGS personnel that is the subject of continuing criminal and civil investigation because of the apparent falsification of infiltration data and associated quality assurance records.

Response. The stylized climate scenario and deep percolation rate in the final rule do not depend only on information provided by the USGS. The NRC has developed its own model and has performed independent field observations and measurements to support this final rule. In addition, the NRC has evaluated other regional information to corroborate its estimates of percolation under different climate regimes (Stothoff and Musgrove, "Literature Review and Analysis: Climate and Infiltration," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2006).

To address uncertainty in estimates of net infiltration (and hence, deep percolation) during future climates, NRC developed its own independent climate and net infiltration models. Some DOE information that NRC judged to be reasonable from a scientific perspective was used in the model inputs. Further, NRC understands that DOE has reaffirmed the quality of data used in response to the USGS e-mail issue investigations. For important model inputs, NRC independently collected data to gain confidence in the model results.

Three of the most important model inputs are precipitation, soil thickness, and incident solar energy. For precipitation, NRC analyzed local and regional data patterns and developed a future climate model based on ice core volumes (Stothoff and Walter, "Long-Term Average Infiltration at Yucca Mountain, Nevada: Million-Year Estimates," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2007). NRC climate model results were compared with indirect observations such as lake records and glacier advances in the Sierra Mountains. For soil thickness, NRC made its own measurements at the ridges and hillslopes of Yucca Mountain (Fedors, "Soil Depths Measured at Yucca Mountain During Site Visits in 1998," Interoffice Note to J. Guttmann, Washington, DC: Nuclear Regulatory Commission, January 9, 2007). NRC used the measurements of soil depth to gain confidence in its own model for soil thickness across the Yucca Mountain area. For the incident solar energy, which is important for evaporation in this semi-arid climate, NRC independently developed its own energy model from the general literature (Stothoff, "BREATH Version 1.1—Coupled Flow and Energy Transport in Porous Media: Simulator Description and User Guide," Washington, DC: Nuclear Regulatory Commission, 1995).

Previously, NRC had developed a bulk bedrock permeability model (Waiting, *et al.* "Technical Assessment of Structural Deformation and Seismicity at Yucca Mountain, Nevada," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, 2001) and performed independent soil permeability measurements, which provided a basis to evaluate the reasonableness of related DOE data "Infiltration Tabulator for Yucca Mountain: Bases and Confimation," San Antonio, TX: Center for Nuclear Waste Regulatory Analyses, August, 2008; and Fedors (Soil Hydraulic Properties Measured During Site Visits to Yucca Mountain, Nevada," Interoffice Note to E. Peters, Washington, DC: Nuclear Regulatory Commission, August, 2008).

NRC's model for estimating net infiltration is independent of the DOE model and uses a different conceptualization. The NRC model is a physically-based numerical heat and mass transfer model, which solves the Richards equation for water flow, with hourly climatic inputs to determine net infiltration for a range of climates and hydraulic property sets. Results from the heat and mass transfer model are used to develop an abstraction that is applied to Geographical Information System (GIS) based inputs covering the Yucca Mountain area. In addition, a surface water flow model based on the kinematic wave equation and linked to a two-layer infiltration algorithm is used to develop abstracted results to account for the effect of runoff and runon. The DOE model, on the other hand, is based on a water balance or "bucket," approach. The DOE model is applied within a GIS framework and includes surface water routing.

Irrespective of the USGS matter, NRC is confident its model for estimating net infiltration is reasonable, because NRC has developed its model independent of DOE and DOE's contractors, NRC performed independent field observations and measurements, and NRC evaluated other regional information to corroborate its estimates of deep percolation rates under different climate regimes.

Issue 8: Does NRC's specification of a particular value for deep percolation at this time limit the consideration of future scientific information for changing the specified value?

Comment. One commenter stated that the specification of an infiltration rate years before DOE's license application is even filed is premature and unwise given the potential for new models for infiltration, which will likely have enhanced spatial and temporal resolution. Another commenter stated that if DOE's climatic analysis and forecast differ from the deep percolation rates set in the amended rule, then NRC's specification for deep percolation should serve as a point of reference in NRC's license review proceedings. NRC license reviewers should be open to the possibility that other analytical methods may exist for addressing future climate changes for such long periods. New models for climate change may include consideration of potential future anthropogenic influences on Yucca Mountain.

Response. The Commission disagrees with the commenters. The NRC recognizes that scientific progress is expected to continue the understanding of potential future climate. However, the intention of the rule is to specify a reasonable basis for evaluating safety using current knowledge. Given the current approach for estimating deep percolation, it would take a major shift in scientific understanding for the deep percolation rates to change significantly. For example, if future scientific advances suggest there is a period when there would be *no* rainfall in the Yucca Mountain area for a period of 100,000 years, this would result in a ten percent

change in the long-term average over the 1-million-year period. Such changes are not expected to significantly change dose estimates. However, if future scientific advances show the regulation is no longer sufficiently protective of public health and safety and the environment, NRC would not hesitate to propose appropriate changes to the regulations.

Further, if any person believes that the specification for climate change no longer provides a reasonable basis for demonstrating compliance based on new scientific evidence, they can petition NRC to amend the rules. In addition, NRC's procedural rules enable any party to an adjudicatory proceeding to petition that application of a rule be waived in circumstances when the rule would not serve the purposes for which it was adopted [See also response to Issue 3 under NRC Adoption of EPA Standards and Response to Issue 7 under Clarification of NRC's Implementation of FEPs for the Performance Assessment for the Period after 10,000 Years of this document].

Issue 9: Does NRC's analytical basis for its specification of a deep percolation rate comply with the Information Quality Act (IQA) and the associated Office of Management and Budget (OMB) guidelines?

Comment. The State of Nevada stated that NRC's calculations and judgments did not undergo scientific peer review, contrary to the IQA and OMB guidelines. The State asserted that NRC is overwhelmingly relying on EPA information and indirectly on EPA's contractor documents cited in the proposed standards.

Response. NRC considers its calculations and technical bases supporting the deep percolation estimates to be consistent with the IQA and the associated OMB guidelines concerning peer review. The OMB peer review guidance applies to "influential scientific information" that will have a clear and substantial impact on important public policies or the private sector (70 FR 2667; January 14, 2005). The distribution and range for deep percolation rates have a limited effect on repository performance and expected dose given the nature of the geologic environment and anticipated performance of engineered barriers (see response to Issue 3 under Climate Change of this document). Specifying deep percolation assumptions in NRC regulations limits unbounded speculation concerning a narrow and discrete aspect of the overall performance assessment. Doing so does not determine either how DOE will apply that range of rates over the entire repository horizon or DOE's related analysis of the consequences for repository performance, much less constrain an NRC conclusion with respect to the acceptability of a potential application. Consequently, NRC does not consider its specification of the deep percolation rates or the data supporting it to be influential scientific information within the meaning of the OMB guidance.

As discussed in relation to Climate Change issues 1 through 7 of this document, NRC's estimates of deep percolation are appropriate and well-supported. Based on public comment, the NRC has revised its specification for deep percolation values and provided additional clarification for the basis of the range of values (*see* Climate Change responses in this document). Further, these values are independent of any work or information provided by EPA or its contractors. With respect to the basis for the deep percolation rates, the NRC is not, as asserted by the State of Nevada, "overwhelmingly relying on EPA information, including EPA's contractor documents" in its calculations and judgments when the responsibility rests with NRC.

4. Use of Current Dosimetry

Issue 1: Is the specification for using current methods of dosimetry and updated models for calculating potential radiation exposures sufficiently clear?

Comment. DOE commented that the proposed approach for using current methods for dosimetry and updated models for dose calculations should be clarified in two specific areas. First, the definition for "weighting factor" in the proposed regulation refers only to the tissue weighting factors provided in Appendix A of EPA's proposed standards and does not directly identify the radiation weighting factors also included in Appendix A. This definition should be expanded to include the radiation weighting factors specified in EPA's proposed standards. Second, Federal Guidance Report 13 is the current guidance report for estimating radiation doses; however, this report considers a slightly different set of organs than those included by EPA in Table A.2 (70 FR 49063), which represents the most current recommendations from the International Commission on Radiological Protection (ICRP). Clarification is needed on using current dosimetry methods because of the potential for differences in the list of organs considered in a particular method. Additionally, DOE suggested that one potential solution was for NRC to simply require that the calculation of doses be consistent with ICRP 60/72 methodology, use current scientific methods, and not provide any specific values in the regulation.

Response. The definition for "weighting factor" for an organ or tissue in the proposed regulation states that "the values" in Appendix A of 40 CFR Part 197 are to be used for calculating the effective dose equivalent. This statement was intended to indicate that all the values in Appendix A (weighting factors for both radiation and for an organ or tissue) are to be used for calculating the effective dose equivalent. The Commission no longer considers it necessary to add a definition of the weighting factor in order to implement the values in Appendix A. Instead, the Commission clarifies the "implementation" of total effective dose equivalent (TEDE), specifically, the manner in which the values in Appendix A are to be used in dose calculations. The new text on the implementation of TEDE now states that the radiation and organ or tissue weighting factors in Appendix A are to be used in calculating the effective dose equivalent. Implementation of TEDE appears in the concepts section of Subpart E (Technical Criteria) in Part 63. Based on the added text on implementation of TEDE, the proposed definition for weighting factor is no longer necessary and has been removed in the final regulation.

The Commission is aware that as dosimetry methods have advanced, additional organs have been considered in determining weighting factors and thus, there are differences in the lists of organs used in specific methods for estimating dose. The intent of the standards and regulations is to provide an approach for using currently accepted dosimetry methods and updated models for estimating radiation exposures and *not* for fixing a list of organs or tissues. The Commission considers currently accepted dosimetry methods to include those incorporated by EPA into federal radiation guidance as well as those included in 40 CFR Part 197, Appendix A. The Commission recognizes that the information presently available from consensus scientific organizations on newer dosimetric models (*e.g.*, tabulations of calculated dose coefficients) differ for internal dose estimation relative to external dose estimation. Given this circumstance, use of external dosimetry methods in existing federal radiation guidance, Federal Guidance Report No. 12 (EPA, 1993), in combination with the more current internal dosimetry methods consistent with 40 CFR Part 197, Appendix A, is an acceptable approach for calculating TEDE.

Whatever dosimetry method is used to estimate dose, it is expected that the calculation will consider the list of organs or tissues appropriate to that specific method. One way to clarify this issue would be to adopt the DOE suggestion to merely require that the calculation of doses be consistent with ICRP 60/72 methodology and use current scientific methods, and not provide any specific values in the regulation. Appendix A of the EPA Standards (73 FR 61256; October 15, 2008) allows NRC to permit DOE to use revised weighting factors as updates are made in the future when these factors have been issued by a consensus of scientific organizations and incorporated by EPA into Federal radiation guidance. Rather than adopt the DOE suggestion that includes a reference to a specific methodology, the Commission considers it more appropriate to add text on implementing TEDE to:

(1) Clarify that whatever methodology is adopted the weighting factors used in the calculation of dose are to be appropriate to the specific method;

(2) Continue to refer to the values provided in Appendix A of the standards as the values that are presently considered to be current and appropriate; and

(3) Prescribe the basis how DOE may be allowed to use newer methods and models.

Thus, the regulations provide a consistency between the requirements for dose calculations and the scientific models and methodologies for calculating dose as scientific knowledge improves. Additionally, NRC's Regulatory Issue Summary 2003–04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," provides further information on this topic.

The implementation of TEDE is applicable in the context of dose calculations performed to demonstrate compliance with the requirements for a potential repository at Yucca Mountain.

Issue 2: Should the definition for TEDE include clarification regarding how operational doses to workers are to be calculated?

Comment. DOE commented that the definition of TEDE should clarify that assessing (monitoring) external exposure to workers during operations should use the deep-dose equivalent, whereas, potential external doses to workers in the future should be calculated using an effective dose equivalent. This clarification is necessary to resolve potential inconsistencies in the application of dose calculations between Parts 20 (*i.e.*, monitored doses) and 63 (calculated doses).

Response. Clarification regarding the monitoring of doses versus calculation of doses is essentially an issue of implementation of TEDE and is not one of redefining the term itself. Therefore, NRC is adding a separate discussion regarding implementation of TEDE in the concepts section of Subpart E (Technical Criteria) in Part 63 to provide the necessary clarification rather than modifying the definition of TEDE. The NRC is also revising the definition for TEDE in Part 63 to be consistent with the definition for TEDE in Part 20 to further clarify this is an issue of implementation of TEDE and not the definition of TEDE.

As correctly stated in the comment, the deep-dose equivalent is an approach used for measuring external doses in the field, as is often done for demonstrating compliance with occupational exposures. The new text on implementation of TEDE clarifies that:

(1) When the external exposure is determined by measurement with an external personal monitoring device, the deep dose equivalent is to be used instead of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC;

(2) The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure; and

(3) The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

The added text on implementation of TEDE provides the necessary clarification on how the deep-dose equivalent is to be used in determining compliance with the regulations for Yucca Mountain. Additionally, NRC's Regulatory Issue Summary 2003–04, "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments," provides further information on this topic.

5. Comments Beyond the Scope of This Rulemaking

Some commenters submitted comments which are beyond the scope of this rulemaking as described in NRC's notice of proposed rulemaking. NRC responds to some of the concerns raised below. In addition, the State of Nevada requested that comments viewed as being beyond the scope of the rulemaking be considered as a petition for rulemaking. The State is familiar with NRC's process for considering petitions for rulemaking which is initiated by submittal of a petition under 10 CFR 2.802 which meets the criteria of 10 CFR 2.802(c).

Issue 1: Were intergovernmental meetings concerning the proposed EPA standards inappropriate?

Comment. The State of Nevada and some other commenters suggested that non-public intergovernmental meetings at which EPA's proposed standards were discussed were somehow inappropriate and cast a cloud on EPA and NRC rules. These commenters cite no laws nor regulations barring such discussions but nevertheless assume that such meetings should not have taken place.

Response. In the Nuclear Waste Policy Act of 1982, as amended (NWPA), Congress recognized the responsibility of the Federal Government to provide for the permanent disposal of HLW and spent nuclear fuel in order to protect public health and safety and the environment. Congress, in the NWPA and later in the EnPA, charged EPA and NRC with specific direction for developing standards and regulations for Yucca Mountain: EPA is to provide public health and radiation protection standards; NRC is to provide implementing regulations for those standards and is to consider a license application from DOE for the construction, operation, and closure of the repository at a site DOE has found suitable. It makes little sense for these agencies to act oblivious to the views of each other as to how protection of public health and safety and the environment with respect to a geologic repository can best be accomplished. It is both appropriate and important for NRC to be able to explain and discuss its regulatory approach in the context of the EPA standard with other Federal agencies. The State, in fact, recognizes this. In its comments, the State urged NRC to "convince EPA to adopt a more reasonable and protective standard."

Although intergovernmental meetings are not normally open to the public, what is important is the fact that no "secret" decisions resulted from interagency discussions. Both the EPA's proposed standards and NRC's proposed regulations, including their rationale, were provided to the public for comment. After careful consideration of the public comments, both EPA and NRC have explained and documented their final standards and regulations, including how public comments were taken into account. The standards and regulations will stand or fall on the basis of the public record on which they rest, not on the basis of any discussions that may have taken place while the standards were being formulated.

Issue 2: Should NRC provide additional requirements for defense-in-depth?

Comment. The State of Nevada believes that a meaningful defense-in-depth standard is missing from the NRC rule. The State also suggested that a requirement pertaining to the expected performance of natural barriers would offer an essential protective feature for coping with early waste package failure (noting that the International Atomic Energy Agency (IAEA) has suggested that "overall performance of the geologic disposal system shall not be unduly dependent on a single barrier or function").

Response. The Commission considers the approach for multiple barriers and defense-in-depth in Part 63 appropriate and protective. When NRC issued final Part 63 on November 2, 2001 (66 FR 55758), the Commission stated the goal of the current regulations regarding multiple barriers and defense-in-depth and explained its reasoning for not specifying requirements for specific barriers:

> The emphasis should not be on the isolated performance of individual barriers but rather on ensuring the repository system is robust, and is not wholly dependent on a single barrier. Further, the Commission supports an approach that would allow DOE to use its available resources effectively to achieve the safest repository without unnecessary constraints imposed by separate, additional subsystem performance requirements.
>
> It is also important to remember that part 63 requires DOE to carry out a performance confirmation program to provide further confidence that barriers important to waste isolation will continue to perform as expected (66 FR 55758).

The court addressed this same issue in Nevada's suit challenging the Part 63 rule:

> Specifically, Nevada contests NRC's use of defense-in-depth at the proposed Yucca Mountain repository through an *overall* system performance assessment rather than using the approach of its older regulations, which approach tests the individual performance of the repository's 'system elements.' * * * In light of NRC's detailed analysis supporting its decision to evaluate the performance of the Yucca Mountain repository based on the barrier system's overall performance, we believe that it adequately explained its change in course. * * * Accordingly, we conclude that NRC acted neither arbitrarily nor capriciously in rejecting part 60's subsystem performance approach in favor of the overall performance approach. *NEI* v. *EPA*; 373 F.3d 1251, 1295–97

(DC Cir. 2004).

Issue 3: Should NRC disabuse EPA of its mistaken impression that there is some significant difference between "reasonable assurance" and "reasonable expectation?"

Comment. The State of Nevada asserted that NRC must disabuse EPA of its mistaken impression that there is some significant difference between the term "reasonable assurance" and the term "reasonable expectation."

Response. As noted by the State, NRC and the State have already agreed that the two terms are substantially identical, *see NEI* v. *EPA;* 373 F.3d 1251, 1301 (D.C. Cir. 2004).

Issue 4: Should NRC prohibit DOE from relying on drip shields that may be installed in the distant future (*e.g.*, 300 years from now)?

Comment. The State of Nevada expressed concern that drip shields could be scheduled for installation many years in the future and, thus, there is no real guarantee that this safety feature will actually be installed. There is no reliable way to commit future decision-makers on this point. Therefore, NRC should not allow DOE to rely on the drip shields in demonstrating compliance with the post-closure performance objectives.

Response. DOE must apply to NRC for authorization to build the proposed repository. Under NRC's regulations, DOE must show, among other things, that its proposal will comply with specified performance objectives for the geologic repository after permanent closure. On June 3, 2008, DOE submitted a license application to NRC for authorization to construct a repository at Yucca Mountain. The NRC staff will evaluate whether DOE's proposed design, including reliance on any specific design feature or component of the engineered barrier system as described in the application, succeeds in making the required demonstration.

The NRC staff will then document its assessment in a Safety Evaluation Report. If the NRC staff recommends that NRC authorize construction, the staff may specify potential license conditions, as needed, to provide reasonable expectation that relevant performance objectives will be met. NRC can only assess the need for such conditions, their reasonableness, and their potential to be enforced in the context of DOE's overall design as presented in a license application. If DOE proposes to install drip shields and if the drip shields are considered important for waste isolation or repository performance, the installation of the drip shield at an appropriate time would become part of the license conditions. At a later date, if DOE proposes not to install the drip shields, DOE would be obligated to seek specific regulatory approval in the form of a license amendment. Any NRC decision to grant or deny such an amendment request would be based on NRC's independent technical review and would be subject to a potential hearing as part of the amendment process.

Issue 5: Should NRC incorporate into the final rule requirements for compliance monitoring and measures to be taken in the event of non-compliance?

Comment. Some commenters pointed out that NRC's proposed rule appears to be silent with regard to requirements for compliance monitoring and related measures to be taken if said monitoring demonstrates noncompliance with established standards. The commenters encouraged NRC to incorporate such requirements into the final rule.

Response. Part 63 contains requirements for monitoring up to the time of permanent closure in Subpart F. Should the NRC grant the DOE a license to operate the repository, DOE must also provide a description of its program for post-permanent closure monitoring in its application to amend its license for permanent closure. *See*, § 63.51(a)(2). The commenters' concerns regarding further monitoring and related measures can be considered at that time.

Issue 6: Will adoption of the EPA standards necessitate revision of the "S–3" rule?

Comment. The State of Nevada believes that NRC's adoption of EPA's standards with no added protections will require NRC to revisit its "S–3" rule, 10 CFR 51.51, because this rule currently includes a "zero-release" assumption that the long-term effects of disposing of spent fuel and HLW will be essentially zero because there would be no releases that would harm people or the environment after the repository is sealed. The State believes that this will no longer be the case if NRC adopts EPA's 3.5 mSv (350 mrem) standard for the post-10,000 year period.

Response. As explained in the response to the comment on Issue 1 under NRC Adoption of EPA Standards of this document, EnPA requires the Commission to modify its technical criteria to be consistent with EPA's standards for a geologic repository at the Yucca Mountain site. Moreover, the question whether the "zero-release" assumption of the S–3 rule may need to be revisited in the future is not presented in this rulemaking proceeding.

IV. Summary of Final Revisions

Section 63.2 Definitions

The definition of "performance assessment" is revised to exclude the limitation of "10,000 years after disposal," consistent with EPA's modified definition of "performance assessment." The definition for "total effective dose equivalent" is revised to be consistent with Part 20.

Section 63.102 Concepts

A discussion of the implementation of total effective dose equivalent (TEDE) is added to the concepts section to clarify how the weighting factors specified in EPA's final standards are to be used for calculating potential exposures.

Section 63.114 Requirements for Performance Assessment

This section specifies the requirements for the performance assessment used to demonstrate compliance with the postclosure performance objectives. This section is revised to conform to EPA's final standards that specify what DOE must consider in the performance assessment for the period after 10,000 years *i.e.*, the performance assessment methods meeting the existing requirements for the initial 10,000 years are appropriate and sufficient for the period after 10,000 years.

Section 63.302 Definitions for Subpart L

The definition for the "period of geologic stability" is modified, consistent with EPA's final standards, 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 is revised to conform to EPA's final standard that specifies for the period after 10,000 years, the arithmetic mean of the estimated doses is to be used for determining compliance.

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 postclosure performance objectives specified at § 63.113. This section is modified to conform to EPA's final standards, which specify the types of changes DOE must 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 is modified to conform with EPA's final standards 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 is modified to conform with EPA's final standards 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 to be consistent with EPA's final standards.

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 is modified to conform to EPA's final standards that specify the types of changes DOE must account for in the performance assessment for the period after 10,000 years and through the period of geologic stability. A range and distribution for deep percolation rates are specified that DOE must use to represent the effects of climate change after 10,000 years and through the period of geologic stability. These criteria are substantially the same as those proposed by EPA and NRC with the exception of the constraint that requires DOE to consider, in its performance assessment, changes to the elevation of the water table under Yucca Mountain (*i.e.*, water table rise) from a seismic event, which is included in the final regulations.

V. 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.

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 final rule, the NRC implements 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 sets generally applicable requirements.

VII. Finding of No Significant Environmental Impact: Availability

Under Section 121(c) of the Nuclear Waste Policy Act, this final rule does not require the preparation of an environmental impact statement under Section 102(2)(c) of the National Environmental Policy Act of 1969 (NEPA) or any environmental review under paragraphs (E) or (F) of Section 102(2) of NEPA.

VIII. Paperwork Reduction Act Statement

This final 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 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 regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission, consistent with the options that are available to NRC in carrying out the statutory directive of EnPA. The analysis is available for inspection in the NRC PDR, Room

O1F21, One White Flint North, 11555 Rockville Pike, Rockville, MD.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects the licensing of only one entity, DOE, which does not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

XI. Backfit Analysis

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

XII. Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

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. 552 and 553; the NRC is adopting 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 revising the definition of "total effective dose equivalent (TEDE)" 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;

* * * * *

Total effective dose equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

* * * * *

■ 3. In § 63.102 paragraph (o) is added to read as follows:

63.102 Concepts.

* * * * *

(o) *Implementation of TEDE.* When external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The radiation and organ or tissue weighting factors in Appendix A of 40 CFR part 197 are to be used to calculate TEDE. After the effective date of this regulation, the Commission may allow DOE to use updated factors, which have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance. Additionally, as scientific models and methodologies for estimating doses are updated, DOE may use the most current and appropriate (*e.g.*, those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation.

■ 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) The performance assessment methods used to satisfy the requirements of paragraph (a) of this section are considered sufficient for the performance assessment for the period of time after 10,000 years and through the period of geologic stability.

■ 5. In § 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.

* * * * *

■ 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 1 million years after disposal, with:

(1) Sections 63.311(a)(1) and 63.311(a)(2); and

(2) Sections 63.321(b)(1), 63.321(b)(2), and 63.331, if performance assessment is used to demonstrate compliance with either or both of these sections.

■ 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 of the changes in these factors that could affect the Yucca Mountain disposal system during the period of geologic stability, consistent with the requirements for performance assessments specified at § 63.342.

* * * * *

■ 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) 1.0 mSv (100 mrem) after 10,000 years, but within the period of geologic stability.

(b) DOE's performance assessment must include all potential 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 the human intrusion, no more than the following annual dose:

(1) 0.15 mSv (15 mrem) for 10,000 years following disposal; and

(2) 1.0 mSv (100 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 of § 63.322.

§ 63.341 [Removed]

■ 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 100,000,000 per year of occurring. 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 occurring 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)(1) 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 100,000 per year of occurring and at least one chance in 100,000,000 per year of occurring.

(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 activity scenarios, subject to the probability limits in paragraph (a) of this section for very unlikely features, events, and processes, or sequences of 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, or sequences of events and processes.

(i) The seismic analysis may be limited to the effects caused by damage to the drifts in the repository, failure of the waste packages, and changes in the elevation of the water table under Yucca Mountain (*i.e.*, the magnitude of the water table rise under Yucca Mountain).

(ii) The igneous activity 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-in-time climate conditions. The analysis may commence at 10,000 years after disposal and shall extend through the period of geologic stability. The constant-in-time values to be used to represent climate change are to be the spatial average of the deep percolation rate within the area bounded by the repository footprint. The constant-in-time deep percolation rates to be used to represent climate change shall be based on a lognormal distribution with an arithmetic mean of 41 mm/year (1.6 in./year) and a standard deviation of 33 mm/year (1.3 in./year). The lognormal

distribution is to be truncated so that the deep percolation rates vary between 10 and 100 mm/year (0.39 and 3.9 in./year).

(3) DOE must assess the effects of general corrosion on 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 9th day of March 2009.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. E9–5448 Filed 3–12–09; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 436

RIN 1904–AB68

Federal Procurement of Energy Efficient Products

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE) today publishes a final rule to promote Federal procurement of energy-efficient products. The final rule establishes guidelines for Federal agencies regarding the implementation of amendments to the National Energy Conservation Policy Act (NECPA) that require Federal agencies to procure ENERGY STAR qualified and Federal Energy Management Program (FEMP) designated products in procurements involving energy consuming products and systems. Today's final rule includes changes in response to comments received on the notice of proposed rulemaking published June 19, 2007. Most notably, today's final rule does not establish a reporting requirement, as initially proposed, for federal agencies under procurement requirement of NECPA.

DATES: This rule is effective April 13, 2009.

FOR FURTHER INFORMATION CONTACT: For technical issues contact Mr. Cyrus Nasseri, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Federal Energy Management Program, EE–2L, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9138, *e-mail: cyrus.nasseri@ee.doe.gov.* For legal issues contact Mr. Chris Calamita, U.S. Department of Energy, Office of the General Counsel, Forrestal Building, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507, *e-mail: Christopher.Calamita@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction and Background
- A. The Energy Policy Act of 2005
- B. ENERGY STAR Qualified and FEMP Designated Products
- C. Proposed Rule
- D. Draft Guidance

II. Discussion of Comments and the Final Rule
- A. Definition of "Covered Product"
- B. Reporting Agency Exceptions to the Procurement Requirement
- C. Compliance With Section 553
- D. Definition of Criteria for ENERGY STAR Qualification or FEMP Designation
- E. Supply Source for Excepted Procurement

III. DOE Guidance
- A. Procurements
- B. Procurement Planning
- C. Exceptions

IV. Regulatory Review
- A. National Environmental Policy Act
- B. Regulatory Flexibility Act
- C. Paperwork Reduction Act
- D. Unfunded Mandates Reform Act of 1995
- E. Treasury and General Government Appropriations Act, 1999
- F. Treasury and General Government Appropriations Act, 2001
- G. Executive Order 12866
- H. Executive Order 12988
- I. Executive Order 13132
- J. Executive Order 13211

V. Congressional Notification

VI. Approval of the Office of the Secretary

I. Introduction and Background

A. The Energy Policy Act of 2005

The Energy Policy Act of 2005 (EPACT 2005) (Pub. L. 109–58; August 8, 2005), amended Part 3 of title V of NECPA (42 U.S.C. 8251–8259) by adding section 553. Section 553 of NECPA requires each Federal agency to procure ENERGY STAR qualified or FEMP designated products, unless the head of the agency determines in writing that a statutory exception applies. (42 U.S.C. 8259b(b)) Section 553 of NECPA was further amended by section 525 of the Energy Independence and Security Act of 2007 (Pub. L. 140–110; December 19, 2007) to clarify that the procurement requirement applies to the procurement of a product in a category covered by the Energy Star program or the FEMP program for designated products. (42 U.S.C. 8259b(b)(1)) Further, each Federal agency is required to incorporate into the specifications of all procurements involving energy consuming products and systems, and into the factors for evaluation of offers received for such procurements, criteria for energy efficiency that are consistent with the criteria used for rating ENERGY STAR qualified products and for rating FEMP designated products. (42 U.S.C. 8259b(b)(3))

Section 553 also requires that all inventories or listings of products operated and maintained by the General Services Administration (GSA) and the Defense Logistics Agency (DLA) clearly identify and prominently display ENERGY STAR qualified and FEMP designated products in any listing or inventory of products, and it requires GSA and DLA to supply only ENERGY STAR qualified and FEMP designated products in all covered product categories, except in cases in which the head of the agency ordering a product specifies in writing that an exception applies. (42 U.S.C. 8259b(c))

Section 553 of NECPA contains two exceptions to the requirement to procure only ENERGY STAR qualified and FEMP designated products, and it excludes a specific category of energy consuming products from coverage.

A procurement may be excepted if the head of an agency finds in writing that either: (1) An ENERGY STAR qualified product or FEMP designated product is not cost-effective over the life of the product taking energy cost savings into account; or (2) no ENERGY STAR qualified product or FEMP designated product is reasonably available that meets the functional requirements of the agency. (42 U.S.C. 8259b(b)(2)) In addition, section 553 excludes from the definition of products subject to these requirements any energy consuming product or system designed or procured for combat or combat-related missions. (42 U.S.C. 8259b(a)(5))

The subsection entitled "REGULATIONS," section 553(f) of NECPA, directs the Secretary of Energy to issue guidelines to carry out the statute. (42 U.S.C. 8259b(f)) NECPA section 553 imposes procurement requirements on agencies and additional requirements on GSA and DLA. DOE does not need to issue regulations to implement those statutory requirements. Moreover, DOE does not have the authority to change by regulation the statutory procurement requirements that are applicable to agencies or the additional requirements that govern GSA and DLA.

Consistent with the direction provided in section 553(f), today's final rule amends 10 CFR part 436, Federal Energy Management and Planning Programs, to establish guidelines for Federal agencies on compliance with section 553.