ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 197

[EPA-HQ-OAR-2005-0083; FRL-]

[RIN 2060-AN15]

PUBLIC HEALTH AND ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR YUCCA MOUNTAIN, NEVADA

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final Rule

SUMMARY: We, the Environmental Protection Agency (EPA), are promulgating amendments to our public health and safety standards for radioactive material stored or disposed of in the potential repository at Yucca Mountain, Nevada. Section 801(a) of the Energy Policy Act of 1992 (EnPA, Public Law No. 102-486) directed us to develop these standards. Section 801 of the EnPA also required us to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. The health and safety standards promulgated by EPA are to be "based upon and consistent with" the findings and recommendations of NAS. On August 1, 1995, NAS released its report (the NAS Report), titled "Technical Bases for Yucca Mountain Standards." These standards (the 2001 standards) were originally promulgated on June 13, 2001 (66 FR 32074). In promulgating our standards, we considered the NAS Report as the EnPA directs.

On July 9, 2004, in response to a legal challenge led by the State of Nevada and the Natural Resources Defense Council, the U.S. Court of Appeals for the District of Columbia Circuit vacated portions of our standards that addressed the period of time for which compliance must be demonstrated. The Court ruled that the compliance period of 10,000 years was not

"based upon and consistent with" the findings and recommendations of the NAS and remanded those portions of the standards to us for revision. These remanded provisions are the subject of this action.

This final rule incorporates multiple compliance criteria applicable at different times for protection of individuals and in circumstances involving human intrusion into the repository. Compliance will be judged against a standard of 150 microsieverts per year (μSv/yr) (15 millirem per year (mrem/yr)) committed effective dose equivalent at times up to 10,000 years after disposal and against a standard of 3.5 millisieverts per year (350 mrem/yr) committed effective dose equivalent at times after 10,000 years and up to 1 million years after disposal. This final rule also includes several supporting provisions affecting DOE's performance projections. DOE will calculate the arithmetic mean of the distribution of doses, will calculate those doses using updated scientific factors, and will incorporate specific direction on analyzing features, events, and processes that may affect performance.

Section 801(b) of the EnPA requires the Nuclear Regulatory Commission (NRC) to modify its technical requirements for licensing of the Yucca Mountain repository to be consistent with the standards promulgated by EPA. In 2001, NRC incorporated EPA's Yucca Mountain standards into its licensing regulations and the compliance period provision of these was similarly vacated by the Court of Appeals. NRC must revise its licensing regulations to be consistent with our amended standards. The Department of Energy (DOE) plans to submit a license application providing a compliance demonstration. The NRC will determine whether DOE has demonstrated compliance with NRC's licensing regulations, which must be consistent with our standards, prior to granting or denying the necessary licenses to dispose of radioactive material in Yucca Mountain.

DATES: *Effective Date:* This final rule is effective on [insert date that is 30 days from date of publication].

ADDRESSES: EPA has established a docket for this action under Docket ID No. **EPA-HQ-OAR-2005-0083**. All documents in the docket are listed on the www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov, for purchase or access from sources identified in the docket (Docket Nos. EPA-HQ-OAR-2005-0083-0086 and EPA-HQ-OAR-2005-0083-0087), or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744.

FOR FURTHER INFORMATION CONTACT: Ray Clark, Office of Radiation and Indoor Air, Radiation Protection Division (6608J), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460-0001; telephone number: 202-343-9601; fax number: 202-343-2305; e-mail address: clark.ray@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The DOE is the only entity regulated by these standards. Our standards affect NRC only because, under Section 801(b) of the EnPA, 42 U.S.C. 10141 n., NRC must modify its licensing requirements, as necessary, to make them consistent with our final standards. Before it may construct the repository or accept waste at the Yucca Mountain site, DOE must obtain a license from NRC. DOE will be subject to NRC's modified regulations, which NRC will implement through its licensing proceedings.

B. How Can I View Items in the Docket?

1. Information Files. EPA is working with the Lied Library at the University of Nevada-Las Vegas (http://www.library.unlv.edu/about/hours.html) and the Amargosa Valley, Nevada public library (http://www.amargosalibrary.com) to provide information files on this rulemaking. These files are not legal dockets; however, every effort will be made to put the same material in them as in the official public docket in Washington, DC. The Lied Library information file is at the Research and Information Desk, Government Publications Section (702-895-2200). Hours

vary based upon the academic calendar, so we suggest that you call ahead to be certain that the library will be open at the time you wish to visit (for a recorded message, call 702-895-2255). The other information file is in the Public Library at 829 East Farm Road in Amargosa Valley, Nevada (phone 775-372-5340). As of the date of publication, the hours are Monday through Friday (9 a.m.-5 p.m.) and Saturday (9 a.m.-1 p.m.). The library is closed on Sunday. These hours can change, so we suggest that you call ahead to be certain when the library will be open.

2. Electronic Access. An electronic version of the public docket is available through the Federal Docket Management System at www.regulations.gov. You may use www.regulations.gov to view comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. To access the docket go directly to http://www.regulations.gov and select "All Documents." In the ID window, type in the docket identification number EPA-HQ-OAR-2005-0083 and click on "Submit." Please be patient since the search could take several minutes. This will bring you to the "Docket Search Results" page. From there, you may access the docket contents (e.g., EPA-HQ-OAR-2005-0083-0002) by clicking on the icon in the "Views" column.

C. Can I Access Information by Telephone or Via the Internet?

Yes. You may call our toll-free information line (800-331-9477) 24 hours per day. By calling this number, you may listen to a brief update describing our rulemaking activities for Yucca Mountain, leave a message requesting that we add your name and address to the Yucca Mountain mailing list, or request that an EPA staff person return your call. In addition, we have established an electronic listserv through which you can receive electronic updates of activities related to this rulemaking. To subscribe to the listserv, go to https://lists.epa.gov/read/all_forums. In the alphabetical list, locate "yucca-updates" and select "subscribe" at the far right of the screen. You will be asked to provide your e-mail address and choose a password. You also can find information and documents relevant to this rulemaking on the World Wide Web at http://www.epa.gov/radiation/yucca. The proposed rule for today's final rule appeared in the Federal Register on August 22, 2005 (70 FR 49014). We also recommend that you examine the preamble and regulatory language for the earlier proposed and final rules, which appeared in the Federal Register on August 27, 1999 (64 FR 46976) and June 13, 2001 (66 FR 32074), respectively.

D. What Documents are Referenced in Today's Final Rule?

We refer to a number of documents that provide supporting information for our Yucca Mountain standards. All documents relied upon by EPA in regulatory decision-making may be found in our docket (EPA-HQ-OAR-2005-0083). Other documents, e.g., statutes, regulations, and proposed rules, are readily available from public sources. The documents below are referenced most frequently in today's final rule.

Item No. (EPA-HQ-OAR-2005-0083-xxxx)

0044 "Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," International Atomic Energy Agency TECDOC-767, 1994

0045 "Regulatory Decision Making in the Presence of Uncertainty in the Context of Disposal of Long Lived Radioactive Wastes," International Atomic Energy Agency TECDOC-975, 1997

0046 "The Handling of Timescales in Assessing Post-Closure Safety: Lessons Learnt from the April 2002 Workshop in Paris, France," Nuclear Energy Agency (Organisation for Economic Co-operation and Development), 2004

0051 "Geological Disposal of Radioactive Waste," International Atomic Energy Agency Draft Safety Requirements (DS154), April 2005

0061 "Principles and Standards for Disposal of Long-Lived Radioactive Wastes," Neil Chapman and Charles McCombie, Elsevier Press, 2003

0062 "An International Peer Review of the Yucca Mountain Project TSPA-SR," Joint Report by the OECD Nuclear Energy Agency and the International Atomic Energy Agency, OECD, 2002

0076 Technical Bases for Yucca Mountain Standards (the NAS Report), National Research Council, National Academy Press, 1995

0077 "Assessment of Variations in Radiation Exposure in the United States," EPA Technical Support Document, July 2005

0085 "Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments," EPA Technical Support Document, July 2005

0086 DOE Final Environmental Impact Statement, DOE/EIS-0250, February 2002

xxxx Response to Comments Document for Final Rule, EPA-xxxx, December 2006

Acronyms and Abbreviations

We use many acronyms and abbreviations in this document. These include:

BID-background information document
CED-committed effective dose
CEDE-committed effective dose equivalent
CFR-Code of Federal Regulations
DOE-U.S. Department of Energy
DOE/VA-DOE's Viability Assessment
EIS-Environmental Impact Statement
EnPA-Energy Policy Act of 1992
EPA-U.S. Environmental Protection Agency
FEIS-Final Environmental Impact Statement
FEPs-features, events, and processes
FR-Federal Register
GCD-greater confinement disposal
HLW-high-level radioactive waste
HSK-Swiss Federal Nuclear Safety Inspectorate
IAEA-International Atomic Energy Agency
ICRP-International Commission on Radiological Protection
KASAM- Swedish National Council for Nuclear Waste
LLW-low-level radioactive waste
MCL-maximum contaminant level
MTHM-metric tons of heavy metal
NAPA- National Academy of Public Administration
NAS-National Academy of Sciences
NEA-Nuclear Energy Agency
NEI-Nuclear Energy Institute
NRC-U.S. Nuclear Regulatory Commission
NRDC-Natural Resources Defense Council
NTS-Nevada Test Site
NTTAA-National Technology Transfer and Advancement Act

NWPA-Nuclear Waste Policy Act of 1982
NWPAA-Nuclear Waste Policy Amendments Act of 1987
OECD-Organization for Economic Cooperation and Development
OMB-Office of Management and Budget
RMEI-reasonably maximally exposed individual
SSI-Swedish Radiation Protection Authority
SNF-spent nuclear fuel
SR-Site recommendation
TRU-transuranic
TSPA-Total System Performance Assessment
UK-United Kingdom
UMRA-Unfunded Mandates Reform Act of 1995
U.S.C.-United States Code
WIPP LWA-Waste Isolation Pilot Plant Land Withdrawal Act of 1992

Outline of Today's Action

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I. What is the History of This Action?

Radioactive wastes result from the use of nuclear fuel and other radioactive materials. Today, we are revising certain standards pertaining to spent nuclear fuel, high-level radioactive waste, and other radioactive waste (we refer to these items collectively as "radioactive materials" or "waste") that may be stored or disposed of in the Yucca Mountain repository. (When we discuss storage or disposal in this document in reference to Yucca Mountain, we note that no decision has been made regarding the acceptability of Yucca Mountain for storage or disposal as of the date of this publication. To save space and to avoid excessive repetition, we will not describe Yucca Mountain as a "potential" repository; however, we intend this meaning to apply.)

Pursuant to Section 801(a) of the Energy Policy Act of 1992 (EnPA, Public Law No. 102-486), these standards apply only to facilities at Yucca Mountain.

Once nuclear reactions have consumed a certain percentage of the uranium or other fissionable material in nuclear reactor fuel, the fuel no longer is useful for its intended purpose. It then is known as "spent" nuclear fuel (SNF). It is possible to recover specific radionuclides from SNF through "reprocessing," which is a process that dissolves the SNF, thus separating the radionuclides from one another. Radionuclides not recovered through reprocessing become part of the acidic liquid wastes that the Department of Energy (DOE) plans to convert into various types of solid materials. High-level waste (HLW) is the highly radioactive liquid or solid wastes that result from reprocessing SNF. The SNF that does not undergo reprocessing prior to disposal remains inside the fuel assembly and becomes the final waste form.

In the U.S., SNF and HLW have been produced since the 1940s, mainly as a result of commercial power production and defense activities. Since the inception of the nuclear age, the proper disposal of these wastes has been the responsibility of the Federal government. The Nuclear Waste Policy Act of 1982 (NWPA, 42 U.S.C. Chapter 108) formalizes the current Federal program for the disposal of SNF and HLW by:

(1) making DOE responsible for siting, building, and operating an underground geologic repository for the disposal of SNF and HLW;

(2) directing us to set generally applicable environmental radiation protection standards based on authority established under other laws[1]; and

(3) requiring the Nuclear Regulatory Commission (NRC) to implement our standards by revising its licensing requirements for SNF and HLW repositories to be consistent with our standards.

This general division of responsibilities continues for the Yucca Mountain repository. Thus, today we are promulgating amendments to our public health protection standards at 40 CFR part 197 (which are, pursuant to EnPA Section 801(a), applicable only to Yucca Mountain, rather than generally applicable). The NRC will issue implementing regulations for these standards. The DOE plans to submit a license application to NRC. The NRC then will determine

[1] These laws include the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011-2296) and Reorganization Plan No. 3 of 1970 (5 U.S.C. Appendix 1).

whether DOE has met NRC's regulations and whether to grant or deny a license for Yucca Mountain.

In 1985, we established generic standards for the management, storage, and disposal of SNF, HLW, and transuranic (TRU) radioactive waste (see 40 CFR part 191, 50 FR 38066, September 19, 1985), which were intended to apply to any facilities utilized for the storage or disposal of these wastes, including Yucca Mountain. In 1987, the U.S. Court of Appeals for the First Circuit remanded the disposal standards in 40 CFR part 191 (NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987)). As discussed below, we later amended and reissued these standards to address issues that the court raised. Also in 1987, the Nuclear Waste Policy Amendments Act (NWPAA, Public Law 100-203) amended the NWPA by, among other actions, selecting Yucca Mountain, Nevada, as the only potential site that DOE should characterize for a long-term geologic repository. In October 1992, the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA, Public Law 102-579) and the EnPA became law. These statutes changed our obligations concerning radiation standards for the Yucca Mountain candidate repository. The WIPP LWA:

(1) reinstated the 40 CFR part 191 disposal standards, except those portions that were the specific subject of the remand by the First Circuit;

(2) required us to issue standards to replace the portion of the challenged standards remanded by the court; and

(3) exempted the Yucca Mountain site from the 40 CFR part 191 disposal standards.

We issued the amended 40 CFR part 191 disposal standards, which addressed the judicial remand, on December 20, 1993 (58 FR 66398). The EnPA, enacted in 1992, set forth our responsibilities as they relate to Yucca Mountain. In the EnPA, Congress directed us to set public health and safety radiation standards for Yucca Mountain. Specifically, section 801(a)(1) of the EnPA directed us to "promulgate, by rule, public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site." Section 801(a)(2) directed us to contract with the National Academy of Sciences (NAS) to conduct a study to provide us with its findings and recommendations on reasonable standards for protection of public health and safety from releases from the Yucca Mountain disposal system. Moreover, it provided that our standards shall be the only such standards applicable to the Yucca Mountain site and are to be based upon and consistent with

NAS's findings and recommendations. On August 1, 1995, NAS released its report, "Technical Bases for Yucca Mountain Standards" (the NAS Report) (Docket No. OAR-2005-0083-0076).

A. Promulgation of 40 CFR part 197 in 2001

Following the direction in the EnPA, we developed standards specifically applicable to releases from radioactive material stored or disposed of in the Yucca Mountain repository. In doing so, we gave special consideration to both the NAS Report and our generic standards in 40 CFR part 191, and also considered other relevant information, precedents, and analyses.

We evaluated 40 CFR part 191 because those standards were developed to apply to any site selected for storage and disposal of SNF and HLW, and would have applied to Yucca Mountain had Congress not directed otherwise. Thus, we believed that 40 CFR part 191 already included the major components of standards needed for any specific site, such as Yucca Mountain. However, we recognized that all the components would not necessarily be directly transferable to the situation at Yucca Mountain, and that some modification might be necessary. We also considered that some components of the generic standards would not be carried into site-specific standards, simply because not all of the conditions found among all potential sites are present at each site. See 66 FR 32076-32078, June 13, 2001 (Docket No. OAR-2005-0083-0042), for a more detailed discussion of the role of 40 CFR part 191 in developing 40 CFR part 197.

We also considered the findings and recommendations of the NAS in developing standards for Yucca Mountain. In some cases, provisions of 40 CFR part 191 were already consistent with NAS's analysis (e.g., level of protection for the individual). In other cases, we used the NAS Report to modify or draw out parts of 40 CFR part 191 to apply more directly to Yucca Mountain (e.g., the stylized drilling scenario for human intrusion). See the NAS Report for a complete description of findings and recommendations (Docket No. EPA-HQ-OAR-2005-0083-0076).

Because our standards are intended to apply specifically to the Yucca Mountain disposal system, in a number of areas we tailored our approach to consider the characteristics of the site and the local populations. Yucca Mountain is in southwestern Nevada approximately 100 miles northwest of Las Vegas. The eastern part of the site is on the Nevada Test Site (NTS). The northwestern part of the site is on the Nevada Test and Training Range (referred to in our proposal as the Nellis Air Force Range). The southwestern part of the site is on Bureau of Land Management land. The area has a desert climate with topography typical of the Basin and Range province. Yucca Mountain is made of layers of ashfalls from volcanic eruptions that happened more than 10 million years ago. There are two major aquifers beneath Yucca Mountain. Regional ground water in the vicinity of Yucca Mountain is believed to flow generally in a south-southeasterly direction. The DOE plans to build the repository about 300 meters below the surface and about 300 to 500 meters above the water table. For more detailed descriptions of Yucca Mountain's geologic and hydrologic characteristics, and the disposal system, please see chapter 7 of the 2001 BID (Docket No. OAR-2005-0083-0050) and the preamble to the proposed rule (64 FR 46979-46980, August 27, 1999, Docket No. OAR-2005-0083-0041).

We proposed the original standards for Yucca Mountain on August 27, 1999 (64 FR 46976). In response to our proposal, we received more than 800 public comments and conducted four public hearings. After evaluating public comments, we issued final standards (66 FR 32074, June 13, 2001). See the Response to Comments document from that rulemaking for more discussion of comments (Docket No. OAR-2005-0083-0043).

The standards issued in 2001 as 40 CFR part 197 included the following:

- A standard to protect the public during management and storage operations on the Yucca Mountain site;
- An individual-protection standard to protect the public after disposal from releases from the undisturbed repository;
- A human-intrusion standard to protect the public after disposal from releases caused by a drilling penetration into the repository;
- A set of standards to protect ground water from radionuclide contamination caused by releases from the disposal system after disposal;
- The requirement that compliance with the disposal standards be shown for 10,000 years;
- The requirement that DOE continue its projections for the individual-protection and human-intrusion standards beyond 10,000 years to the time of peak (maximum) dose, and place those projections in the Environmental Impact Statement (EIS) for Yucca Mountain;

- The concept of the Reasonably Maximally Exposed Individual (RMEI), defined as a hypothetical person whose lifestyle is representative of the local population living today in the Town of Amargosa Valley, as the individual against whom the disposal standards should be assessed; and
- The concept of a "controlled area," defined as an area immediately surrounding the repository whose geology is considered part of the natural barrier component of the overall disposal system, and inside of which radioactive releases are not regulated.

More detail on these aspects of the 2001 final rule may be found at 66 FR 32074-32134, June 13, 2001, and 70 FR 49019-49020, August 22, 2005.

B. Legal Challenges to 40 CFR part 197

Various aspects of our standards were challenged in lawsuits filed with the U.S. Court of Appeals for the District of Columbia Circuit in July 2001. Oral arguments were conducted on January 14, 2004. These challenges and the outcome are described briefly here, emphasizing the aspects leading to today's final rule, and in more detail in the preamble to the proposed rule (70 FR 49014, August 22, 2005).

The State of Nevada, the Natural Resources Defense Council (NRDC), and several other environmental and public interest groups challenged several aspects of our final standards on the grounds that they were insufficiently protective and had not been adequately justified. The focus of this challenge was the 10,000-year compliance period. Nevada and NRDC claimed that EPA's promulgation of standards that apply for 10,000 years after disposal violated the EnPA because such standards are not "based upon and consistent with" the findings and recommendations of the NAS. NAS recommended standards that would apply to the time of maximum risk, within the limits imposed by the long-term geologic stability of the site, and stated that there is "no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value."

The D.C. Circuit Court's ruling was issued on July 9, 2004. The Court dismissed most challenges by Nevada and NRDC, as well as those filed by the Nuclear Energy Institute (NEI). However, on the question of EPA's 10,000-year compliance period, the Court upheld the challenge, ruling that EPA's action was not "based upon and consistent with" the NAS Report, and that EPA had not sufficiently justified its decision to apply compliance standards only to the first 10,000 years after disposal on policy grounds. Nuclear Energy Institute v. Environmental Protection Agency, 373 F.3d 1 (D.C. Cir. 2004) (NEI) (Docket No. OAR-2005-0083-0080). On that point, the Court stated that:

> NAS's conclusion that EPA "might choose to establish consistent policies" is of little importance…And although our case law makes clear that a phrase like "based upon and consistent with" does not require EPA to hew rigidly to NAS's findings, EnPA Section 801(a) cannot reasonably be read to allow a regulation wholly inconsistent with NAS recommendations.

NEI, 373 F.3d at 30.

Similarly, the Court rejected EPA's reasoning that the requirement of 40 CFR 197.35 that DOE project performance to the time of peak dose and place those projections in the Yucca Mountain EIS addressed the intent of the NAS recommendation by ensuring that assessments would not be arbitrarily cut off at some earlier time:

> Although EPA's addition of this provision might well represent a nod to NAS, it hardly makes the agency's regulation consistent with the Academy's findings. NAS recommended that the compliance period extend to the time of peak risk, yet EPA's rule requires only that DOE calculate peak doses and expressly provides that "[n]o regulatory standard applies to the results of this analysis."

Id. at 31, emphasis in original.

While the Court suggested that under different circumstances the Agency's standard might have been upheld, it nevertheless rejected the Agency's limitation of the compliance period to 10,000 years:

> In sum, because EPA's chosen compliance period sharply differs from NAS's findings and recommendations, it represents an unreasonable construction of section 801(a) of the Energy Policy Act. Although EnPA's "based upon and consistent with" mandate leaves EPA with some flexibility in crafting standards in light of NAS's findings, EPA may not stretch this flexibility to cover standards that are inconsistent with the NAS Report. Had EPA begun with the Academy's recommendation to base the compliance period on peak dosage and then made adjustments to accommodate policy considerations not considered by NAS, this might be a very different case. But as the foregoing discussion demonstrates, EPA wholly rejected the Academy's recommendations. We will thus vacate part 197 to the extent that it requires DOE to show compliance for only 10,000 years following disposal.

Id. at 31.

Finally, the Court concluded that "we vacate 40 CFR part 197 to the extent that it incorporates a 10,000-year compliance period…" (Id. at 100.) The Court did not address the protectiveness of the 150 µSv/yr (15 mrem/yr) dose standard applied over the 10,000-year compliance period, nor was the protectiveness of the standard challenged. It ruled only that the compliance period could not be found consistent with or based upon the NAS findings and recommendations, and therefore was contrary to the plain language of the EnPA.

As the Court noted, NAS stated that it had found "no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value," and that "compliance assessment is feasible…on the time scale of the long-term stability of the fundamental geologic regime – a time scale that is on the order of 10^6 years at Yucca Mountain." As a result, and given that "at least some potentially important exposures might not occur until after several hundred thousand years…we recommend that compliance assessment be conducted for the time when the greatest risk occurs" (NAS Report pp. 6-7).

However, NAS also stated "although the selection of a time period of applicability has scientific elements, it also has policy aspects that we have not addressed. For example, EPA might choose to establish consistent policies for managing risks from disposal of both long-lived hazardous nonradioactive materials and radioactive materials" (NAS Report p. 56).

II. Summary of Proposed Amendments to 40 CFR part 197 and Public Comments

The primary goal of our proposal was to satisfy the Court decision and NAS recommendation to assess compliance at the time of maximum dose (risk). Therefore, our proposed amendments centered on the extension of the compliance period to capture the peak projected dose from the Yucca Mountain disposal system "within the limits imposed by the long-term stability of the geologic environment" (NAS Report p. 2).

A. How Did We Propose to Amend Our 2001 Standards?

We considered carefully the language and reasoning of the Court's decision to determine its applicability to each element of our 2001 standards. As originally promulgated in 2001, 40 CFR part 197 contained four sets of standards against which compliance would be assessed. The storage standard applies to exposures of the general public during the operational period, when waste is received at the site, handled in preparation for emplacement in the repository, emplaced in the repository, and stored in the repository until final closure. The three disposal standards apply to releases of radionuclides from the disposal system after final closure, and include an individual-protection standard, a human-intrusion standard, and a set of ground-water protection standards.

The Court's ruling vacated only one aspect of 40 CFR part 197, the 10,000-year compliance period. Therefore, the storage standard, which is applicable only for the period before disposal, is not affected by that ruling. Further, the Court recognized that the ground-water protection standards were issued as an expression of EPA's overall ground-water protection policies, and were not among the standards addressed by the NAS, either in form or purpose ("…NAS treated the compliance-period and ground-water issues quite differently…NAS made no 'finding' or 'recommendation' that EPA's regulation could fail to be 'based upon and consistent with'" (NEI, 373 F.3d at 46-47)). Thus, the Court viewed the ground-water standards as independent of any NAS recommendation. Therefore, we concluded that the Court's vacature of the 10,000-year compliance period, which was explicitly tied to those recommendations, does not extend to the ground-water provisions. As a result, we did not propose to amend the ground-water protection standards. Nothing in today's final rule affects those standards.

We proposed to revise only the individual-protection and human-intrusion standards, along with certain supporting provisions related to the way DOE must consider features, events, and processes (FEPs) in its compliance analyses. In addition, we proposed to adopt updated scientific factors for calculating doses to show compliance with the storage, individual-protection, and human-intrusion standards. We requested comments only on those aspects of the individual-protection and human-intrusion standards which were to be amended. Specifically, we proposed to:

- Extend the compliance period for the individual-protection and human-intrusion standards to 1 million years after disposal (closure), consistent with NAS estimates regarding the "long-term stability of the geologic environment";
- Retain the dose standard of 150 µSv/yr (15 mrem/yr) committed effective dose equivalent (CEDE) for the first 10,000 years after disposal, as promulgated in 2001;
- Establish a dose standard of 3.5 mSv/yr (350 mrem/yr) CEDE for the period between 10,000 years and 1 million years;
- Clarify that the arithmetic mean of projected results will be compared to the dose standard for the initial 10,000 years, and specify use of the median of projected results between 10,000 and 1 million years;
- Retain the probability threshold (1 in 10,000 chance of occurring in 10,000 years, or 1 in 100 million chance of occurring per year) below which "very unlikely" FEPs may be excluded from consideration;
- Allow FEPs above the probability threshold to be excluded if they would not significantly affect the results of performance assessments in the initial 10,000 years;
- Require consideration of seismic and igneous events causing direct damage to the engineered barrier system during the 1 million-year period;

- Require consideration of the effects of increased water flow through the repository resulting from climate change, which could be represented by constant conditions between 10,000 and 1 million years;
- Require consideration of the effects of general corrosion of the engineered barriers between 10,000 and 1 million years; and
- Require use of updated scientific factors, based on ICRP Publications 60 and 72, to calculate dose for comparison with the storage, individual-protection, and human-intrusion standards.

B. What Factors Did We Consider in Developing our Proposal?

Our primary concern in extending the compliance period to 1 million years is the increasing uncertainty associated with numerical projections of radionuclide releases from the Yucca Mountain disposal system and subsequent exposures to the Reasonably Maximally Exposed Individual (RMEI). This uncertainty affects not only the projections themselves, but also the interpretation of the results. There is general agreement in the international community that dose projections over periods as long as 1 million years cannot be viewed in the same context or with the same confidence as projections for periods as "short" as 10,000 years. As a result, the nature of regulatory decision-making fundamentally changes when faced with the prospect of a compliance demonstration over 1 million years. International guidance from the International Atomic Energy Agency (IAEA) and Nuclear Energy Agency (NEA), as well as geologic disposal programs in other countries, recognize this difficulty and accommodate it by viewing longer-term projections in a more qualitative manner, to be balanced and supplemented by other considerations that would provide confidence in the long-term safety of the disposal system. In effect, numerical projections are given less weight in decision-making at longer times. Such approaches discourage comparison of projections against a strict compliance limit.

This uncertainty was the overriding reason for limiting the compliance period to 10,000 years in our 2001 rule. We did require DOE to continue projections through the time of peak dose, but did not require them to be judged against a compliance standard. By doing so, we essentially adopted the approach favored by the international community. However, while we considered this approach to be consistent with the intent of the NAS recommendation to assess compliance at the time of maximum dose (risk) and the committee's acknowledgment that policy considerations would also play a role in determining the compliance period, the Court concluded that it was inconsistent with the recommendation itself. We determined that the most direct way to address the Court's ruling would be to establish a compliance standard for the time of peak dose, within the period of geologic stability at Yucca Mountain, which NAS judged to be "on the order of one million years" (NAS Report p. 2).

We also recognize that our role as the standard-setting agency limits our ability to specify how NRC should weigh those standards in licensing. Therefore, we must consider that any standard established for the 1 million-year period plays the same role in our regulation as do standards applicable for 10,000 years. As a result, we do not believe that extending the 10,000-year individual-protection standard of 15 mrem/yr to apply for 1 million years adequately accounts for the considerations outlined above. In fact, we made such a statement in our 2001 final rule: "Setting a strict numerical standard at a level of risk acceptable today for the period of geologic stability would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard." (66 FR 32098, June 13, 2001) We turned back to the international literature for advice regarding appropriate points of comparison for doses projected over hundreds of thousands of years. A number of sources suggested that natural sources of radioactivity would provide an appropriate benchmark for such comparisons. We also found that the variation in background radiation across the United States covered a wide range (from roughly 100 mrem/yr to 1 rem/yr), primarily because of local variation in radon exposures. We chose for our proposal a level of 350 mrem/yr, which is close to the national average background radiation exposure, but specifically represented the difference between estimated background levels in Amargosa Valley and the State of Colorado. This level was proposed for both the individual-protection and human-intrusion standards as offering both a reasonable level of protection and a sound basis for regulatory decision-making when exposures are projected to occur hundreds of thousands of years into the future. Selecting such a level also provides an indication that exposures incurred by the RMEI in the far future from the combination of natural background radiation and releases from the Yucca Mountain disposal system would not exceed exposures incurred by residents of other parts of the country today from natural sources alone.

Uncertainty in long-term projections also influenced other aspects of our proposal. Given the probabilistic nature of performance assessments, it is inevitable that some combinations of parameter values will result in very high doses. Although there may be only a few results that are very high, extreme results have the potential to exert a strong influence on the arithmetic mean, which could make the mean less representative of overall performance. This possibility may be increased by the natural tendency to introduce additional conservatisms as a way to account for uncertainties. We expressed a preference for a statistical measure that would not be strongly affected by either very high- or low-end estimates, believing it appropriate to focus on the "central tendency" of the distribution, where the bulk of the results might be expected to be found. We proposed the median of the distribution as the representation of central tendency. Because it is always located at the point where half the distribution is higher and half lower, the median depends only on the relative nature of the distribution, rather than the absolute calculated values. Given our concerns about specifying a peak dose compliance value against which performance would be judged, we believed the median would provide a reasonable test of long-term performance.

Our consideration of FEPs also was affected to some extent by uncertainty, as well as by conclusions of the NAS committee. In our proposal, the overall probability threshold for inclusion of FEPs remained the same as in the 2001 rule, which we believe provides a very inclusive initial screen that captures both major and minor factors potentially affecting performance. Uncertainty plays a role in the sense that very gradual or infrequent processes and events may begin to influence performance only at times in the hundreds of thousands of years, when the overall uncertainty of assessments is increasing. The additional uncertainty introduced by these slow-acting FEPs led us to propose the exclusion of FEPs if they were not significant to the assessments in the initial 10,000 years. We believed this would still provide for robust assessments that would address the factors of most importance over the entire 1 million-year period. We did consider in our proposal whether significant FEPs might not be captured using this approach. In evaluating whether excluded FEPs might become more probable or more significant after 10,000 years, and therefore should not be eliminated, we identified general corrosion as a FEP that is certain to occur and represents a significant failure mechanism at longer times, even though it is less significant in the initial 10,000 years.

We also consulted the NAS Report for advice on handling long-term FEPs. NAS identified three “modifiers” that it believed could be reasonably included in assessments: seismic events, igneous events, and climate change. We developed provisions addressing these FEPs that incorporated the views expressed by the NAS committee. For seismic and igneous events, we proposed that DOE focus its attention on events causing direct damage to the engineered barriers. We took this approach because failure of the engineered barrier system, particularly the waste packages, is the predominant factor in determining the timing and magnitude of the peak dose, and is the overriding uncertainty in assessing performance of the disposal system. To address climate change, we required DOE to focus on the effects of increased water flow through the repository, which is the climatic effect with most influence on release and transport of radionuclides. We determined that such a focus would provide the basis for a reasonable test of the disposal system, and that climate change beyond 10,000 years could be represented by constant conditions, which eliminates unresolvable speculation regarding the timing, magnitude, and duration of climatic cycles over this time frame. We also directed that NRC should establish the exact nature of future climate characteristics to be used in performance assessments. NRC subsequently issued a proposal to specify deep percolation into the repository (70 FR 53313, September 8, 2005).

Finally, we proposed to update the factors used to calculate dose for the storage, individual-protection, and human-intrusion standards. Our generic standards in 40 CFR part 191, and by inference our Yucca Mountain standards in 2001, specified the factors associated with Publications 26 and 30 of the International Commission on Radiation Protection (ICRP). Since we issued 40 CFR part 191, ICRP has modified the models and associated organ-weighting factors to more accurately calculate dose. ICRP’s recommendations are embodied in its Publications 60 and 72. We used this newer method in 1999 to develop our Federal Guidance Report 13, “Cancer Risk Coefficients from Exposure to Radionuclides” (Docket No. EPA-HQ-OAR-2005-0083-0072). Where possible, we believe it is appropriate to adopt the latest scientific methods.

C. In Making Our Final Decisions, How Did We Incorporate Public Comments on the Proposed Rule?

Section 801(a)(1) of the EnPA requires us to set public health and safety radiation protection standards for Yucca Mountain by rulemaking.[2] Pursuant to Section 4 of the Administrative Procedure Act (APA), regulatory agencies engaging in informal rulemaking must provide notice of a proposed rulemaking, an opportunity for the public to comment on the proposed rule, and a general statement of the basis and purpose of the final rule.[3] The notice of proposed rulemaking required by the APA must "disclose in detail the thinking that has animated the form of the proposed rule and the data upon which the rule is based." (*Portland Cement Association* v. *Ruckelshaus*, 486 F. 2d 375, 392–94 (D.C. Cir. 1973)) The public thus is enabled to participate in the process by making informed comments on the proposal. This provides us with the benefit of "an exchange of views, information, and criticism between interested persons and the agency." (*Id.*)

There are two primary mechanisms by which we explain the issues raised in public comments and our reactions to them. First, we discuss broad or major comments in the succeeding sections of this preamble. Second, we are publishing a document, accompanying today's action, entitled "Response to Comments" (Docket No. EPA-HQ-OAR-2005-0083-xxxx). The Response to Comments document provides more detailed responses to issues addressed in the preamble. It also addresses all other significant comments on the proposal. We gave all the comments we received, whether written or oral, consideration in developing the final rule.

D. What Public Comments Did We Receive?

The public comment period ended November 21, 2005. We received more than 300 individual submittals, although any particular submittal could contain many specific comments. We also received many more submissions as part of mass comment efforts, in which organizations encourage commenters to use prepared texts or comment on specific aspects of the proposal. All, or representative, comments are available electronically through the Federal

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[2] EnPA, Public Law No. 102-486, 102 Stat. 2776, 42 U.S.C. 10141 n. (1994)
[3] 5 U.S.C. 553

Document Management System (FDMS), available at http://www.regulations.gov. See the "General Information" section of this document for instructions on how to access the electronic docket. Some submittals may be duplicated in FDMS, as a commenter may have used several methods to ensure the comments were received, such as fax, email, U.S. mail, or directly through FDMS.

A significant number of comments addressed the proposed peak dose standard of 3.5 mSv/yr (350 mrem/yr), which would apply between 10,000 and 1 million years. Most commenters opposed our proposal, arguing that it is much higher than any previous standard, is not protective, is not equitable to future generations, and is based on inappropriate use of background radiation data. Many commenters also took issue with our proposal to use the median of the distribution of results as the statistical measure between 10,000 and 1 million years, viewing this measure as inconsistent with NAS recommendations to use the mean. Commenters also viewed the median as too "lax" and likely to discount scenarios that would result in high exposures. We also received comment on our proposal to address FEPs beyond 10,000 years, with some comments expressing the opinion that we had inappropriately constrained the analyses, leaving out potentially significant FEPs. Some commenters disagreed with our general premise that uncertainty increases with assessment time, and that we should take uncertainties into account when considering standards applicable to the far future. These specific comments, and our responses to them, will be discussed in more detail in Section III and in the Response to Comments document associated with this action (Docket No. EPA-HQ-OAR-2005-0083-xxxx).

Some commenters also questioned our conclusion that extending the compliance period is the appropriate way to respond to the Court ruling. These commenters point out that the Court's opinion could be interpreted to permit us to justify the approach taken in our 2001 standards. They cite statements by the Court such as "[i]t would have been one thing had EPA taken the Academy's recommendations into account and then tailored a standard that accommodated the agency's policy concerns" and "[h]ad EPA begun with the Academy's recommendation to base the compliance period on peak dosage and then made adjustments to accommodate policy considerations not considered by NAS, this might be a very different case"

(*NEI*, 373 F.3d at 26 and 31, respectively) to support the thesis that the Court's judgment was based primarily on the presentation of our case, rather than the substance. In the commenters' view, the Court would have been receptive to our arguments had they been presented differently, and the Court provided a clear "road map" to justify keeping our original standards in place. In addition, these and other commenters viewed extending the compliance period to 1 million years as not justifiable either scientifically or as a matter of public policy. While it is clear that we share many of the concerns expressed by these latter commenters regarding the meaning and implementability of a 1 million-year compliance period, we believe this is in fact the most appropriate approach in view of the language in the Court's decision and the weight accorded by the Court's decision to the committee's technical recommendations concerning the period of geologic stability. As we stated in our proposal, "it is not clear how EPA's earlier explanation of its policy concerns might be reconciled with NAS's technical recommendation." (70 FR 49032) Accordingly, as the Court suggested, in today's final rule we have taken steps to implement the NAS technical recommendation with regard to the length of time for the compliance period and to "accommodate" our policy concerns in the provisions related to the peak dose standard, statistical measure of compliance, and FEPs.

We received some comments that suggested we should have provided more or better opportunities for public participation in our decision making process. For example, that we should have rescheduled public hearings, extended the public comment period, and provided alternatives to the public hearing process. We provided numerous opportunities and avenues for public participation in the development of these standards. For example, we held public hearings in Washington, DC; Las Vegas, NV; and Amargosa Valley, NV. We also opened a 60-day public comment period and met with key stakeholders before and during that time. In response to requests from stakeholders, we extended the public comment period by 30 days and held an additional public hearing in Las Vegas. We conducted targeted outreach to Native American tribal groups and have fully considered all comments received through December 31, 2005, after the end of the extended public comment period. These measures are in full compliance with the public participation requirements of the Administrative Procedure Act.

Several comments supported our role in setting standards for Yucca Mountain. Other comments thought that aspects of our standards duplicate NRC's implementation role. We believe the provisions of this rule clearly are within our authority and they are central to the concept of a public health protection standard. We also believe our standards leave NRC the necessary flexibility to adapt to changing conditions at Yucca Mountain or to impose additional requirements in its implementation efforts, if NRC deems them to be necessary.

We also received many general comments, and others addressing topics that are outside the scope of our authority under the EnPA. Several commenters simply expressed their support for, or opposition to, the Yucca Mountain repository. The purpose of our standards is to ensure that any potential releases from the disposal system do not result in unacceptably high radiation exposures. Our standards make no judgment regarding the suitability of the Yucca Mountain site or whether NRC should issue a license for the site. Such a decision is beyond the scope of our statutory authority.

Some comments suggested our standards should explicitly consider radiation exposures from all sources because of the site's proximity to the Nevada Test Site (NTS) and other sources of potential contamination. We are aware of the other such sources of radionuclide contamination in the area. However, our mandate under the EnPA is to set standards that apply only to the storage or disposal of radioactive materials on the Yucca Mountain site, not to these other sources.

A number of commenters suggested that we should explore alternative methods of waste disposal, such as neutralizing radionuclides. Comments also expressed concern regarding risks of transporting radioactive materials to Yucca Mountain. Considerations like these all are outside the scope of our authority. Congress delegated to us neither the authority to postpone the promulgation of these standards in favor of the development of other disposal methods nor the regulation of transportation of waste to Yucca Mountain.

Many comments touched on issues related to our authority and standards, but outside the limited scope of this rulemaking. In particular, many comments urged us to extend the ground-water protection limits to the time of peak dose within the 1 million-year compliance period. Many of these commenters disagreed with our position that the ground-water standards were not the subject of the Court's ruling, and that in fact the Court left us with discretion regarding the content and application of those standards. Others believed that we are obligated to accept comments on this topic, since we were proposing not to change the standards. We stated clearly in our proposal that we were not soliciting, and would not consider, comments on this issue.

III. What Final Amendments Are We Issuing With This Action?

This section describes the provisions of our final rule and summarizes public comments on various aspects of our proposal. Today's final rule establishes the dose standards applicable for a period up to 1 million years after disposal, the statistical measures used to determine compliance with those standards, the methods to be used to calculate the dose, and the requirements for including features, events, and processes (FEPs) in the performance assessments. The discussion that follows addresses the factors we considered in developing our final rule.

III.A. What Dose Standards Will Apply?

Today's final rule includes an individual-protection standard consisting of two parts, which will apply over different time frames. One part of the standard, which will apply over the initial 10,000 years after disposal, consists of the 150 μSv/yr (15 mrem/yr) committed effective dose equivalent (CEDE) individual-protection standard promulgated in 2001 as 40 CFR 197.20. The other part of the standard, which we described in our proposal, will apply beyond 10,000 years to the time of peak dose, up to a limit of 1 million years after disposal. A dose limit of 3.5 mSv/yr (350 mrem/yr) CEDE will apply to the long-term peak dose projections. (Hereafter, these dose limits will be generally referred to as "15 mrem/yr," and "350 mrem/yr," respectively.) We believe this approach establishes a peak dose standard for this longer period that is protective of public health and safety, while also appropriately recognizing the relative manageability of uncertainties at such disparate times, and the resulting level of confidence that can be derived from performance projections.

Many commenters stated their belief that neither the NAS Report nor the D.C. Circuit's decision allows us to apply different standards covering different time periods within the overall compliance period. These commenters take the position that the Court's vacature of the 10,000-year compliance period in the 2001 standards precludes us from having a standard that applies for that initial period, and only permits a single dose limit applicable for the entirety of the extended compliance period. We disagree with these commenters for several reasons. As we noted in our proposal, there was no legal challenge and the Court made no ruling on the protectiveness of our standards up to 10,000 years. Further, the Court ruled that we must address peak dose, but did not state, and we do not believe intended, that we could not have additional measures to bolster the overall protectiveness of the standard. As the Court noted, the EnPA requires that EPA "establish a set of health and safety standards, at least one of which must include an EDE-based, individual protection standard" (NEI, 373 F.3d at 45, Docket No. EPA-HQ-OAR-2005-0083-0080), but does not restrict us from issuing additional standards. Thus, as long as we issue "at least one" standard addressing the NAS recommendation regarding peak dose, we are not precluded from issuing other, complementary, standards to apply for a different compliance period. The Court's concern was whether we had been inconsistent with the NAS recommendation by not extending the period of compliance to capture the peak dose "within the limits imposed by the long-term stability of the geologic environment." (NAS Report p. 2) Today's final rule defines the period of geologic stability for purposes of compliance as ending at 1 million years after disposal. We believe the decision to establish multiple compliance standards applicable during this period, one of which is the required "EDE-based" individual protection standard applying to the peak dose during the period of geologic stability between 10,000 years and 1 million years, falls well within our policy discretion and is supported by scientific considerations concerning the impact of uncertainties in projecting doses over extremely long time frames, as discussed in Section III.A.5 of this document ("How Did We Consider Uncertainty and Reasonable Expectation?").

Although NAS itself did not directly address the approach of having separate standards to apply over different time periods, we believe this approach is not inconsistent with the intent of the committee. As discussed in more detail in Section III.A.4 ("How Does Our Rule Protect Future Generations?"), the committee contrasted an approach in which "a health-based risk standard could be specified to apply uniformly across time and generations" with "some other expression of the principle of intergenerational equity" to be determined by "social judgment." (NAS Report pp. 56-57) We believe the committee clearly recognized the potential for a compliance standard that changes as the time period covered by the assessment increases to be one possible outcome of the rulemaking process. We also find it useful to consider the testimony before the Senate Environment and Public Works Committee on March 1, 2006, by Mr. Robert Fri, chair of the NAS committee. We emphasize that Mr. Fri was testifying in his individual capacity and was not representing the NAS committee; however, we believe his testimony provides assistance in interpreting the NAS committee's statements. Mr. Fri pointed out that "the specification of the time horizon and the selection of the person to be protected are intimately connected." As a result, he noted that retaining the RMEI as the receptor (which the NAS committee recognized as more conservative than its preferred probabilistic critical group) while at the same time extending the compliance period "runs the risk of excessive conservatism," potentially putting the rule where the "committee specifically did not want to be." He noted that the committee had considered and rejected such an approach. (NAS Report pp. 100-103) Mr. Fri viewed our proposal of a higher dose limit between 10,000 and 1 million years as a way "to avoid becoming overly conservative." Therefore, while he offered no opinion on the *level* of the proposed post-10,000-year standard, he indicated that, in his opinion, our *approach* was not in conflict with the committee's intention, and would in fact move us closer to the committee's overall goal. He concluded by stating "the committee recognized that EPA properly had considerable discretion in applying policy considerations outside the scope of our study to the development of the health standard for Yucca Mountain." (See generally NAS Report p. 3) We believe the decision to establish multiple compliance standards falls well within our policy discretion and in that context the 10,000-year individual-protection standard is analogous to our ground-water protection standards.

III.A.1. What is the Dose Standard for 10,000 Years After Disposal?

Today's final rule retains the standard promulgated in 2001 as §197.20, which requires that DOE demonstrate a reasonable expectation that the RMEI will not incur annual doses greater than 15 mrem from releases of radionuclides from the Yucca Mountain disposal system for 10,000 years after disposal. DOE will make this demonstration using the arithmetic mean of performance assessment results (see Section III.A.8, "How Will NRC Judge Compliance?" for further discussion of the mean). We believe this is appropriate, protective, and will maintain consistency with our generic standards at 40 CFR part 191 (now applied to the WIPP) and other applications in both our regulations for hazardous materials and internationally for radioactive waste. Further, NAS stated that the "range [of 10^{-5} to 10^{-6} per year for risk] could therefore be used as a reasonable starting point for EPA's rulemaking" (NAS Report p. 49, emphasis in original). By maintaining the 15 mrem/yr standard for 10,000 years we clearly establish a "starting point" for assessing compliance that is consistent with both the NAS recommendations and our overall risk management policies, and serves as a logical foundation for us to incorporate concerns regarding far future projections.

As we stated in our proposal, an important reason for retaining a standard applicable for the first 10,000 years is to address the possibility, however unlikely, that significant doses could occur within 10,000 years, even if the peak dose occurs significantly later, as DOE currently projects. We received some comments suggesting that DOE's estimates of waste package performance are overly optimistic and that significant early package failures are possible, if not to be expected. Some commenters incorrectly argued that we had inappropriately "ratified" DOE's projections of waste package performance and our proposal "would provide essentially no protection for the period before 10,000 years," because early failure of a system licensed against a 350 mrem/yr peak dose standard would have greater consequences than would early failure of a system licensed against a 15 mrem/yr standard. We recognize that DOE's estimates of waste package integrity rely heavily on extrapolations of laboratory testing data, which involves significant uncertainties, especially when considering time frames well in excess of all practical experience. It is not possible to claim unequivocally that no information will come to light that might cause a reassessment of the containers' behavior and its effect on disposal system performance. However, while DOE must defend its estimates in licensing, our rulemaking is not dependent on resolution of this issue. DOE will have to demonstrate that there is a reasonable expectation that the dose to the RMEI will not exceed 15 mrem/yr in the first 10,000 years after closure. Thus, the addition of the peak dose standard in no way weakens the protection provided by our 2001 standards, since disposal system performance must still be assessed against the 15 mrem/yr limit. Significant numbers of earlier-than-expected waste package failures in reality will challenge the capabilities of the disposal system, regardless of the level of the peak dose standard. Should evidence arise that legitimately challenges DOE's projections that waste package lifetimes will exceed 10,000 years, the 15 mrem/yr standard for that initial period assures that a level of performance equivalent to that required by 40 CFR part 191 must still be demonstrated at Yucca Mountain. The peak dose standard adds a new level of protection for the post-10,000-year period that was not defined in our 2001 standards. We believe it important to structure our regulations to preclude the chance that protection at Yucca Mountain would be less than that provided for WIPP or the Greater Confinement Disposal facility (GCD, which is a group of 120-feet deep boreholes, located within NTS, which contain disposed transuranic wastes). It would be inappropriate to apply a standard designed to accommodate the uncertainties in projections many tens to hundreds of thousands of years into the future to projections within 10,000 years, when uncertainties are more manageable.

III.A.2. What is the Peak Dose Standard Between 10,000 and 1 Million Years After Disposal?

Today we are finalizing our proposed peak dose standard of 3.5 mSv/yr (350 mrem/yr), which will apply for the period between 10,000 years and 1 million years after closure of the facility. In our proposal, we discussed several factors that we considered to be important in setting a dose standard for the time of peak dose within the period of geologic stability. We emphasized the cumulative and increasing uncertainty in projecting potential doses over great time periods, and argued against viewing projected doses as predictions of disposal system performance. This is consistent with the position taken by the NAS committee: "The results of compliance analysis should not, however, be interpreted as accurate predictions of the expected behavior of a geologic repository." (NAS Report p. 71) We believe a higher dose standard for the period beyond 10,000 years is both protective of public health and safety and appropriate given the increased uncertainties in projecting releases from the Yucca Mountain disposal system.

We have also considered how the role of quantitative projections in making compliance decisions must change as the times covered by those projections increases. We noted that emphasizing incremental dose increases when such increases may be overwhelmed by fundamental uncertainties inappropriately takes attention away from an evaluation of the overall safety of the disposal system. In our view, the role of the peak dose standard in the overall decision of disposal system safety must be consistent with the relative confidence that can be placed in quantitative projections over extremely long times. We have recognized the strong consensus in the international radioactive waste community that dose projections extending many tens to hundreds of thousands of years into the future can best be viewed as qualitative indicators of disposal system performance, rather than as firm predictions that can be compared against strict numerical criteria. We agree that confidence in the way the projections were performed, and supporting qualitative information, may be more important to an overall judgment of safety at longer times. However, since our task is to establish a firm regulatory limit, rather than a qualitative standard or dose target, we believe a higher peak dose standard for the period between 10,000 and 1 million years is justified in the context of regulatory decision-making. We continue to believe, as we stated in our 2001 rulemaking, "Setting a strict numerical standard at a level of risk acceptable today for the period of geologic stability would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard" (66 FR 32098, June 13, 2001, Docket No. EPA-HQ-OAR-2005-0083-0042).

As in our proposal, we considered the range of variation in background radiation across the United States in arriving at the final peak dose standard. Given the extremely long time frame under consideration, we believe variations in background radiation across the United States provide a reasonable and logical context for evaluating long-term disposal system safety. In that context, our goal was to establish a peak dose standard, such that total exposures to the Reasonably Maximally Exposed Individual (RMEI) from the combination of background radiation and releases from the Yucca Mountain disposal system would be no greater than exposures incurred by residents of other parts of the country from natural sources alone. The specific basis for the final peak dose standard is described in detail in Section III.A.3 of this document ("How Did We Consider Background Radiation in Developing the Peak Dose Standard?").

We believe that a standard of 3.5 mSv/yr (350 mrem/yr) appropriately satisfies our statutory and judicial mandates by blending the considerations outlined above with current and historical thinking regarding risks associated with background radiation, while recognizing the conceptual difficulties inherent in projecting and evaluating potential events hundreds of thousands of years into the future.

We received many comments questioning both the legality and the protectiveness of our proposed standards. As described previously in Section III.A, commenters stated that the NAS Report and Court decision required us to retain a single dose standard (i.e., 15 mrem/yr) for the entire 1 million-year compliance period, equivalent to the period of geologic stability defined in our rule. Commenters pointed out that the 350 mrem/yr level was well above the range identified by NAS as a starting point for our rulemaking (which ranged from about 2 to 20 mrem/yr), and therefore stated that only the 15 mrem/yr level could be considered consistent with the committee's recommendation. Similarly, some commenters interpreted the Court ruling to require us to adjust the time period covered by the existing 15 mrem/yr standard, which was not challenged. We do not believe this interpretation to be correct. It should be emphasized that the NAS provided only a "reasonable starting point" for our rulemaking, and that none of the regulatory precedents considered by NAS applied for periods approaching 1 million years. (NAS Report pp. 5 and 49, respectively) In fact, NAS explicitly declined to recommend a level of protection, recognizing that this was a matter best left to EPA to establish through rulemaking: "We have not recommended what levels of risk are acceptable…The specific level of acceptable risk cannot be identified by scientific analysis, but must rather be the result of a societal decision-making process. Because we have no particular authority or expertise for judging the outcome of a properly constructed social decision-making process on acceptable risk, we have not attempted to make recommendations on this important question." (NAS Report p. 20) Indeed, NAS explicitly acknowledged "that determining what risk level is acceptable is not ultimately a question of science but of public policy." (NAS Report p. 5) Further, NAS noted that the final outcome of the rulemaking might diverge substantially from the starting point suggested by NAS: "Finally we have identified several instances where science cannot provide all of the guidance necessary to resolve an issue…In these cases, we have tried to suggest positions that could be used by the responsible agency in formulating a proposed rule. Other starting positions are possible, and of course *the final rule could differ markedly from any of them*." (NAS Report p. 3, emphasis added) Thus, we agree with NAS that the selection of a level for the peak dose standard is one of the regulatory policy issues left to EPA's discretion by the EnPA.

We also find it instructive to consider again the personal Senate testimony of NAS committee chair Robert Fri, as described in Section III.A ("What Dose Limits Will Apply?"). Mr. Fri noted that simply extending the compliance period in our 2001 rule to 1 million years "runs the risk of excessive conservatism" and could place our standard where the "committee specifically did not want to be." He recognized that a higher standard at the time of peak dose would be one way to reduce that conservatism. Mr. Fri was not prepared to address the consistency of our proposed dose level with the NAS findings and recommendations; however, he indicated that, in his view, retaining the 15 mrem/yr standard at the time of peak dose would not be consistent with those findings and recommendations if other aspects of our rule remained unchanged (specifically, the choice of receptor). We find this perspective noteworthy, in that it suggests that there are circumstances in which applying 15 mrem/yr throughout the 1 million-year compliance period could result in a standard directly contrary to the committee's overall goals, which emphasized the use of "cautious, but reasonable" assumptions and care in the use of "pessimistic scenarios and parameter values." (NAS Report pp. 100 and 79, respectively) Further, we do not believe the Court's decision can be seen to provide direction independent of the NAS Report; rather, the Court's underlying purpose was to ensure that our standards would be consistent with the committee's findings and recommendations, as required by the EnPA.

In considering appropriate dose standards for periods approaching 1 million years, we also considered the development of our generic standards in 40 CFR part 191. In both our 1985 and 1993 rulemakings, we emphasized that the 10,000-year compliance period for both the containment requirements and individual-protection limit would lead to a combination of site characteristics and engineered barriers that would be capable of providing containment and isolation of the waste for these long periods of time. We did not, however, anticipate that such performance could be maintained indefinitely. Our generic technical analyses, in fact, suggested that significant releases and doses to individuals could result at later times, depending on the characteristics of the site in question and the presumed location of the receptor. For example:

> The Agency examined potential doses to individuals, considering various times in the future, from waste disposal systems in several different geologic media. In most of the

> cases studied, radionuclide releases resulting in exposures to individuals did not occur until more than 1,000 years after disposal due to the containment capabilities of the engineered barrier systems. Beyond 1,000 years, but prior to 10,000 years, as the engineered barriers begin to degrade, releases resulting in doses on the order of a few rems per year appeared for some of the geologic media studied…For other, better geologic media, the Agency's generic analyses estimate no releases for 10,000 years. The Agency believes that selecting a 10,000-year time for the requirements, rather than a 1,000-year time frame, will encourage the selection of better sites and/or the design of more robust engineered barrier systems capable of significantly impeding radionuclide releases. These actions, in turn, will serve to reduce the individual risks associated with the disposal of radioactive waste.

58 FR 66401, December 20, 1993.

We note that sites whose natural features did not provide strong containment were not necessarily considered unsuitable, but we recognized that in those instances, the focus would have to be on "the design of more robust engineered barrier systems capable of significantly impeding radionuclide releases." We believe that it is unrealistic to assume that these sites would then exhibit better performance after the failure of those barriers than they would in the initial 10,000-year period. Consequently, we believe the potential for doses higher than 15 mrem/yr to individuals in the far future has always been implicit in the concept of geologic disposal. Reliance on engineered barriers cannot be assumed for time frames approaching 1 million years, nor do we believe it is reasonable to judge the safety of a disposal system over such time frames against a level of performance consistent with the initial containment period.

Comments on the protectiveness of our proposal pointed out that 350 mrem/yr is much higher than any previous EPA regulation, resulting in risks outside the range of 10^{-4} to 10^{-6} lifetime chance of developing a fatal cancer typically applied by the Agency across programs and pollutants. Many further cited estimates of cancer incidence or fatality as high as 1 in 36 or greater. Using current EPA cancer risk coefficients, we estimate that members of a population receiving an extra 350 mrem/yr over a lifetime would have an additional cancer mortality risk of 1 to 2 in 100 (i.e., 1 to 2%). However, we deliberately did not provide risk estimates associated with 350 mrem/yr in our proposal because the selection of that level, which is to apply over an unprecedented time period, was not based on considerations of risk in the same way as previous standards have been developed, nor do we believe it should be viewed in the same way. Rather, it takes into account larger, less quantifiable factors such as the uncertainties involved in projecting doses over 1 million years and the meaning that can be assigned to such projections, as well as the relative importance they should assume, in a regulatory context. Further, in considering how the overall safety of a geologic disposal system can be portrayed over times approaching 1 million years, we consulted various international sources, which suggested that natural sources of radiation can provide an appropriate benchmark for public health protection over very long times. From a global perspective, doses in the range of natural background radiation do not threaten life or limit the ability of future generations to pursue their interests (see Section III.A.3, "How Did We Consider Background Radiation in Developing the Peak Dose Standard?" and 70 FR 49036-49039 for more discussion of background radiation). Finally, it must be emphasized that the 350 mrem/yr level applies to the RMEI, who is described as a person subject to doses at the high end of the local population. Most residents in the vicinity of Yucca Mountain would receive much lower doses from the disposal system than the RMEI, if any dose at all.

A number of comments compared our proposal to international practices and concluded that our standard would be "the weakest standard in the world" or otherwise inconsistent with those practices. Most commenters offered no specific examples or contrary examples to support those conclusions. In general, we find few similarities in the details of the international approaches that are directly applicable, and no obvious basis for comparing the different approaches. At the same time, we did find broad points of similarity in the overall approach to long-term projections, and referred to organizations such as IAEA and NEA, as well as specific countries, such as Sweden. The more typical approach internationally is to require compliance with quantitative performance assessment for only a limited period of time (in some cases, less than 10,000 years). Longer-term doses may be compared to dose or risk targets or reference levels, but are viewed more as qualitative indicators of performance, to be weighed in conjunction with other qualitative arguments for confidence in the overall safety of the facility. At longer times, the weight given to quantitative projections typically decreases. We attempted such an approach in our 2001 rulemaking, which gave NRC flexibility to consider longer-term dose projections as it thought appropriate within the licensing process (i.e., NRC would decide how much meaning or weight should be assigned to those projections). We considered that a better approach than establishing a compliance limit for times approaching 1 million years, given the increased uncertainties associated with projections over such times.

Today's final rule is responsive to the NAS recommendations and to the D.C. Circuit's decision, but is atypical for such situations in actually prescribing a compliance limit for very long times. It is also atypical in the sense that it is a site-specific standard for which a license application is actively being prepared, whereas most countries have not progressed beyond the identification of candidate sites and may have significantly different legislative and regulatory frameworks in place. Therefore, it is not directly comparable to international situations. However, we did consider the international perspective regarding uncertainties and the confidence that can be placed in very long-term projections for regulatory decision-making. We believe a higher peak dose standard is justified on both counts, particularly since we are establishing a dose limit, rather than a target or reference level that could be exceeded for unspecified reasons. Further, as discussed in more detail in the next section, we also considered international views regarding the use of natural sources of radiation as a framework for evaluating long-term dose projections. We believe our peak dose standard of 350 mrem/yr is protective, consistent with international views, and appropriately accommodates those views within the overall context of reasonable expectation. More detailed discussion of specific international approaches may be found in Section 4 of the Response to Comments document for this final rule.

III.A.3. How Did We Consider Background Radiation In Developing the Peak Dose Standard?

As noted above, we considered a variety of factors in selecting our final peak dose limit, with a strong emphasis on its consistency with the range of variation of background radiation across the United States. Many of the comments we received criticized our proposed use of background radiation as a benchmark for evaluating human-caused exposures in the very far future. Besides taking issue with specifics of our approach, as discussed below, commenters expressed the strong opinion that exposures cannot be considered "safe" just because they are natural, and a high level of natural exposures in one location does not justify allowing additional exposures to another population.

As described in this section, the way in which we have incorporated considerations of background radiation into our decision has changed somewhat. However, we still believe it provides a reasonable perspective from which to judge the overall acceptability of the Yucca Mountain disposal system over a period of 1 million years, as well as providing a context for consideration of the uncertainties involved in projecting doses at such long times. From that perspective, doses in the range of background radiation do not threaten life or limit the ability of future generations to pursue their interests. We cited a number of international sources suggesting that such comparisons are appropriate as uncertainties increase over long times (70 FR 49036-49039). For example, IAEA has stated that, for time frames extending from about 10,000 to 1 million years, "it may be appropriate to use quantitative and qualitative assessments based on comparisons with natural radioactivity and naturally occurring toxic substances." ("Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," IAEA-TECDOC-767, p. 19, 1994, Docket No. EPA-HQ-OAR 2005-0083-0044) The IAEA also suggests that "[i]n very long time frames…uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases." ("Geological Disposal of Radioactive Waste," Final Safety Requirements Document WS-R-4, Section A.7, p. 37, 2006, Docket No. EPA-HQ-OAR-2003-0085-xxxx) In this context, the "dose constraint" referred to by IAEA is akin to our 15 mrem/yr standard. As discussed previously in Section III.A.2, the typical international approach is not to set a strict regulatory limit at times beyond 10,000 years, as we are doing today. As indicated by the citation above, this could lead to situations in which the initial regulatory limit is exceeded, but an overall judgment of safety is supported by other considerations, which take on more importance.

In developing our proposal, we compiled average background radiation exposure data for individual states across the country (see "Assessment of Variations in Radiation Exposure in the United States," technical support document for the 2005 proposed amendments, Docket No.

EPA-HQ-OAR-2005-0083-0077, updated for this final rule as described below). For our purposes, background radiation included cosmic, terrestrial, and indoor radon exposures. After considering that data, the geographic distribution, and the significant variation represented, we determined that our overall approach would be to select a level such that total exposures to the RMEI from the combination of background radiation and releases from the Yucca Mountain disposal system would be no greater than exposures incurred by residents of other parts of the country from natural sources alone.

Following that approach, we focused our proposal on a specific comparison of estimated background radiation in Amargosa Valley and the State of Colorado. Using Amargosa Valley as one point of comparison allows us to provide some assurance that the RMEI location would be adequately taken into account. We estimated the background level in Colorado to be 700 mrem/yr; however, because our data compilation provided only statewide averages, we did not have data specific to Amargosa Valley (although state averages varied significantly, localized data is even more variable and affected by the more limited data points). We consulted DOE's 2002 FEIS, which showed only estimates for Amargosa Valley consistent with national averages, totaling 300 mrem/yr. We adjusted that figure on the basis of EPA's 1993 studies of radon potential, which indicated that Nye County has a higher radon potential than Clark County, which contains two-thirds of the state's population. We then compared the 700 mrem/yr estimate for Colorado with the adjusted estimate of 350 mrem/yr for Amargosa Valley, which resulted in a difference of 350 mrem/yr between the two locations. We discussed specific locations because we believed this type of comparison would be easier to understand than a more generalized discussion of variation in background radiation across the United States. We also thought it illustrated very well our underlying premise for the proposed peak dose limit, which is that exposures from Yucca Mountain in the very far future should be held to a level such that total exposures to the RMEI would not exceed exposures incurred today by residents of other parts of the country from natural sources alone.

However, a significant number of comments questioned our comparative background approach on the grounds that we had incorrectly included indoor radon in our definition of background radiation, that our data was otherwise flawed, or that the basis of comparison we used was inadequately justified. On the question of indoor radon, many commenters argued that it should not be considered "natural" background radiation because it is an "artifact of construction" (some comments referred to indoor radon as "man-made," which is clearly incorrect), because it is extremely variable, and because this approach is at odds with EPA's program to encourage radon mitigation, and in fact assumes the failure of that program. We agree that radon concentrations are highly variable, and emphasized that fact in our proposal as a reason to rely more on statewide averages. Further, we agree that indoor radon exposures are influenced by the type of building considered (e.g., if it has a basement or is a multi-story apartment house) as well as by the amount of time inhabitants spend in the relatively high radon concentration areas. Again, because these factors make it difficult to precisely correlate concentrations to exposures, we believe a wider base of data is desirable. However, we do not agree that indoor radon should be excluded from the definition of background radiation. Indoor radon is the most significant daily exposure incurred by the majority of the population and is likely to be the primary differential in considering relative exposures between locations. Organizations such as ICRP, NCRP, and UNSCEAR commonly discuss indoor radon in the context of background radiation. As for EPA's radon abatement program, we noted in our proposal that EPA does not recommend action be taken at concentrations below 4 pCi/l (which we have typically translated to 800 mrem/yr), and recommends that building owners consider appropriate actions only between 2 and 4 pCi/l (about 400-800 mrem/yr). When establishing a dose standard that will apply for up to 1 million years to a hypothetical RMEI, we believe it is reasonable to consider indoor radon to define representative variations in current background radiation.

We received credible information that our estimated background radiation for Amargosa Valley, which was adjusted from what were essentially "average" figures, is significantly higher than available monitoring and lifestyle information would support. For example, the Desert Research Institute has conducted monitoring that suggests the average background radiation in Amargosa Valley is closer to 110 mrem/yr for terrestrial and cosmic radiation exposure (Docket No. EPA-HQ-OAR-2005-0083-0364.2-1). However, it has also been noted that a significant proportion of the residents of Amargosa Valley live in mobile homes, which could affect indoor radon levels. We also note the recent publication of a study in the October 2006 edition of *Health Physics* by Dr. Dade Moeller ("Comparison of Natural Background Dose Rates for

Residents of the Amargosa Valley, NV, to those in Leadville, CO, and the States of Colorado and Nevada," co-authored by Lin-Shen Sun). Dr. Moeller is a well-known health physicist and past chair of the Health Physics Society. Dr. Moeller also presented his results at a public meeting of the NRC's Advisory Committee on Nuclear Waste (ACNW) in November 2005, and a preliminary version of his paper was submitted with public comments by the Department of Energy. Several other commenters referred to aspects of Dr. Moeller's study.

Dr. Moeller explores the various factors affecting background radiation doses in more detail than we did in our supporting document ("Assessment of Variations in Radiation Exposure in the United States," Docket No. EPA-HQ-OAR-2005-0083-0077, updated for this final rule as described below). He suggests that a more appropriate comparison with Amargosa Valley would be the town of Leadville, Colorado, which is comparable in population. He believes this provides a better basis for comparison than the average for the state as a whole. He also located information indicating that the vast majority of residents of Amargosa Valley live in mobile homes (roughly 91%), which we did not account for in our estimate. This could significantly affect the indoor radon levels encountered. Dr. Moeller calculates that the overall average exposure in Amargosa Valley would be reduced by more than 60% from our estimate. He concludes that the difference in background radiation between Amargosa Valley and Colorado is 254 mrem/yr (compared to our estimate of 350 mrem/yr), and the difference between Amargosa Valley and Leadville (his preferred comparison) is 396 mrem/yr, about 14% higher than our proposed dose standard.

Two factors may have influenced Dr. Moeller's estimates relative to our own. Dr. Moeller employs the Lawrence Berkeley National Laboratory (LBNL) radon database, which is derived from data collected by EPA in the early 1990s, but cannot be directly compared to the data we used. Dr. Moeller also employed a radon dose conversion factor lower than ours, which he cites as consistent with UNSCEAR and forthcoming NCRP recommendations. The factor we employed for our proposal is that published by NCRP in its initial studies of background radiation in Publications 93 and 94. Much work has been done in this area, but there is no consensus that the earlier factors are outdated. However, for the states of Colorado and Nevada, where our estimates are directly comparable, we see no consistent difference. Dr. Moeller's estimate for Colorado is roughly 45% lower than ours (386 compared to 700 mrem/yr), while his estimate for Nevada is almost exactly the same as ours (227 compared to 222 mrem/yr). As noted above, his estimate for Amargosa Valley based on site-specific considerations is considerably lower than ours (derived from DOE estimates), but is also lower than indicated by actual monitoring data (excluding indoor radon). Dr. Moeller finds considerable uncertainty associated with his estimates, primarily in conjunction with the radon component, which is not surprising.

Given the comments we received and Dr. Moeller's work, we revised our estimates of background radiation using the radon conversion factor employed by Dr. Moeller ("Assessment of Variation in Radiation Exposure in the United States," technical support document for the 2006 final amendments, Docket No. EPA-HQ-OAR-2005-0083-xxxx). As expected, our state estimates were reduced proportionally to the fraction of background radiation represented by radon. However, the range of estimates remains greater than 350 mrem/yr, and comparison with Dr. Moeller's conclusions continues to show inconsistencies. While our revised estimate for Colorado is now almost identical to Dr. Moeller's (387 to 386), our estimate for Nevada is less than two-thirds his value (141 to 227). In addition, when considering two different approaches to estimating radon exposures, our estimates for background radiation exposures for Amargosa Valley residents range from approximately 110 mrem/yr to 160 mrem/yr (Docket No. EPA-HQ-OAR-2005-0083-xxxx). Therefore, while we cautioned in our proposal that background radiation rates are highly variable (particularly the indoor radon component), and that no definitive or comprehensive source of data exists, we have considered this additional information and explored other data sources to determine whether a better or more complete data set might be available. Ultimately, however, we conclude that the data in our record is reasonable and as credible as that from other sources, although we did examine the LBNL radon database for a specific purpose, as noted below.

Finally, we received a number of comments questioning our rationale for selecting Colorado as the appropriate end-point for this comparison, as well as suggestions for other locations. Most simply expressed concern that a state at the high end of the background range was used as a reference point and believe our statements of similarity between the two locations are not well-reasoned. As noted above, Dr. Moeller believed the town of Leadville, Colorado would represent a more appropriate comparison, citing similarities in population and "altitude and accompanying relatively high cosmic radiation dose rate" as reasons for his selection. He believed the use of the statewide average would not be appropriate because it would not explicitly consider locations with higher than average dose rates. Commenters also suggested using variations in background radiation in the vicinity of Yucca Mountain, and pointed out that the variation within the state of Nevada is greater than 350 mrem/yr, which we confirmed by examining the LBNL radon database. By this reasoning, a resident of Amargosa Valley could remain in the state and incur 350 mrem/yr additional background radiation. We note that Dr. Moeller considered the comparison with the statewide average for Nevada, as suggested by some comments, to be "a very questionable option" in his presentation to the ACNW.

Taken together, these comments on the quality of the data used and the justification for comparison of specific locations illustrate the difficulty we have had in formulating a standard based on variation in background radiation. Unfortunately, as we stated earlier, there is no definitive or comprehensive source of background radiation data, and all available datasets have limitations. Further, we presented the proposal of 350 mrem/yr in the context of the difference in background radiation between two specific locations. We believed this would provide readers with a clear understanding of the implications of our proposal, and a way to evaluate those implications from the perspective of daily life. It is clear that many readers found this comparison unsatisfying. The comparison was intended to be illustrative, not definitive, and we did not intend to invite debate regarding which location is most similar to Amargosa Valley.

In issuing our final rule, therefore, we believe it is more effective to address the question of variation in background radiation in a wider context, without reference to specific locations. From that perspective, 350 mrem/yr is within that variation, whether considered nationally, regionally (e.g., western states), or within Nevada itself. The 350 mrem/yr level is also comparable to the widely-accepted "average" U.S. natural background of 300 mrem/yr as described by NCRP. We view this difference as well within the margin of uncertainties in estimates of background radiation. Finally, we believe this level continues to fulfill the overall objective expressed in our proposal: exposures incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain would be no greater than exposures incurred by residents elsewhere from natural sources alone.

Some comments criticized our citations to international sources regarding comparisons with natural radioactivity as a benchmark for long-term doses. Comments maintain that we misrepresented statements from these sources regarding fractions of background radiation at very long times, recasting them to support a much larger dose standard at relatively short times. The comments point out, for example, that a reference at an NEA workshop to "a dose constraint derived from natural background levels" for periods up to 100,000 years (70 FR 49036) actually considered 10% of worldwide variation (excluding indoor radon), or roughly 30 mrem/yr, as the "derived" level (Chapman, Neil, "Long Timescales, Low Risks: Rational Containment Objectives that Account for Ethics, Resources, Feasibility and Public Expectations – Some Thoughts to Provoke Discussion," available in the proceedings of the NEA Workshop on "The Handling of Timescales in Assesssing Post-Closure Safety of Deep Geological Repositories," April 16-18, 2002, Docket No. EPA-HQ-OAR-2005-0083-xxxx). We would point out, however, that the cited reference goes on to suggest that beyond 100,000 years, the objective would be "that the eventual redistribution of the residual radioactivity in the environment by erosion and other natural processes should be indistinguishable from regional variations in natural terrestrial radioactivity in near-surface rocks, soils, and waters: with 'regional' taken in the broad sense of, for example, Europe or North America." In that period, "it must be recognized and accepted that the potential exists for uranium ore deposits, or spent fuel or HLW repositories, to give rise locally to doses that are higher than the global average for natural radiation (~2.5 mSv/a)." We do not wish to debate the meaning of "indistinguishable"; however, in this approach, a distinction is clearly being suggested between radiation levels in the vicinity of the repository and those on a much larger scale. We continue to believe these types of statements can be interpreted as generally supporting the proposition that, if a dose standard is to be applied over long times, it is reasonable for the dose standard to change as the time period covered by the assessment increases. Further, we believe these sources provide even stronger support for the proposition that the context in which doses are considered necessarily changes over time. The source cited above also suggests similar changes are necessary in the way in which "the spirit of current radiological protection principles could be applied."

We do not anticipate that all readers will agree with our rationale for the final peak dose standard or with our interpretation of these various sources, nor is it likely they all agree with each other. There will be disagreement regardless of the content of our final standards. For example, we received a number of comments on both our 1999 and 2005 proposals stating that a 15 mrem/yr standard is insufficiently protective. We believe the approach we have taken is a reasonable one that appropriately balances the need for a fixed quantitative long-term peak dose limit standard consistent with NAS and judicial direction, the limitations in quantitative performance assessment methodologies, and the need for a definite marker against which to judge compliance in a regulatory process. We believe our final peak dose standard is both protective and provides the basis for a reasonable test of the disposal system over such extended time frames.

III.A.4 How Does Our Rule Protect Future Generations?

We received extensive comment on our proposal from the perspective of its potential impact on future generations as compared to the current or next few generations. Commenters on this point questioned our reasoning behind proposing a higher dose standard for the far future, and disagreed with our interpretation of literature on the subject. Ultimately, most commenters expressed the view that there is no justification for the level of protection to be different from today's level, whether it is 10,000 or 1 million years (or even longer) from now.

EPA remains committed to the principle of intergenerational equity, which holds (in part) that the risks from a current action should not be greater to future generations than would be acceptable today. A strict reading of this principle initially would lead to the conclusion that the same level of protection must apply at all times, or for as long as the action presents risks. However, we believe that peak dose limits over periods approaching 1 million years should be viewed as qualitatively different from limits applied at earlier times; in other words, the basis for judgment at different times is not the same. We believe the peak dose standard we proposed, and are establishing in our final rule today, appropriately considers this differing basis for judgment and provides the necessary protections for far future generations.

In particular, we have tried to understand how the concept of intergenerational equity is viewed when applied to periods up to 1 million years, because only in the context of radioactive waste management has there been serious consideration of such time frames. For example, does the idea of "risks no greater than would be acceptable today" take on a different meaning over periods during which human evolutionary change may occur? Many commenters expressed the view that it does not. However, as we discussed in our proposal, a number of regulatory and scientific bodies suggest that it may be appropriate to relate longer-term standards to background radiation levels, which strictly speaking would be "greater than would be acceptable today" from a waste management practice, but are not routinely considered as a major risk factor in collective and individual decision-making.

In addition, while the concept of intergenerational equity is of sufficient importance to underlie two of the nine fundamental radioactive waste management safety principles endorsed by IAEA ("The Principles of Radioactive Waste Management," Safety Series 111-F, 1995, in particular Principles 4 and 5, which relate to protection of future generations and burdens on future generations, respectively) and has been incorporated into the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (an international agreement ratified by more than 30 countries, including the U.S.), we have viewed it as necessary to consider other principles that have been put forward in the context of making decisions with implications for the future, with particular attention to those relevant to radioactive waste management. The arguments for maintaining a single level of protection for all times as an expression of intergenerational equity are well-known. We were also interested in examining arguments that intergenerational concerns could be accommodated, and equity achieved, by approaching the problem in other ways. This led us to consider documents prepared by the National Academy of Public Administration (NAPA) and Swedish National Council for Nuclear Waste (KASAM). NAPA is a Congressionally-chartered organization whose purpose is to provide assistance to government in assessing and effectively addressing issues of governance, including future implications of contemplated actions. KASAM was created by the Swedish government in 1985 to provide an independent review of issues related to nuclear waste.

We emphasize that we do not question whether there is an obligation to future generations, but we believe there is no consensus regarding the nature of that obligation, for how long it applies, whether it changes over time, or how it can be discharged. Regarding radioactive waste management and geologic disposal, there is general agreement that assurances can be provided that the protections offered will be similar to those acceptable today for periods approximating 10,000 years, which is a very long time. However, as one considers times in the hundreds of thousands of years, can similar assurances be offered when, as we believe, the underlying bases for those assurances has fundamentally changed? What form can those assurances take (i.e., can we reasonably make assurances regarding our ability to distinguish among and control incremental radiation exposures over long times)? Can they provide the same level of confidence? We are establishing today a standard that would not affect the quality of life for future generations. We believe this is a reasonable level of commitment for such long times, given the complexities of the situation and what we see as our responsibility to establish a level of compliance, not a soft target or reference level that could be exceeded for unspecified reasons and by unspecified amounts.

Some comments criticized our discussion of the literature from international sources, believing we misrepresented these sources as stating that dose assessments should not be conducted over times approaching 1 million years. We believe these comments confuse two concepts, the conduct of dose assessments and the establishment of dose standards. We believe we accurately represented international sources on both points. These sources do generally take the position that numerical assessments eventually lose their utility (e.g., "calculations of dose and risk should not be extended to times beyond those for which the assumptions underlying the models and data can be justified," NEA, cited at 70 FR 49027). This sentiment is in complete agreement with NAS statements regarding geologic stability: "After the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72, see also Section III.A.5 of this document) However, even for shorter periods when assessments can provide insights into disposal system performance, the typical approach internationally is not to hold the results of those assessments to strict numerical limits, but to view them more as qualitative indicators of performance (see, for example, 70 FR 49026-49027). This approach, which we adopted in our

2001 rule, acknowledges that the nature of dose projections changes over time, so that comparison of those projections to strict numerical limits may not be the most meaningful indicator of equity over long time frames.

A number of other commenters cite the statements of the NAS committee regarding intergenerational equity to support their position that a higher dose level for longer times is contrary both to that principle and the NAS recommendation. We disagree, and have discussed the second point in some detail in Section III.A.2 ("What is the Peak Dose Standard Between 10,000 and 1 Million Years After Disposal?"). Regarding the question of intergenerational equity, we cited the NAS discussion in our proposal (page 49036). In citing NRC and IAEA sources, the NAS wrote:

> A health-based risk standard could be specified to apply uniformly over time and generations. Such an approach would be consistent with the principle of intergenerational equity that requires that the risks to future generations be no greater than the risks that would be accepted today. Whether to adopt this *or some other expression of the principle of intergenerational equity* is a matter for social judgment.

NAS Report pp. 56-57, emphasis added.

We generally agree with the NAS statement. A single dose standard applicable at all times would typically be consistent with the principle of intergenerational equity. However, as we noted in Section III.A.2, there may be some reason to believe that a 15 mrem/yr peak dose limit in our rule could be viewed as "overly conservative" from the NAS perspective and not consistent with the intent of the committee. In such a case, it must be considered whether such a conclusion would have implications for the appropriate expression of the principle of intergenerational equity. Further, NAS clearly acknowledges that "some other" approach could also be consistent with that principle. We believe it is reasonable to conclude that "some other" approach must include situations where the same dose standard does not apply at all times. The rulemaking process we are following is the accepted way for "social judgment" to be incorporated into regulations.

Determining whether a dose limit is adequately protective of both current and future generations must also consider the ability of performance assessments, and those who interpret them, to distinguish between differing repository designs, as well as different conceptualizations of total system performance over very long time frames. In our view, it makes little sense to assert that a 15 mrem/yr dose limit for the period within 10,000 years is more "protective" than a higher limit much later in time if, in the time frame of hundreds of thousands of years, the uncertainties in projecting disposal system performance cannot easily make distinctions at such incremental levels. As we stated in our proposal, "In our view, the 350 mrem/yr level and these other values are within a range of values for which projections might well be indistinguishable after several hundred thousand years. That is, when taking increasing uncertainties into account in the very long term, the effects of factors that would distinguish projections of 100, 200, and 350 mrem/yr within a 10,000-year time frame are more difficult to identify clearly at very long times, so that such projections may be qualitatively identical to each other and to the level of performance represented by projections of 15 mrem/yr at 10,000 years." (70 FR 49038) Where fundamental uncertainties have significant effects, decisions about overall safety based on incremental doses may be less defensible.

We believe this is a very real challenge at Yucca Mountain. As discussed in more detail in Section III.A.5 ("Uncertainty and Reasonable Expectation"), we estimate that uncertainties in transport through the natural barrier system alone contribute roughly two orders of magnitude to the spread of projected doses within the period of geologic stability, when starting with a defined situation at 10,000 years where uncertainty in projections is already present (Docket ref). We believe that a peak dose standard of 350 mrem/yr, which is comparable to average background radiation exposures and well within the variation of such exposures across the United States today, represents a protective and reasonable approach that appropriately balances the influence of uncertainty on long-term projections with the demands of intergenerational equity. More discussion of this topic may be found in Section 9 of the Response to Comments Document for this final rule (Docket No EPA-HQ-OAR-2005-0083-xxxx).

III.A.5 Uncertainty and Reasonable Expectation

In our proposal, we stressed the uncertainties inherent in projecting disposal system performance over times as long as 1 million years to support our proposal for a higher peak dose standard beyond 10,000 years. Such uncertainties, we argued, make it more difficult to distinguish among incremental projected doses and influence the judgment that those projections will meet a standard with "reasonable expectation." We concluded that, in light of increased uncertainty, "the concept of reasonable expectation underlying our standards implies that a dose limit for that very long period that is higher than the 15 mrem/yr limit that applies in the relatively 'certain' pre-10,000-year compliance period could still provide a comparable judgment of overall safety." (70 FR 49029)

Many commenters disputed this conclusion, contending that our emphasis on uncertainty, reasonable expectation, and a related concept, implementability by NRC in a licensing process, is intended to disguise our true intent, which is to set a standard that Yucca Mountain can pass. A number of commenters took the position that, while our concern about uncertainty may be legitimate, the only legitimate response is to say the site cannot be licensed in the face of such overwhelming uncertainty. Still other commenters challenged our position that uncertainty generally increases as the time covered by the assessment increases (or as the time of peak dose moves farther out in time). They cite statements by the NAS such as "analyses that are uncertain at one time might not be so uncertain at a later time; for example, the uncertainties about cumulative releases to the biosphere that depend on the rate of failure of the waste packages are large in the near term but are smaller later, when enough time has passed that all of the packages will have failed." (NAS Report pp. 29-30) Some commenters also pointed to numerous NAS statements regarding use of "bounding" assumptions as an indication that the committee did not believe that uncertainties become more difficult to manage at longer times.

On this last point, we believe it should be clear that NAS did view overall uncertainties as increasing with time: "We recognize that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs increases." (NAS Report p. 56) On the role of bounding assessments, we have been more cautious, as described in our proposal (70 FR 49021, 49029, 49042). We do believe that bounding analyses have value, but that value can be compromised if the analyses are excessively conservative in the assumptions underlying the analysis or the spread of parameter values chosen for the analysis. One purpose of bounding analyses is to assess reasonably conservative scenarios in order to provide confidence that actual doses will be lower than projected. However, uncertainty associated with conceptual models or data can drive the use of bounding analyses, although reliance on them can come at the expense of more realistic scenarios that may contribute more to the understanding of site performance. NAS also took this position in stating "care should be given as to how one could combine the robust, bounding estimate type of assessment with a probabilistic analysis." (NAS Report p. 79) In this regard, we also disagree with commenters who advocated deliberately increasing the amount of conservatism in the modeling as a way to address uncertainty. While we agree that some conservatism is inevitable and may be desirable, we do not believe judgments of disposal system safety should focus on scenarios selected to be extreme.

In general, as we discussed at length in our proposal, there is overall agreement that uncertainties in long-term dose projections increase, which decreases confidence in numerical projections and makes it more questionable to rely on them as the basis for regulatory decision-making. The typical response to this internationally is to require strict compliance with a dose or risk limit for only a few thousand years. Numerical results for much longer periods are considered as indicative of disposal system performance, but do not have quantitative standards associated with them. However, we believe the appropriate response to the Court decision is to establish a numeric dose limit against which compliance can be assessed at the time of peak dose, within the period of geologic stability. That dose limit must be protective, meaningful, implementable, and consistent with the NAS Report, the Court ruling, and the principles of reasonable expectation. It is incumbent on us, in meeting these goals, to consider how the factors affecting long-term dose projections, including uncertainty, influence the selection of the peak dose limit.

In responding to comments on this issue, we considered how it might be possible to demonstrate the increase in projected uncertainties and provide a quantitative estimate of the degree of increased uncertainty that might be encountered. To examine the long-term propagation of uncertainty in dose projections, we used a simplified Yucca Mountain site performance assessment model and constructed a hypothetical disposal system that would, under site conditions, produce a mean dose to the RMEI of 15 mrem/yr at 10,000 years. That is, we estimated the number of waste package failures that would be necessary to produce a disposal system operating at the "edge of compliance" at 10,000 years. This disposal system, which would still meet the performance standard at 10,000 years, was the reference base case for our uncertainty analyses. The number of "failed" waste packages needed to produce the reference case dose (a mean of 15 mrem/yr at 10,000 years) was calculated using the site model and parameters, and assumed the components of the engineered barrier did not function to provide containment (i.e., the titanium drip shields designed to divert water from the waste packages, as well as other components of the engineered barrier system, were removed from the model). Further, upon "failure" of a waste package, the entire inventory of that package was assumed to be available for dissolution and transport.

To assess the progressive effects of uncertainty, the number of "failed" packages was limited to the number necessary to produce 15 mrem/yr at 10,000 years, and the site model was used to make dose projections from 10,000 years (the reference base case) through the period of peak dose within the period of geologic stability. Thus, the system established as a starting point for the peak dose projections was one in which some degree of release and transport to the RMEI had already taken place, providing a basis for judging how the continuation of these processes would change the results over time. These analyses therefore examined only the effects of uncertainties from the natural barrier portion of the disposal system, since additional waste package failures were not considered. It should be recognized that the base case was determined using probabilistic methods, so the results at 10,000 years already showed some effects of uncertainty, as indicated by the range of projected doses. We found that the uncertainty in dose projections, from the base case (at 10,000 years) to peak dose (as measured by the spread in dose estimates between the 5 and 95 percentiles at these times), increased by approximately two orders of magnitude. These results showed quantitatively that uncertainty in performance projections does increase with time for the Yucca Mountain system, and supports the premise that increasing uncertainty reduces the degree of confidence that can be assumed for very long-term performance assessments. The increasing uncertainty in dose projections over very long time periods lessens the ability of performance assessment modeling to meaningfully distinguish between alternative (and equally "likely") "futures" represented by individual model simulations, and ultimately to distinguish between alternate models and assumptions for site performance assessments.

Although we were primarily interested in the relative uncertainty of the dose projections, we also note that the mean peak doses calculated, for various variations of modeling parameters and assumptions, were found to be in the range of approximately 300 – 400 mrem/yr. This result offers a significant insight into the degree of uncertainty growth, in that the increases were not excessive, pushing the reference mean peak dose into the many rem/yr range or higher at peak dose, nor were the uncertainties low enough (such that the separation of high-end results from the remainder of the distribution is more limited) such that the calculated mean peak doses remained in the tens of mrem/yr range. While it does not directly inform our selection of the peak dose limit in today's final rule, this observation suggests that the 350 mrem/yr peak dose limit could, as we stated in our proposal, be "qualitatively identical…to the level of performance represented by projections of 15 mrem/yr at 10,000 years" (70 FR 49038), and supports our reasoning that for very long periods within the geologic stability period, a dose limit based on variations in background radiation levels is a reasonable approach to setting a dose limit, considering the increasing uncertainties affecting performance projections and the associated difficulty in interpreting them. In this sense, we believe our uncertainty analyses do provide some confirmatory evidence for the line of reasoning used to set the post-10,000-year peak dose limit. From that perspective, we do not believe that longer-term limit should be perceived as a "loosened" standard relative to the 10,000-year standard. More detail on the site model we used, parameter databases, sensitivity analyses and discussion of the results, is provided in the technical reports describing this work (docket references).

It should be understood that these assessments do not explore how the disposal system will actually perform over time, and should not be directly compared to DOE's performance assessments, which include the engineered components of the repository and show results from the integrated disposal system. The disposal system examined in our analyses was a hypothetical one developed exclusively to examine the effects of uncertainty in the performance of the natural barrier over time and the consequences on dose projections. Our study indicates that, while the timing of waste package failures is perhaps the uncertainty with the greatest overall effect on projected peak dose, the natural barrier system also contributes significant uncertainty, contrary to some comments. For the actual performance of the disposal system, the engineered barriers will function in addition to the natural barrier to provide containment and isolation, and the entire inventory of waste packages in the repository will contribute to the long-term behavior of the disposal system. It is not possible to predict exactly how uncertainty will influence dose projections for the actual disposal system, since all the variables will be in play in such assessments. Our analyses are useful to demonstrate quantitatively that uncertainties do increase over time and provide an "order-of-magnitude" estimation of the effects, as well as to show that uncertainties lessen the ability of performance assessments to meaningfully distinguish between alternative "futures" and performance scenarios. Regarding the quantitative estimates of uncertainty, it should also be noted that there is a difference between relative uncertainty and absolute uncertainty in projecting potential health effects, which also plays into interpretation of results. For example, a spread of doses from 0.1 mrem/yr to 10 mrem/yr represents two orders of magnitude. A spread of doses from 10 mrem/yr to 1,000 mrem/yr also represents two orders of magnitude, yet the absolute uncertainty in the latter case is clearly greater. Finally, the results of our analyses indicate that our rationale for selecting a peak dose limit comparable to background radiation levels is not unreasonable when compared to the magnitude of uncertainties and their effects on projected doses.

III.A.6 What is Geologic Stability and Why is it Important?

Underlying the NAS recommendation to assess compliance at the time of maximum risk is the concept of geologic stability (i.e., peak dose should be assessed "within the limits imposed by the long-term stability of the geologic environment," NAS Report p. 2). NAS viewed this as an important consideration in assessing performance, both analytically and in regulatory review. Indeed, NAS discussed two important kinds of uncertainty in describing this concept, which are spatial and temporal uncertainty. The committee concluded that spatial uncertainties will always exist no matter what time frame is used for the performance assessments. Temporal uncertainties, on the other hand, will vary over different time frames, and the presence of such uncertainties indicates the advisability of defining a "period of geologic stability," during which performance projections can be made with some degree of confidence. For time periods where conditions at the site would change dramatically in a relatively short time, projections of site conditions would be highly speculative, and consequently performance assessments would have very limited if any validity. It is important to understand that "stable" in this context is not synonymous with "static and unchanging." Rather, NAS recognized that many "physical and geologic processes" are characteristic of any site and have the potential to affect performance of the disposal system. NAS concluded that these processes could be evaluated as long as "the geologic system is relatively stable and varies in a boundable manner" (NAS Report p. 9). Thus, the site itself could be anticipated to change over time, but in relatively narrow ways that can be defined ("bounded"). Implicit in the NAS recommendation is the idea that the maximum risk might occur outside the period of geologic stability, but assessments performed at that time would have little credibility and would not be a legitimate basis for regulatory decisions: "After the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72)

NAS judged this period of "long-term stability" to be "on the order of one million years." (NAS Report p. 2) We describe in Section III.A.7 ("Why is the Period of Geologic Stability 1 Million Years?") the policy judgment on our part to explicitly equate the period of geologic stability with 1 million years. More important, however, is to understand the relationship among the regulatory definition, the physical reality of the site, and the performance assessment models. In reaching its conclusion, NAS considered information available on the site properties and the processes as they currently operate. This provides a basis for understanding how the site functions today, but would not be sufficient to project that understanding for periods of millions of years into the future. To do that, NAS also considered information obtained through studies of the geologic record at the site, to see if evidence existed for times when processes were either fundamentally different or they operated at different rates. This is similar to our recommendation that DOE consider at least the last two million years (the Quaternary period) in characterizing FEPs. In fact, examination of the Quaternary geologic record is an important component in understanding the evolution of the geologic setting over time. NAS expressed confidence that neither the processes active at the site, nor the site itself, had changed in fundamental ways over the Quaternary Period and longer, and probably would continue to behave much as it does today for the next million years. NAS therefore suggested that conditions could be bounded with reasonable confidence for periods "on the order of one million years."

Models used to assess performance need to incorporate a description of the bounds under which the model can be considered valid, so as to avoid physically impossible situations, as well as assure that the conceptual models upon which the performance assessments are based reasonably represent the way the site is expected to behave over the period of stability. They must be defined so that significant changes to the properties of the site and physical and geologic processes are not projected inadvertently to create conditions of "geologic instability." That is, they must avoid crossing over into sets of conditions that would in reality not be a geologically stable situation, or are outside the bounds under which the model can be considered valid. Here again the examination of the geologic record at the site provides the means of constructing the models to adequately make simulations of future performance that reflect the range of expected conditions at the site over the regulatory compliance period. Parameter distributions used in the simulations, which are the fundamental input information used to make the dose assessments, should not be limited only to data collected for the present situation at the site, but should consider how those parameter values could change over the period of stability. Expert judgment where appropriate, based upon site-specific information and broader understanding of how these processes operate in general, plays an important role in defining such modeling input data.

The geologic record is the primary source of information on the question of geologic stability and was considered by NAS in reaching its conclusions about the geologic stability period. We believe that the geologic record at the site clearly supports the position that the site will be stable over the course of the next million years. Conclusions based on extrapolation beyond what can be supported in the geologic record should be avoided.

III.A.7 Why is the Period of Geologic Stability 1 Million Years?

Today's final rule includes a compliance period of 1 million years, during which DOE must demonstrate compliance with the individual-protection and human-intrusion standards. As discussed at length in our proposal and more briefly in Sections I and II of this document, our rulemaking is in response to the D.C. Circuit decision vacating the 10,000-year compliance period in our 2001 rule. The Court concluded that the 10,000-year compliance period was not based upon and consistent with recommendations of the NAS, as the EnPA required. The NAS recommended "that compliance with the standard be assessed at the time of peak risk, whenever it occurs, within the limits imposed by the long-term stability of the geologic environment, which is on the order of one million years." (NAS Report p. 2) NAS found that "compliance assessment is feasible for most physical and geologic aspects of repository performance on the time scale of the long-term stability of the fundamental geologic regime," and accordingly "there is no scientific basis for limiting the time period of an individual-risk standard." (NAS Report p. 6) As a matter of policy, we believe it is appropriate and necessary to define a compliance period within which our standards apply. This section discusses the considerations that led us to conclude that a compliance period of 1 million years is appropriate from a policy perspective and consistent with NAS statements regarding geologic stability at Yucca Mountain.

As discussed in Section III.A.6 ("What is Geologic Stability and Why is it Important"?), the NAS introduced the concept of geologic stability in its report and referred to it repeatedly in its discussions (NAS Report, e.g., pp. 9, 55, 69, 71, and 72). In discussing the physical properties and geologic processes leading to the transport of radionuclides away from the repository, the NAS committee concluded "that these physical and geologic processes are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance can be assessed over time frames during which the geologic system is relatively stable or varies in a boundable manner." (NAS Report p. 9) While variation of site characteristics over time produces some uncertainty (NAS Report p. 72), NAS believed that such changes could be bounded during the period of geologic stability of the site (NAS Report p. 77), i.e., as long as the conditions do not change significantly. NAS also noted that "[a]fter the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72) While NAS made no additional qualification on what constituted "significant" changes, it made numerous references in its report to a stability period for the site "on the order of one million years." The committee concluded that during this period it would be feasible to make projections of repository site conditions. We concur and believe that assessments can be made and bounded where uncertainty exists, and consequently performance assessments can be developed with adequate confidence for regulatory decision-making within the context of the requirements adopted in today's final rule. We discuss some additional qualifications to this proposition in the remainder of this section.

While the NAS characterized the length of the geologic stability period in loose terms ("on the order of"), we believe it is appropriate to fix the stability period duration as a matter of regulatory policy. We find support on this point from NAS: "It is important, therefore, that the 'rules' for the compliance assessment be established in advance of the licensing process." (NAS Report p.73). We believe, therefore, as a matter of regulatory philosophy and policy, that a relatively loosely defined stability period "on the order of" one million years is not sufficiently specific for regulatory purposes, i.e., implementing our standards and reaching a compliance decision. Indeed, NAS clearly considered that the compliance period could be one of the "rules" that should be established for compliance assessments. (NAS Report p. 56) Some commenters suggested that the period of geologic stability could be longer (or interpreted "on the order of one million years" as possibly as long as ten million years), and said our rule should allow consideration of longer timescales if justified by considerations of geologic stability. The actual period of geologic stability at Yucca Mountain is unknowable, and we disagree that an open-ended compliance standard is justified over such time frames. We believe that the applicant (DOE) and the compliance decision-maker (NRC) must have definitive markers to judge when compliance is demonstrated, and that a loosely defined time frame does not provide such a marker for implementation of our standards in a licensing process. We believe that the geologic stability period of 1 million years that we have defined provides the necessary marker, and is within our discretion to set as a matter of policy. (See generally NAS Report p. 3) To do otherwise we believe would leave the licensing process in a potentially untenable situation of dealing with possibly endless debate over exactly when a peak dose occurs in relation to a compliance period time limit. Such debate can arise because of the inherent uncertainty that exists in characterizing the complex processes and variables involved in projecting performance of the disposal system over very long periods of time. As the NAS explained, "although the selection of a time period of applicability has scientific elements, it also has policy aspects we have not addressed." (NAS Report p. 56)

As commenters have pointed out, the rate of waste package failure is a dominant factor in determining when the peak dose for a probabilistic assessment will occur. With all the parameters (and the uncertainty in their values over time) involved in a total system performance assessment, as well as the assumptions necessary to select processes involved in projecting performance, it is quite possible that significant debate could result in the licensing process over selection of the parameter values and the resulting timing of the peak dose results. We do not believe such debate is warranted because it would not advance the goal of providing a reasonable test of the disposal system. We also believe that the 1 million year stability period provides the needed definitive marker for judging the time over which the standards apply and is an appropriate exercise of our policy discretion.

Throughout our proposal and in this final rule we have cited a significant number of international references to support policy judgments such as the one discussed here. Readers may recall that we cited such references suggesting that dose projections beyond 1 million years have little credibility and believe that we used those arguments to justify proposing the 1 million-year compliance period (70 FR 49036, August 22, 2005). We did not explicitly discuss in the proposal our reasons for selecting 1 million years as the compliance period and equating it to the period of geologic stability, other than references to the NAS language that it is "on the order of" 1 million years. However, these sources do generally reflect widespread acceptance of the proposition that quantitative performance projections at very long time frames have limited utility for regulatory decision-making, and that 1 million years may be a reasonable reference point beyond which such projections either should not be required or should be considered only in their broadest sense.[4] Further, while it should be clear that we agree with the thrust of those international sources regarding the effects of uncertainty on long-term dose projections and the relative level of confidence that can be placed in them for decision-making, we believe the peak dose standard in today's final rule appropriately accommodates those considerations and is protective, meaningful, implementable, and provides a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation.

To support these general policy arguments, which would lead us to consider a time period of approximately 1 million years as an appropriate regulatory time frame, it is necessary to address NAS's scientific judgments. While NAS did not define with precision the period of time that the geologic environment likely would remain stable, for purposes of our regulation we believe scientific information can be relied upon to support a firm definition of that period as ending at 1 million years after disposal. Further, we believe that equating a specific time period

[4] For example, in general guidance documents, the IAEA has stated that "little credibility can be attached to assessments beyond 10^6 years." ("Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," IAEA-TECDOC-767, p. 19, 1994, Docket No. EPA-HQ-OAR-2005-0083-0044) In its final 2006 Safety Requirements for Geological Disposal of Radioactive Waste, IAEA also states "Care needs to be exercised in using the criteria beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making." (Docket No. EPA-HQ-OAR-2005-0083-038x, page 11, paragraph 2.12) As a country-specific example, final guidelines from the Swedish Radiation Protection Authority state that "the risk analysis should be extended in time as long as it provides important information about the possibility of improving the protective capability of the repository, although at the longest for a time period of one million years." (Docket No. EPA-HQ-OAR-2005-0083-xxxx) Also, in an example where the official guidelines specify a risk target that is of undefined duration, the United Kingdom's National Radiological Protection Board has stated that "[o]ne million years is…the timescale over which stable geological formations can be expected to remain relatively unchanged," while concluding that the scientific basis for risk calculations past one million years is "highly questionable.' ("Board Statement on Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes," 1982 Documents of the NRPB, Volume 3, No. 3, p. 15, Docket No. EPA-HQ-OAR-2005-0083-xxxx)

with the “period of geologic stability” is a site-specific decision, as NAS’s statements regarding geologic stability were wholly in the context of Yucca Mountain. (See, for example, NAS Report p. 69: “The time scales of long term geologic processes at Yucca Mountain are on the order of 10^6 years”; and NAS Report p. 85: “The geologic record suggests this time frame is on the order of about 10^6 years.”) Therefore, we have considered how the natural processes and characteristics at the Yucca Mountain site would support defining the period of geologic stability as ending at a specified time after disposal. In considering the natural setting, many comments expressed the view that the site’s natural characteristics are so conducive to rapid release and transport of radionuclides, only the waste packages and other engineered barriers would make it possible for significant doses to be delayed much beyond 10,000 years. We believe it is therefore also appropriate to consider the geologic stability period from the perspective of a reasonable length of time to allow significant waste package failure, which is the limiting factor in projecting doses within a specific time period, as discussed earlier. Natural processes and events would contribute to both the package failures and to the subsequent transport of radionuclides, even if such failures occur relatively late in the period under consideration.

A consideration of the past history of the site, in the areas of igneous and seismic activity, also supports a 1 million year stability period. Information compiled by the NRC (Docket No. EPA-HQ-OAR-2005-0083-0373) concerning basaltic igneous activity around the site shows that this type of activity has been the only activity around the site through the Pliocene (beginning roughly 5.4 million years ago), and that the volume of eruptive activity (both tuff and basaltic material) has decreased continually over the last 10 million years (Coleman et al., 2004, Docket No. EPA-HQ-OAR-2005-0083-0378). From the identification of surface features as well as indicators of buried remnants of past volcanic activity, the episodes of basaltic activity around the site can be shown to have occurred in clusters of events around 1 million and 4 million years ago (Hill, 2004, Docket No. EPA-HQ-OAR-2005-0083-0373). The occurrence of these clusters indicates that the nature and extent of past volcanic activity can be reasonably well characterized and that annual probabilities for such events can be reasonably estimated from the geologic record around the site. Annual probabilities of volcanic disruptions to the repository have been estimated by various investigators, and range from as high as 10^{-6} to as low as 5.4×10^{-10} (Coleman et al, 2004, Docket No. EPA-HQ-OAR-2005-0083-0378).

Further, while geologic stability may be viewed as being affected primarily by large-scale events, accumulations of small-scale changes over very long time periods also have the potential to alter the geologic setting and affect the technical basis for performance assessments. Tectonic events have such a potential at Yucca Mountain. Rates of displacement on the nearest potentially significant fault in the region average about 0.02 mm/yr. (DOE, Science & Engineering Report, 2002, p. 4-409, Docket No. EPA-HQ-OAR-2005-0083-0069) This means that in 10,000 years, there could be 20 cm (0.65 ft) of displacement, a relatively small change not likely to affect performance of the geologic system. However, in 1 million years, the same rate of movement results in 20 m (65 ft) of displacement on the fault. Using the larger estimates of movement within the range of potential movement, displacement could be as much as 30 m (100 ft) over 1 million years. Such changes in the geologic setting at Yucca Mountain have the potential to erode the scientific basis for performance assessment so as to render the assessment of little value to decision-makers.

NAS also stated that "we see no technical basis for limiting the period of concern to a period that is short compared to the time of peak risk or the anticipated travel time." (NAS Report p. 56) This statement suggests that the stability period must be long enough to allow FEPs that pass the probability and significance screens to demonstrate their effects, if any, on the results of the performance assessments, even from waste package failures occurring relatively late in the period. In contrast to the accumulated small-scale changes discussed above, larger-scale seismic events are more likely to contribute directly to radionuclide releases through the effects of ground motion. Strong seismic events could damage waste package integrity by causing emplacement drift collapse or vigorous shaking of the packages themselves. Earthquake recurrence intervals for the site indicate that strong events could reasonably be assumed to test waste package integrity at various times within the 1 million-year period (Docket No. EPA-HQ-OAR-2005-0083-0374 and 0379). In addition, we note that estimates of ground water travel time from the repository to the RMEI location is on the order of thousands of years (see the BID for the 2001 final rule, Docket No. EPA-HQ-OAR-2005-0083-0050). At these rates, the effects of disruptive volcanic and seismic effects on releases would not be delayed from reaching the RMEI location during the stability period, e.g. added releases from a low probability seismic event at 800,000 years would have ample time to be captured by the performance assessments. Based on these considerations, the 1 million-year period is a sufficiently long time frame to evaluate the potential consequences of both gradual processes and disruptive events on disposal system performance.

In summary, for regulatory policy as well as site-specific scientific considerations, we believe that fixing the period of geologic stability for compliance assessments at 1 million years provides a reasonable test for the disposal system performance. We believe a fixed time period is necessary both to provide a definitive marker for compliance decision-making and to prevent unbounded speculation surrounding the factors affecting engineered barrier performance and the ultimate timing of peak dose projections. Examination of site characteristics indicates that the influences of natural processes and events on release and transport of radionuclides would be demonstrated even for waste package failures occurring relatively late in the period. We believe that setting a 1 million year limit is a cautious but reasonable approach consistent with the NAS position on bounding performance assessments for uncertain elements affecting disposal system performance. Finally, explicitly defining the period during which our standards apply will focus attention on times for which the geologic setting and associated processes are more quantifiable and boundable, rather than entering debate on disposal system performance in time periods where the fundamental geologic regime may have sufficiently changed so that the "scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72)

III.A.8 How Will NRC Judge Compliance?

Today's final rule includes a modification of our proposal that NRC use the median of the distribution of projected doses from DOE's probabilistic performance assessments to determine compliance with the 350 mrem/yr peak dose standard between 10,000 and 1 million years. After consideration of public comments, today's final rule directs NRC to use the arithmetic mean of the distribution of projected doses to determine compliance with the peak dose standard, provided that the value of the arithmetic mean is less than or equal to the 75^{th} percentile value of the distribution of results. If the arithmetic mean is greater than the 75^{th} percentile value at the time of peak dose, the 75^{th} percentile value shall be used instead. To determine compliance with the 15 mrem/yr standard applicable for the first 10,000 years after closure, NRC shall use the arithmetic mean of the distribution of projected doses without qualification.

In reaching this decision, we considered comments raising legal, technical, and policy points. We believe the use of the arithmetic mean beyond 10,000 years, constrained by the 75th percentile of the distribution of probabilistic dose projections, appropriately balances both the commenters' and our concerns, consistent with the principles of reasonable expectation, as described in the following discussion.

The legal basis for our proposal was challenged by commenters who focused on a statement by the NAS committee: "We recommend that the mean values of calculations be the basis for comparison with our recommended standards." (NAS Report p. 123) This is the entirety of the statement, which appeared in the final section of the report describing commonalities with 40 CFR part 191. Unlike its other recommendations, the committee did not provide any scientific or technical basis for use of the mean. Similarly, the committee did not discuss how its recommendation to assess compliance at times "on the order of one million years" might influence applicability of the mean (when 40 CFR part 191 applied for 10,000 years). Specifically, NAS did not address the statistical nature of probabilistic analyses, nor did it indicate that technical or policy considerations might come into play if projections are extremely skewed or otherwise suggest the mean would not be representative of expected performance. Given its context, lack of amplifying discussion, and location in the report, we have not viewed this statement as comparable to the other recommendations made by the committee. We did receive some comments making the case that our proposal to use the median could be consistent with the NAS statement, in the sense that, as noted above, the committee's recommendation was in the context of a standard covering only 10,000 years, but did not show any appreciation that the distribution of projections covering hundreds of thousands of years might differ in significant ways from those shorter-term projections. Nevertheless, in addition to public comments urging us to use the mean, the committee's use of the word "recommend," coupled with the D.C. Circuit's interpretation of the consistency of our 2001 rule with the NAS recommendations, makes the median a less attractive option for our final standard. As a result, we have decided today to start with the mean as the compliance measure, as recommended by NAS, and qualify its use to address important policy concerns.

Many commenters also took issue with our proposal to use the median on technical and policy grounds. Most commenters objected to our proposal on the grounds that the median would be a less stringent measure than the arithmetic mean (i.e., the median would be lower than the arithmetic mean), and therefore compliance would be easier to demonstrate. We agree that the arithmetic mean value likely will be higher than the median value of the distribution of calculated doses, given the nature of these long-term projections. However, it does not necessarily follow that the median would not be protective of public health and safety. As we discussed in our 2001 rulemaking, even for periods of 10,000 years we pointed out that scenarios resulting in very high dose estimates had the potential to strongly influence the mean value. In such cases, we warned that "as the only alternative for a compliance measure, the mean in some cases may be interpreted too restrictively." (66 FR 32125, June 13, 2001)

In that 2001 rulemaking, we stated that the mean value of the distribution would be the "literal mathematical interpretation" of "reasonable expectation" (66 FR 32125). Further, as we noted in our 2005 proposal, NAS used the term "expected value of a probabilistic distribution" to define a value to compare to the regulatory standard. For a probabilistic analysis in which parameter values are typically not single values but are distributed and sampled randomly, and the calculated results are weighted by their probabilities, the "expected value" of the resulting distribution is most often equated to the arithmetic mean. In the context of disposal system performance, the arithmetic mean would then be considered to represent the "expected performance" of the system.

As we discussed in our 2005 proposal, however, the arithmetic mean can be strongly influenced by the values at the high end of the probabilistic distribution, known as the extreme values. As a result, depending on the nature of the extreme values, the arithmetic mean may give a distorted picture of expected performance. A single data point at the very high end could potentially affect the arithmetic mean more strongly than multiple data points that are more centrally located within the distribution. The arithmetic mean may then reflect a very few data points with very high values. When compared to a normal (bell-shaped) or other symmetrical distribution, where values are distributed equally around the most common value, a distribution in which most data points have values higher than the most common value (the "peak"), and which contains some extreme values at the high end, will appear stretched toward the high end, so that the upper-end "tail" is longer. Such a distribution is considered "positively skewed." Such a characteristic is typical of long-term disposal system projections, as the random selection of parameter values and the very long times under consideration are likely to result in a few outcomes with unusually high doses.

As skewness in the distribution increases, it becomes increasingly likely that the arithmetic mean will become farther removed from the bulk of the observed data points. In such cases, the "expected value" may not actually be close to the result that would be "expected" if another calculation were performed. It may in fact be found in a part of the distribution with very few results, if the upper-end "tail" is very long. We pointed out that this effect, as applied to long-term disposal system performance, could be unrealistically conservative (tending to overstate the risk) and thus would not be consistent with "reasonable expectation." In essence, an arithmetic mean value could drive regulatory decision-making on the basis of very unlikely combinations of parameter values and not on projected performance. In our 2001 rulemaking, we suggested that in cases where the arithmetic mean is highly influenced by extreme values, use of the median could in fact be more consistent with "reasonable expectation." (66 FR 32125)

Some comments took our statements as justifying the use of the median on the grounds that DOE's modeling will be excessively (and improperly) conservative. That is, commenters believed we had already concluded that the modeling would be conservative, and chose the median as a way to compensate for this problem. That was not our intent; however, we acknowledge that we stressed this point, and that our primary reason for not proposing the arithmetic mean was the concern that a limited number of high-end estimates would disproportionately skew the mean toward those extreme values. We cautioned strongly in our proposal against introducing excessive conservatism into either the models or the parameter value distributions, and do not agree with the implication of many commenters that a more conservative compliance measure is by default preferable as a regulatory policy. Excessive conservatism is not desirable and can lead to assessments based on a system that is unlikely to exist. The decisions that follow from such assessments would then be focused on extreme situations. Upon further consideration, therefore, and in light of the NAS language, we believe the more appropriate approach is to apply the arithmetic mean with the qualification described here and emphasize the "reasonable expectation" concept as explicitly discouraging reliance on extreme assumptions, while encouraging "cautious but reasonable" projections. For similar reasons, we reject comments calling on us to require that the single maximum possible projected dose be used to determine compliance. This approach would rely only on the extreme worst case results, discarding altogether the performance information to be gained from other, equally likely outcomes, as well as the overall character of the realization resulting in the maximum projected dose. It should be clear that this approach is inconsistent with "reasonable expectation," the intent of the NAS committee, and previous EPA radioactive waste standards (i.e., 40 CFR parts 191 and 194, which are our generic standards and WIPP-specific compliance certification criteria, respectively). The principles of "reasonable expectation" require that uncertainties be recognized and reliance on extreme situations be avoided.

Having determined now that we will apply the arithmetic mean between 10,000 and 1 million years, we have considered how best to address our concerns regarding the potential influence of extreme values on the mean. We proposed the median as a way to address these concerns and to meet the overall goal of "reasonable expectation," which would focus on ensuring that the statistical measure captures the area of the curve where the results are most likely to fall. In determining how we might qualify the arithmetic mean in a way that would be consistent with the NAS recommendation and at the same time address the policy issues NAS did not consider, we looked to the committee report for further insight. The report clearly recognizes that results should not be driven by extremes. For example, the committee stated that "unrealistic assumptions are inappropriate" and noted that "[t]he situation to be avoided, therefore, is an extreme case defined by unreasonable assumptions regarding the factors affecting dose and risk, while meeting the objectives of protecting the vast majority of the public." (NAS Report pp. 103, 5, and 52) While these points were made in the context of a discussion of the appropriate receptor to which the standard would apply, they also are consistent with adoption of a performance measure that is not overly sensitive to extreme results caused by conservative or bounding assumptions. At the same time, the committee recognized that in some areas bounding analyses might be all that are possible. When the NAS committee concluded that long-term changes, such as those caused by climate, seismicity, and volcanism, could be addressed in a peak dose performance assessment, it also recognized that these analyses may have to be based on "bounding assumptions." Specifically, the NAS committee concluded that "the probabilities and consequences of modifications generated by climate change, seismic activity, and volcanic eruptions at Yucca Mountain are sufficiently boundable so that these factors can be included in performance assessments that extend over periods on the order of about 10^6 years." (NAS Report p. 91)

Once the time frame for peak dose performance projections is extended into the very long term, the confidence that can be placed on either the high- or low-end release scenarios becomes progressively more difficult to estimate even though a "bounding" approach may simplify calculations. Consequently, using the arithmetic mean in compliance decisions could potentially over-emphasize high-end release results. We believe placing appropriate bounds on the arithmetic mean is consistent with "reasonable expectation." Using the arithmetic mean with the upper level constraint discussed above allows the recognition of growing uncertainties and the potential for individual realizations to produce unrealistic physical situations leading to extremely high dose estimates, while at the same time specifying characteristics of the distribution that must apply at all times to avoid being overly affected by extreme data points.

For these reasons, the basic approach of our final rule issued today will require NRC to use the arithmetic mean of the distribution of results for comparison with the individual-protection standard at all times. However, in assessing the peak dose between 10,000 and 1 million years, NRC shall only use the arithmetic mean if it does not exceed 75% of the projected results. At the time of peak dose within 1 million years, if the arithmetic mean exceeds 75% of the results projected at that time, NRC shall use the 75th percentile value for comparison with the post-10,000-year standard. It should be clear that we are not adopting the 75th percentile value as the general measure for comparison with the standard in all circumstances; instead, that value only comes into play if the arithmetic mean is above that percentile in the distribution. In other words, compliance would be shown if the mean is below the standard, even if the 75th percentile value is above the standard. As a point of comparison, the arithmetic mean at the time of peak dose (roughly 476,000 years) in DOE's FEIS was at approximately the 70th percentile.

In arriving at this approach, we weighed both our concerns regarding extreme influences and the concerns of commenters regarding the protectiveness of our proposal. In our proposal, we emphasized the concept of central tendency in judging whether a specific statistical measure could adequately represent the overall nature of the distribution. We proposed the median as a reasonable representation of "central tendency," in that it is a measure that always corresponds to the value at the mid-point of the distribution of projected results, where one might expect to see the bulk of projected doses. In general, the "central tendency" is a way to consider where the "middle" of a distribution can be found, in order to gauge where most of the results are "likely" to fall. As described previously, the arithmetic mean is typically considered the best measure of central tendency when the distribution is relatively symmetrical; however, as symmetry decreases and the distribution becomes increasingly skewed (appearing stretched to the high side), the median is often relied upon. As an illustration of this concept that will be familiar to readers, the median (i.e., the 50th percentile) is generally considered a better indicator of economic conditions such as housing prices or income, because a relatively small number of very high values can give a misleading picture if the mean is used. Because the published results of disposal system performance assessments generally tend to be skewed in this way, we believe the sensitivity of the arithmetic mean to extreme values would make its unqualified use in this context inconsistent with the principles of reasonable expectation. We are not aware of any consensus regarding the transition point at which the distribution becomes overly skewed and the arithmetic mean becomes unrepresentative of performance assessment results, or whether such a point exists. However, in our judgment, the 75th percentile provides a realistic measure at which the arithmetic mean could still be considered reasonably representative for the reasons discussed above, should it reach that level.

In today's final rule, we see the establishment of the 75th percentile as clearly providing assurance that the "central tendency" will remain the focus of the compliance determination, while also limiting the potential for extreme results to raise the compliance measure to levels that might be considered less representative overall. By accounting for projected doses above the

50th percentile (the median), this approach also clearly improves upon the protectiveness of our proposal by incorporating up to an additional one-quarter of the results. The margin between the 50th and 75th percentile values could be more or less significant depending on a number of factors, including the skewness of the distribution. As an example that is illustrative only and should not be taken as indicative of future projected doses, if we consider again results from DOE's FEIS, the arithmetic mean at the time of peak dose was about 155 mrem/yr (~70th percentile), while the median was at about 55 mrem/yr. Taken together, we believe the use of the arithmetic mean, with the bounds established today, will provide a reasonable test of the disposal system over very long times.

We emphasize that limiting the use of the arithmetic mean to the 75th percentile is a policy decision on our part. NAS recommended that we use the mean as the compliance measure (NAS Report p. 123); however, scientific considerations alone do not dictate how to apply that measure (e.g., whether or how to limit the application of the arithmetic mean). From a technical perspective, the difficulty of comparing the arithmetic mean to a dose limit does not increase when the mean is above the 75th percentile. However, our primary concern has always been whether dose projections at very long times are meaningful in themselves, and how much they can be relied upon for decision-making in the face of rising uncertainty. As the times covered by assessments increase, we believe the assumptions and concepts embedded in the models become increasingly important to informing the regulators, and the numbers generated by the models become less so.

We believe this policy decision is consistent with both the NAS Report and the Court ruling. We refer to the statements of the Court: "It would have been one thing had EPA taken the Academy's recommendations into account and then tailored a standard that accommodated the agency's policy concerns"; "Had EPA begun with the Academy's recommendation to base the compliance period on peak dosage and then made adjustments to accommodate policy considerations not considered by NAS, this might be a very different case" (NEI, 373 F.3d at 26 and 31, respectively).

We believe this view also represents the intent of the NAS committee, which stated that "[t]he challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events." (NAS Report p. 28) As described previously in Section III.A ("What Dose Standards Will Apply?"), in personal testimony before the Senate Environment and Public Works Committee on March 1, 2006, Mr. Robert Fri, chair of the NAS committee, pointed out that "the specification of the time horizon and the selection of the person to be protected are intimately connected." As a result, he believed that retaining the RMEI as the receptor (which the NAS committee recognized as more conservative than its preferred probabilistic critical group) while at the same time extending the compliance period "runs the risk of excessive conservatism," effectively putting us in a position where the "committee specifically did not want to be." He noted that the committee had considered and rejected such an approach. (NAS Report pp. 100-103) He viewed our proposal of a higher dose limit between 10,000 and 1 million years as a way "to avoid becoming overly conservative." He concluded by stating "the committee recognized that EPA properly had considerable discretion in applying policy considerations outside the scope of our study to the development of the health standard for Yucca Mountain." (See generally NAS Report p. 3) In our view, determining how to judge compliance with a dose limit is also part of the standard-setting process, and therefore must be responsive to the same policy considerations as the selection of the dose limit itself.

It is worth noting that the NAS committee member who favored a more conservative receptor, mentioned in Mr. Fri's testimony, also disagreed with the committee's recommendation of the mean ("expected value") as the statistical measure of compliance. (NAS Report p. 179) This member believed use of the mean did not adequately capture the uncertainties in projected doses over long time periods. He therefore proposed that the standard should include a dose range within which some percentage of projected doses should be required to fall. This approach is similar to the statistical distribution that we discussed in our proposal (70 FR 49033-49034, August 22, 2005), which we also considered because it would effectively consider the uncertainties in the entire distribution. The NAS member suggested the 95th percentile value as the point of comparison (that is, 95% of projected doses would have to be within the specified interval). In effect, the 95th percentile value would become the dose standard. Mr. Fri's response made clear that the committee viewed the member's proposed subsistence farmer receptor as potentially "extreme" rather than "cautious but reasonable." (NAS Report p. 188) Without knowing the dose range under consideration, one cannot say whether use of the 95th percentile value might similarly be considered extreme. However, it may be reasonable to consider whether using the 95th percentile value to determine compliance over the time frames in question would be consistent with the committee's guidance to be "cautious but reasonable."

We note that the measure of compliance we are adopting today also contains elements of the statistical distribution approach discussed in the preamble to our proposed rule. That approach would have required the bulk of DOE's projected results to fall within a specified range. No more than a certain percentage of results could be above the high end or below the low end of that range. Applying the arithmetic mean with a constraint at the 75th percentile does not truly duplicate the statistical approach because the percentage of results that may exceed the standard is dependent on the relationship of the mean to the rest of the distribution. However, the approach in today's final rule conveys an advantage similar to the statistical approach in that it recognizes growing uncertainties but constrains how much of a role that uncertainty should play in the compliance demonstration by specifying characteristics of the distribution that must apply at all times to avoid being overly affected by extreme results. In some sense, the use of the median could also be viewed in this way, as it represents the selection of a specified percentile value (i.e., the 50th percentile) that must not exceed the standard. At the same time, today's approach avoids our concern with the statistical distribution approach by explicitly incorporating the calculated doses into the determination of the performance measure. We also believe it is more transparent to the public and provides more clarity regarding the level of disposal system performance.

To reiterate, we believe the arithmetic mean, bounded by the 75th percentile, is a reasonable measure to apply for the period between 10,000 and 1 million years, as well as consistent with the NAS recommendation. However, we emphasize again that it may not be if the assumptions and data used in assessments are selected to over-estimate the projected doses. It is not that we see no role for conservatism. On the contrary, we noted in our proposal that "conservatism in long-term performance projections may be unavoidable in practice" (70 FR 49042). In some cases, assumptions or parameter values may be labeled as conservative when there is insufficient evidence to support that claim, meaning that they may actually be seen as realistic if more information was available. Rather, it is the consistent reliance on conservatism when choices present themselves that should be viewed with caution. It is understandable that limitations in data and models used to represent highly complex systems with many interacting components create an inclination to assume those components will perform less effectively than they should. Both applicant and regulator may take comfort in seeing conservative assessments comply with the regulatory standard, indicating that a margin of safety is present. This position was also expressed by NAS in its frequent references to "bounding" analyses. However, neither applicant nor regulator should be reassured if there is embedded conservatism that is difficult to identify and extract so it can be analyzed. From our perspective, it is valuable and important for conservatisms to be recognized, understood, and accounted for in decision-making. We refer again to a statement by the joint IAEA-NEA Peer Review of DOE's Site Recommendation TSPA:

> At a fundamental level, it is useful to resort to a probabilistic analysis of a system evolution in time if a realistic model can be attempted but legitimate uncertainties persist. However, if the starting model is built *a priori* to be conservative, exercising it probabilistically has little or no added value, as one would still obtain conservative results. In the TSPA–SR a hybrid conservative/probabilistic methodology is used, which causes assumptions and reality to be mixed in a confusing way. *In the future it may be appropriate to present: (i) A probabilistic analysis based on a realistic or credible representation; and (ii) a set of complementary analyses with different conservatisms, in order to place the best available knowledge in perspective.* These ancillary analyses could be given a probabilistic weight as well. This should satisfy the regulatory requirements whilst providing a better basis for dialogue and decision-making.

pp. 54-55, emphasis in original (70 FR 49028).

We believe the point that should be taken from this statement is that it is proper for DOE's treatment of conservatisms and uncertainties to be transparent, so that all interested parties in the licensing review can evaluate how these issues have been addressed (see also NAS

Report p. 69: "transparency in the use of assumptions is critical to evaluating the calculated risk"). We also believe it is appropriate to reiterate the role of NRC in implementing "reasonable expectation" in its licensing review. That review will not simply consist of a comparison of projected doses with the regulatory standard. Rather, the principles of "reasonable expectation" will guide NRC's review of DOE's modeling efforts. Application of these principles should ensure that the analyses do not rely on extreme assumptions or parameter values, whether conservative or optimistic. Instead, the full range of reasonable and defensible parameter values will be emphasized in the performance assessments and considered in reaching a compliance determination. Transparency in describing these assumptions and parameter values, and the uncertainties associated with them, will aid in reaching that determination.

We considered other methods to address our concerns regarding the potential influence of extreme values on the statistical measure. One method that is applied in some situations is to "trim" the distribution by removing a certain number of values at both the high and low ends of the distribution, then calculating the "trimmed mean." We decided not to pursue this approach, primarily because there is no clear basis at this time to justify trimming the distribution or to specify where the distribution should be trimmed. Similarly, were we to leave the trimming to NRC's judgment, we would feel it appropriate to provide guidance, if not direction in our rule, for NRC to use in identifying extreme values. The process to be followed in that case is also not clear to us. On this point, we believe every realization is an equally likely representation of disposal system performance. That is, one cannot view a zero result as more or less likely than the highest projected dose, and each extreme has the same probability of being the "actual" performance as does the 50th (or 75th) percentile projection. Therefore, each realization independently carries important information that should not be discounted. In that sense, it can be argued that no result should be considered faulty or subject to elimination simply because it is extreme, if it is calculated using the same probabilistic parameter values as more "realistic" results. This is why it is important to understand the reasons for a seemingly anomalous result, rather than just eliminating it because it appears anomalous.

It may be argued that limiting the arithmetic mean to the 75th percentile value would in fact effectively eliminate high-end values from consideration. However, we believe there is a critical distinction between our approach and the "trimmed mean" approach described above.

The "trimmed mean" approach eliminates values at the "tails" of the distribution (both high- and low-end) before calculating the mean. As a result, the mean considers only a subset of the entire distribution. In the approach we are adopting today, the entire distribution is used to calculate the mean and identify the 75th percentile value. The influence of high-end values, including those that may be considered extreme, is fully incorporated into this result. The arithmetic mean in this case is likely to be higher than the "trimmed mean" because, depending on the trimming approach and the relative number and magnitude of the values being trimmed, the high-end values eliminated from the calculation could have more influence on the mean than would the low-end values. The 75th percentile value would be expected to demonstrate similar characteristics under the two approaches. We believe it is appropriate for those high-end values to be considered in deriving the compliance measure, but do not believe it is appropriate for the compliance determination to be driven by a relatively small number of realizations. We believe this is consistent with the NAS committee's view, cited earlier, that "[t]he challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events." (NAS Report p. 28)

We received a few other comments on our proposed use of the median, which we will touch on briefly here. Many commenters expressed the concern that using the median would allow half the projected results to exceed the dose standard. That is true; however, it would also require half the projected doses to be below the standard. It should be pointed out that, regardless of the dose level that is selected, using the arithmetic mean also allows some percentage of results to exceed the standard, as recognized by the dissenting NAS committee member's preferred approach. As the degree of skewness decreases from what is more typical of disposal system performance assessments, and the distribution approaches normality, the percentage of results exceeding the mean increases. When the distribution is normal, the mean and median are coincident as the most representative measure, and half the results exceed the mean.

A number of commenters incorrectly concluded that using the median would allow half the population to receive doses in excess of the standard. This is not the case. Projected doses are based on the RMEI, who is a hypothetical individual representative of the current population and lifestyle in Amargosa Valley. The RMEI is not a population concept, nor is the RMEI an "average" person. Rather, characteristics of the RMEI, specifically location and use of ground water, are selected to place that person among the most highly-exposed members of the population. The vast majority of people in the vicinity of Yucca Mountain would be expected to receive much lower doses, if any.

Finally, some commenters believe our proposal gave a misleading picture of the "true" peak dose limit we proposed, in the sense that the difference would no longer be simply that between 15 mrem/yr and 350 mrem/yr, but also the difference between using the arithmetic mean for the first 10,000 years and the median for the period beyond 10,000 years. A number of commenters claimed that a median dose of 350 mrem/yr would be comparable to an arithmetic mean of 1,000 mrem/yr or more.

Regarding the relationship of the arithmetic mean to the median, as noted above, given the nature of the projections of disposal system performance, we do expect that the arithmetic mean will be higher than the median. However, it is not possible to know how much higher unless the results of the analysis are known. It appears that many of the commenters have extrapolated from results presented in the 2002 FEIS, which showed the arithmetic mean at about 155 mrem/yr and the median at about 55 mrem/yr, and have speculated that <u>if</u> the median were 350 mrem/yr, then the arithmetic mean <u>would be</u> about 1,000 mrem/yr (1 rem/yr). We believe such speculation is not appropriate because it assumes a complete performance projection that has not yet been made for the Yucca Mountain disposal system. We note that DOE's post-10,000-year projections to support its actual license application, which will be based upon assumptions and approaches specified in our final rule, may differ in significant ways from its FEIS projections, which were meant only to be illustrative in the very long term, but we cannot forecast the results of those analyses.

We believe our action today to require NRC to determine compliance with our standards using the arithmetic mean of the distribution of projected doses, and to limit application of the arithmetic mean to the 75^{th} percentile at the time of peak dose between 10,000 and 1 million years, fully considers and is consistent with the NAS recommendation, and appropriately addresses our policy concerns, public comments on this issue, and historic information to place our action in context (e.g., previously published performance assessment results).

III.A.9 How Will DOE Calculate the Dose?

Today's final rule requires DOE to calculate the annual committed effective dose equivalent (CEDE) for comparison to the storage, individual-protection, and human-intrusion standards using the radiation- and organ-weighting factors in ICRP Publication 60 ("1990 Recommendations of the ICRP"), rather than those in ICRP Publication 26 ("1977 Recommendations of the ICRP"). As we described in our proposal, this action will incorporate updated scientific factors necessary for the calculation, but will not change the underlying methodology. We explained in some detail the use of the terms "effective dose equivalent" and "effective dose" in the EnPA, the D.C. Circuit decision, the ICRP publications, and our previous actions to support our position that use of the weighting factors in ICRP 60 (and its follow-on implementing Publication 72) is consistent with calculation of effective dose equivalent, as required by the EnPA. (70 FR 49046-49047)

We received some comment disagreeing with our conclusion that use of the term "effective dose equivalent" is consistent with the use of the ICRP 60 weighting factors. As we discussed in our proposal, we believe a close reading of ICRP 60 supports our interpretation that effective dose equivalent and effective dose are synonymous concepts. ICRP defined two weighting factors in ICRP 26, the radiation weighting factor, W_R, and the tissue weighting factor, W_T. In ICRP 26, the tissue weighting factor was presented as a rigid construct with defined values for specific organs. In ICRP 60, the tissue weighting factor was redefined as a set of recommended values for an expanded set of organs, and it was explained that the attributes of the tissue weighting factor include the components of detriment cited by the comments (fatal and non-fatal cancers, length of life lost, and hereditary effects). However, ICRP made a clear distinction between its renaming of the doubly weighted dose quantity from "effective dose equivalent" (ede) to "effective dose" (E) and its redefining of W_T. The association of effective dose equivalent with the ICRP 26 tissue weighting factors is thus coincidental but not required. We cited ICRP to that effect in our proposal:

> The weighted equivalent dose (a doubly weighted absorbed dose) has previously been called the effective dose equivalent but this name is unnecessarily cumbersome, especially in more complex combinations such as collective committed effective dose equivalent. The Commission has now decided to use the simpler name effective dose, E. The introduction of the name effective dose is associated with the change to equivalent

dose, *but has no connection with changes in the number or magnitude of the tissue weighting factors…*

ICRP Publication 60, p. 7, paragraph 27, Docket No. EPA-HQ-OAR-2005-0083-0087, emphasis added.

Similarly, ICRP also states:

The values of both the radiation and tissue weighting factors depend on our current knowledge of radiobiology *and may change from time to time*. Indeed, new values are adopted in these recommendations….It is appropriate to treat as additive the weighted quantities used by the Commission but assessed at different times, despite the use of different values of weighting factors. The Commission does not recommend that any attempt be made to correct earlier values. *It is also appropriate to add values of dose equivalent to equivalent dose and values of effective dose equivalent to effective dose without any adjustments*.

ICRP Publication 60, p. 9, paragraph 31, Docket No. EPA-HQ-OAR-2005-0083-0087, emphasis added.

In summary, we believe the intent of Congress in specifying effective dose equivalent is that the Yucca Mountain standards be based on a doubly weighted dose quantity, not that the assessment of that quantity be tied to factors developed at a particular time, when newer science indicates those factors should be updated. We use effective dose equivalent for consistency with the terminology used in the EnPA, but are adopting in today's final rule the current recommended values for W_T. Our approach is thus fully consistent with both the current ICRP recommendations and the EnPA.

Today's final rule does incorporate a change to the proposed definition of "committed effective dose equivalent" in §197.2 to make it consistent with language in Appendix A regarding the potential use of future ICRP recommendations. We received some comment suggesting that the appendix should not include specific weighting factors, but state only that doses are to be calculated in accordance with the methods of ICRP 60/72. The commenter believes this is appropriate because NRC's proposed licensing requirements included the tissue weighting factors, but not the radiation weighting factors. Further, the commenter points out that dose coefficients in ICRP 72 (and Federal Guidance Report 13) consider a somewhat different set of organs than do the tissue weighting factors. We prefer not to adopt the commenter's suggestion, which we believe could lead to questions regarding the appropriate factors to use. We note that ICRP 60, unlike ICRP 26, is not tied to a specific set of weighting factors, and allows for the possibility that users will substitute their own preferred set of factors. Stating only that the methods of ICRP 60/72 be used to calculate dose, without the additional stipulations in the appendix, would not provide sufficient clarity on this point. Therefore, we are adding language to the definition in §197.2 to the effect that NRC can direct that other weighting factors be used to calculate dose, consistent with the conditions presented in Appendix A. We believe this will effectively address the commenter's concern.

III.B How Will Today's Final Rule Affect DOE's Performance Assessments?

Today's final rule requires DOE to demonstrate compliance with the individual-protection standard through use of performance assessment. A performance assessment is developed by first compiling lists of features (characteristics of the disposal system, including both natural and engineered barriers), events (discrete and episodic occurrences at the site), and processes (continuing activity, gradual or more rapid, and which may occur over intervals of time) anticipated to be active during the compliance period of the disposal system. These items are collectively referred to as "FEPs" (features, events, and processes). Once FEPs are identified, they are evaluated for their probability of occurrence (i.e., how likely they are to occur during the compliance period) and their effect on the results of the performance assessment (i.e., do they significantly affect projected doses from the disposal system). Addressing these aspects of performance assessment for a compliance period of 1 million years was a central aspect of our proposal and is the focus of this section.

After considering public comments, we are retaining §197.36 as proposed, with two modifications. First, the probability threshold for FEPs to be considered for inclusion in performance assessments conducted to show compliance with §§197.20(a)(1), 197.25(b)(1), and 197.30 is now stated as an annual probability of 1 in 100 million (10^{-8} per year). Because the same FEPs included in these performance assessments will also be included in performance assessments conducted to show compliance with §§197.20(a)(2) and 197.25(b)(2), the same probability threshold applies in all cases. Second, we are adding a provision to address a potential effect of seismicity on hydrology that was identified by NAS. The final rule now requires the potential effects of a rise in the ground-water table as a result of seismicity to be considered. If NRC determines such effects to be significant to the results of the performance assessment, it shall specify the extent of the rise for DOE to assess.

Our 2001 rule set forth three basic criteria for evaluating FEPs for their potential effects on site performance and their incorporation into the scenarios used for compliance performance assessments (§197.36). These criteria retained the same limitations originally established in 40 CFR part 191, which were developed to apply to any potential repository for spent nuclear fuel, high-level waste, or transuranic radioactive waste. The approach in part 191 provided a reasonable way to address this issue. We believe that approach remains reasonable for the site-specific Yucca Mountain standard, and we believe it is desirable to maintain consistency between the two regulations for geologic repositories in the basic criteria for evaluating FEPs. The criteria for evaluating FEPs are:

- A probability threshold below which FEPs are considered "very unlikely" and need not be included in performance assessments;
- A provision allowing FEPs above the probability threshold to be excluded from the analyses if they would not significantly change the results of performance assessments; and
- An additional stipulation that "unlikely" FEPs need not be considered in performance assessments conducted to show compliance with the human-intrusion and ground-water protection standards.

As an initial step, a wide-ranging set of FEPs that potentially could affect disposal system performance is identified. The term "potentially" is key here, because at this early stage, the list is deliberately broad, focusing more on "what could happen" rather than "what is likely to happen at Yucca Mountain." Under the 2001 rule, each of these FEPs is then examined to determine whether it should be included in an assessment of disposal system performance over a 10,000-year period by evaluating the probability of occurrence at Yucca Mountain and, as appropriate, the effects of the FEP on the results of the performance assessment. Based on these evaluations, a FEP may be excluded from the assessment of disposal system performance on the basis of probability, or if the results of the performance assessments would not be changed significantly by its exclusion.

We included in our proposal provisions describing how FEPs should be incorporated into assessments of disposal system performance during the period of geologic stability, defined as ending at 1 million years after closure. Our purpose was to build upon the provisions applicable to the 10,000-year compliance period in our 2001 rule to address the complexities introduced by extending the compliance period to 1 million years. In general, the database of FEPs applicable to Yucca Mountain should be the same, regardless of the period covered by the assessments. In developing our proposal, however, we considered how these general provisions might change when the compliance period extends to 1 million years. We also proposed specific provisions to address climate change, seismicity, and igneous events, which were identified by NAS as potential "modifiers" whose effects could be bounded within the period of geologic stability.

Some commenters questioned whether our authority to establish public health protection standards for Yucca Mountain extended to specifying how FEPs must be considered, contending that this function properly lies with the implementing authority (NRC). We disagree. While NRC clearly has authority to specify such provisions, it is also within our purview to stipulate such conditions as are necessary to place our regulations in context and ensure they are implemented as we intended. For analyses covering 1 million years, it is important to focus on those factors most affecting performance, if necessary by excluding other aspects that are more likely to have little or no significance. We believe this approach is consistent with the direction of the NAS. NAS was charged with providing advice to EPA on "reasonable standards for protection of public health and safety" (EnPA Section 801(a)(2)). NAS provided its findings and recommendations in the context of standards to be developed by EPA, including discussion of FEPs, for example: "the radiological health risk from volcanism can and should be subject to the overall health risk standard to be required for a repository at Yucca Mountain." (NAS Report p. 95) Further, NAS discussed the question of uncertainty in quantifying physical and chemical processes and their operation over long time periods and the inevitability of "residual, unquantifiable uncertainty," stating "[t]he only defense against it is to rely on informed judgment." (NAS Report p. 80) Therefore, we believe it appropriate to specify, where necessary, additional provisions for the treatment of FEPs in disposal system assessments to avoid boundless speculation. We have explained our understanding of the proper use of bounding performance scenarios, and we believe we are consistent with the NAS on this point. Bounding assessments addressing uncertainty in understanding the long-term behavior of the site should be constructed using informed judgment, not speculative assumptions without credible supporting evidence.

Two of the criteria for evaluating FEPs, probability and significance of the impacts on performance assessments, are of primary importance in considering how the provisions applicable to the 10,000-year period might change when the compliance period is extended to 1 million years. In the proposed rule, we concluded that the 10,000-year FEPs screening could serve as an adequate basis for longer-term assessments because it is sufficiently inclusive to be appropriate for the entire 1 million-year compliance period, while at the same time reasonably bounding the scenarios that must be considered over the longer time frame. We thought our statements in the preamble on this point were sufficiently clear, but we understand that the way we structured §197.36 of the proposal, essentially separating the two time periods, may have caused some confusion. For example, we did not intend to indicate or imply that the post-closure performance assessments would consist of two separate and dramatically different calculations, with each having distinctly different scenario construction, parameter value distributions, or other attributes. Regardless of the standard against which compliance is being judged, the probability of occurrence and the significance of the impacts on performance assessment are the two primary criteria for including a FEP in the compliance analysis. The initial screening provides a database of FEPs, which is then used for both the 10,000-year and post-10,000-year peak dose analyses, with some additional stipulations for the period beyond 10,000 years. The discussion that follows addresses each of these screening criteria in turn.

Probability

In the proposed standards, we defined the probability threshold for "very unlikely" FEPs as a 1 in 10,000 chance of occurrence within 10,000 years, or roughly a 1 in 100 million (10^{-8}) chance per year of occurring. In today's final rule, the probability threshold is now stated only as an annual probability of 1 in 100 million (10^{-8}). We believe it is appropriate to clarify that FEPs have associated probabilities of occurrence that generally are independent of time. That is, the database of FEPs deemed sufficiently probable would serve equally well as the basis for assessments covering 1,000, 10,000, 100,000, or 1 million years. These probabilities of occurrence are established by examining the geologic record and considering potential mechanisms for components of the repository and its natural setting to undergo changes. FEPs with a probability of occurrence greater than 1 chance in 100 million per year should be considered for inclusion in the performance assessments to show compliance with the 10,000-year standards, and the same FEPs included in those assessments should be used to develop the performance assessment scenarios to be analyzed for the peak dose performance assessments between 10,000 and 1 million years. We believe that this is an inclusive threshold level that fully considers a range of low-probability FEPs, while at the same time limiting speculation over highly improbable FEPs. We believe the probability screening threshold provides the foundation for a reasonable test of the disposal system, as discussed further below.

Although we discussed the meaning of the probability threshold in some detail in our proposal, we emphasize it again as the foundation for constructing the performance assessment. A 1 in 100 million annual probability of occurrence, when considered over a 10,000-year period, includes FEPs with a cumulative chance of occurring of one one-hundredth of one percent (0.01%). Similarly, over 1 million years, the cumulative probability increases to only a one percent (1%) chance of occurrence within that time frame. We believe that the database of information necessary to assess FEPs at this low probability is the same as that necessary for examining their importance over the entire 1 million-year compliance period. We believe this probability criterion leads to an inclusive set of potential FEPs for both the 10,000-year and peak dose assessments, and in our view would support a reasonable test of the disposal system that encompasses the climate change, seismic, igneous, and corrosion scenarios specified in our proposal.

In our proposed rule, we concluded that the 10,000-year FEPs screening could serve as an adequate basis for longer-term assessments because it is sufficiently inclusive to be appropriate for use in developing performance scenarios applicable to the entire 1 million-year compliance period. That is, we did not propose to require DOE to consider FEPs with an annual probability lower than 10^{-8} to accommodate the lengthened compliance period. We believe excluding FEPs with less than a 1% chance of occurrence in 1 million years is consistent with the principles of reasonable expectation. We believe that lowering the annual probability level below 10^{-8} would allow for speculative scenarios to be considered in the peak dose performance assessment, which would be neither reasonable nor justifiable, as explained below.

Some commenters disagreed, stating that, because we are extending the compliance period by a factor of 100, the probability threshold for excluding FEPs should also be extended by a factor of 100, resulting in a threshold of 1 chance in 10 billion of occurrence per year. Similarly, we received some comments questioning altogether the need for or validity of a probability threshold. The comments suggest that, because the effects are weighted by the probability of occurrence, any potential FEP, no matter how unlikely, should be characterized and assessed because its influence will be mitigated by its low probability. They cite NAS to the effect that "all these scenarios need to be quantified" with respect to probability and consequence. (NAS Report p. 72) Therefore, the commenters conclude that our concerns about introducing excessive speculation are unfounded. We disagree. We addressed this topic in our proposal, in the expectation that we would be encouraged to adjust the probability threshold by two orders of magnitude (i.e., widening the probability range by a factor of 100) to account for the similarly lengthened compliance period. We believe that simply extending the approach of using a one in 10,000 probability over a 1 million-year period to give 1 in 10 billion chance per year of occurring (10^{-10}) would be so speculative as to be unreasonable (70 FR 49052). Nor do we believe it would be consistent with the NAS's view that the overall goal was "to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events." (NAS Report p. 28) Further, NAS itself suggested situations in which scenarios need not be quantified. NAS discusses, in the context of volcanism, a 10^{-8} annual probability of occurrence as a level that "might be sufficiently low to constitute a negligible risk" below which "it might not be necessary to consider" how the event might contribute to releases from the disposal system. (NAS Report p. 95) We believe this example is instructive, given that volcanism is the single scenario resulting in direct release of radioactive material from the repository into the biosphere, resulting in relatively immediate exposures. We believe it is reasonable to extend the concept expressed by NAS as "negligible risk" to FEPs whose influences are seen in the gradual release and transport of radionuclides over long periods of time. Therefore, we believe that lowering the probability threshold, or eliminating it altogether, would be inconsistent with the important NAS cautions to focus assessment efforts on FEPs that can be bounded within the limits of geologic stability.

In our view, were we to lower or eliminate the probability threshold, it would be necessary to consider and describe FEPs that may have been present or occurred in the initial years of the planet's existence. Similarly, FEPs with an annual probability of 10^{-10} may be only hypothetical, since the age of the Earth is generally considered to be "only" 4.6 x 10^{9} years, suggesting that planetary-scale changes might have a 50% chance of occurring within the probability window. Indeed, the volcanic rocks comprising Yucca Mountain and its surroundings are only on the order of 10-12 million years old (~10^{7} years). In determining the probability of particular FEPs, the geologic record at the site is the source of information to identify what FEPs have occurred at the site in the past and may occur in the future (through the period of geologic stability). Since the host rock formations at the site are only about 10 million years old, an annual probability cut-off of 10^{-10} would mean that probability estimates for some FEPs would have to be made in spite of the fact that there is no evidence for their occurrence at the site in the past. As it is, the 10^{-8} probability threshold presents a significant challenge to characterize FEPs with some degree of confidence, given the limits of today's science and technology. ICRP makes a similar point in its 2006 draft recommendations: "The use of probability assessment is limited by the extent that unlikely events can be forecast. The estimates of annual probabilities of initiating events much less than 10^{-6} must be treated with doubt because of the serious uncertainty of predicting the existence of all the unlikely initiating events." (Docket No. EPA-HQ-OAR-2005-0083-xxxx, Section 8.3, paragraph 319) Overall, we believe events with a lower annual probability than 10^{-8} would introduce speculation beyond what is appropriate to define a reasonable test of disposal system performance.

We also received comments stating that maintaining the probability screening criteria for the extended compliance period undermines our arguments for increasing uncertainty. To the contrary, we believe the physical meaning of the probability threshold (0.01% chance of occurrence within 10,000 years, but a 1% chance within 1 million years) appropriately incorporates the concept of uncertainty increasing with time, while still applying a substantially conservative screening criterion.

We believe that the guidance we have provided for executing a FEPs evaluation and screening process assures that it is executed in a thorough manner. For example, we have stated that the geologic record through the Quaternary Period (a period extending back approximately 2 million years from today) at and around the site should be examined to identify relevant FEPs. While we believe that the Quaternary Period offers the most reliable data for identifying and characterizing site geologic FEPs, we do not believe that evidence preserved in older portions of the geologic record should be ignored in the FEPs identification process. We did not mean to imply that DOE need only consider the previous 10,000 years when developing evidence for the probability of occurrence of future events. Rather, our statements regarding the Quaternary Period as an appropriate geologic record were intended to confirm that, where available, reliable geologic records for earlier time periods should be consulted. For example, determining the probability of seismic and igneous events would make use of the geologic record at the site for as far back in time as reliable estimates of past events can be made so that defensible probability estimates can be made. We believe the Quaternary Period offers the best information to quantify the probabilities and consequences of geologic FEPs relevant to site performance. However, we did not intend that significant information about FEPs be ignored simply because that information appears in the geologic record at the site prior to the Quaternary Period.

In fact, a longer portion of the geologic record has been examined by DOE and NRC in developing FEP probabilities. For example, to determine the nature and frequency of volcanic activity around Yucca Mountain, volcanic activity around the site through the Quaternary Period was extensively examined, as well as volcanic activity prior to that time (ACNW Workshop on Volcanism at Yucca Mountain, September 22, 2004 –Docket No. EPA-HQ-OAR-2005-0083-0373 and 0378). We believe that the information necessary to evaluate FEPs against the probability threshold we established (10^{-8} annual probability) will be extensive, and that increasing the compliance period from 10,000 to 1 million years does not require that additional studies be performed beyond those necessary to derive the FEPs probabilities under the screening process done for the 10,000-year time frame assessments. As we have noted previously, the database for evaluating FEPs probabilities is the same, whether the time frame is 10,000 years or 1 million years.

On this last point, we stress that the revised §197.36(a) issued today should not be interpreted as compelling DOE to extend the databases for its technical justifications. We are restating the probability screening criterion, not recasting the entire framework for the analysis. We recognize that in any licensing process the burden of proof is on the applicant to demonstrate that the necessary factors and influences have been evaluated. It must also be recognized that there will always be limits to the ability of science and technology to characterize FEPs and their effects on the disposal system. However, NAS has stated that many of these processes and their uncertainties are boundable. In our judgment, given the capabilities of today's science and technology, it would be contrary to the principle of reasonable expectation to require DOE to affirm the same level of confidence in assessments covering 1 million years as it would for a much shorter 10,000-year analysis.

Similarly, we believe that this clarification does not create the prospect of speculative scenarios of very low probability (from combinations of FEPs) being proposed, thereby opening the performance assessments to unbounded speculation. For example, if two low probability independent FEPs were proposed to occur simultaneously because of the longer time horizon under consideration, the probability of that combination would be the product of their respective probabilities. In other words, the probability of the combined FEPs occurring during the same year will be much lower, by possibly orders of magnitude, than the probability of either FEP occurring individually. Therefore, since the contributions of various FEPs (or scenarios) to the dose assessments is the product of their respective probabilities and consequences, the consequence of the combined FEPs would need to be inversely proportionally higher, typically by orders of magnitude, than the combined consequences of the individual FEPs considered separately, in order to make a significant change in the overall dose assessment.

We did receive some comment suggesting that we had inappropriately excluded the type of volcanic events that created the Yucca Mountain tuff some 12 to 14 million years ago, instead focusing on the past several million years. However, as we stated in our proposal, the geologic record of the past several million years in the area around the site indicates that basaltic volcanism is the type of volcanism that has occurred recently and has the potential to recur in the future. The earlier events were of a much different, cataclysmic nature, producing rock units more than 6000 ft (1800 m) thick. The type of volcanic activity that created Yucca Mountain and the surrounding area has not recurred over the approximately 10 million years since the deposits were originally laid down and is extremely unlikely to occur within the next 1 million years (Docket No. EPA-HQ-OAR-2005-0083-0050, pp. 7-42 through 7-49). Further, we question whether such cataclysmic events could be reasonably considered to fall within the bounds of geologic stability as envisioned by NAS. Inclusion of such events in the peak dose assessment up to 1 million years would be inconsistent with the intent of the NAS when it noted that long-term performance can be assessed (because physical and geologic processes are sufficiently quantifiable, and the related uncertainties sufficiently boundable) when the geologic system is relatively stable or varies in a boundable manner. (NAS Report p. 9) However, NAS noted that "[a]fter the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72) We believe that volcanism of that magnitude would result in fundamental change of the geologic environment and would not represent a reasonable test of the disposal system. Therefore, we continue to see no basis for requiring this type of event be included in the performance assessment.

Some may view our approach using a single probability threshold for determining which FEPs should be considered for inclusion in the performance assessments as inconsistent with the application of different dose standards for the initial 10,000 years and the period up to 1 million years. We do not see an inconsistency primarily because the nature and effects of uncertainty on event probability and dose projections are dissimilar. The overall uncertainty in projecting doses using a model simulating the complex interplay of the disposal system components over long times, each of which has inherent uncertainties in their characteristics, and the associated difficulty in relying on such projections for regulatory decisions, should not be confused with the uncertainty implied in assigning a probability of occurrence to a particular FEP, which in many cases derives from an examination of the geologic record at the site. We have noted the difficulty in extrapolating performance to very long times, and believe it is appropriate to address this difficulty by establishing a somewhat higher, but still protective, dose limit for the period beyond 10,000 years. FEP probabilities are assigned based on observations that may cover long periods of time, such as for geologic processes, or from laboratory testing and the extrapolation of such results to conditions that may exist in the distant future, such as for corrosion processes. In today's final rule, the FEP probability threshold that must be considered in developing performance assessments represents a policy judgment about how such events should be addressed in order to meet the regulatory challenge recognized by NAS, supported by technical reasoning about the nature of the site database for identifying and characterizing FEPs.

Significance

The second criterion for evaluating FEPs, the evaluation of the significance of the impacts on performance assessment, allows FEPs above the probability threshold to be excluded from the analyses if they would not significantly change the results of performance assessments. In other words, this evaluation is intended to identify those FEPs whose projected probability would otherwise make them candidates for inclusion in the performance assessment, but whose effect on repository performance (however probable) can be demonstrated not to be significant. We are retaining the provisions presented in the proposed rule related to screening FEPs for their effects on the performance assessment results, and, for the reasons discussed below, are adding an additional provision regarding the analysis of seismic FEPs in §197.36(c).

Today's final rule continues to focus on seismic and igneous events that cause direct damage to the engineered barrier system (e.g., repository drifts and waste packages). Regardless of other effects of these events on the disposal system, the timing and degree of waste package degradation has a significant effect on peak dose. The longevity of waste packages, when considering periods of hundreds of thousands of years, is uncertain and dependent on a number of factors. Therefore, the aspect of primary interest in evaluating seismic and igneous FEPs is their potential to breach waste packages and make radioactive material available for transport by infiltrating water (or, in the case of volcanic events, for direct release into the biosphere).

We recognize that setting forth the significance screening criterion in §197.36(a) of our proposal as pertaining to the 10,000-year period could be construed as creating a situation in which important long-term processes could be excluded altogether from the analysis if they were not significant in the earlier period. However, we do not believe it is reasonable to interpret the significance criterion in this way. We have taken specific steps to ensure that significant long-term FEPs will be considered in the assessments. Consistent with NAS, we have addressed the long-term effects of seismic, igneous, and climatic FEPs. In addition, as described below, we examined FEPs affecting the engineered barriers and have directed that the effects of general corrosion on the barrier system be evaluated. Further, contrary to some comments, we explicitly required that FEPs included in the 10,000-year analysis must continue to be included for the longer-term (10,000 years to 1 million years) assessment. That is, FEPs included in the initial 10,000-year assessments will continue to operate throughout the period of geologic stability. These FEPs are already identified as appropriate for inclusion, and include fundamental physical and geologic processes that play roles in the release and transport of radionuclides, regardless of the time period covered by the assessment.

As noted above, to further bolster the significance screening criterion, in our proposal we considered whether some FEPs eliminated from consideration during the first 10,000 years should be included in the longer-term assessment if they would have a significant bearing on performance at later times, even if they could legitimately be dismissed for the initial 10,000-year period. We focused our attention on FEPs affecting the engineered barriers since, as noted above, waste package failure is the dominant factor in the timing and magnitude of the peak dose, and is the primary reason for considering time frames up to 1 million years. To illustrate one consideration, thermal conditions in the repository change dramatically within the initial 10,000-year period, affecting the relative importance of some FEPs during and after the thermal pulse. However, FEPs involved in release and transport of radionuclides would generally be the same, regardless of when the waste package fails. Further, while FEPs associated with the natural characteristics of the site are active today or can be observed in the geologic record, FEPs related to engineered barrier longevity involve extrapolation of shorter-term testing data. The degree to which natural FEPs can contribute to the breaching of waste packages is dependent to a large extent on the condition of those packages over time, making FEPs specific to the engineered barriers of particular importance. We took this approach for two reasons. First, we needed to clearly outline the reasons why a FEP that could be excluded on the basis of significance from the performance assessments for the initial 10,000-year period might potentially need to be re-considered for the lengthened compliance period. Second, we wanted to further our goal of issuing an implementable standard by limiting potentially unconstrained speculation over the longer compliance period. By discussing the considerations involved in evaluating FEPs that could be previously excluded, we hoped to lay out clearly the reasoning that could be used to justify inclusion of additional FEPs beyond those identified by the NAS committee.

We identified only one such FEP, general corrosion of the waste packages and engineered barriers, which we explicitly addressed in our proposal because it is likely to be a significant degradation process at later times. We identified this FEP as being significant at times greater than 10,000 years because we believe it is the principal process FEP that could lead to "gross breaching" of the waste package over those extended time frames. Processes and events that could lead to "gross breaching" are of greatest significance to long term performance because, as noted by the NAS, "canisters are likely to fail initially at small local openings through which water might enter, but out of which the diffusion of dissolved wastes will be slow until the canister is grossly breached." (NAS Report p. 86) It is the time of "gross breaching" that determines the time of more rapid release of dissolved wastes from the repository and hence may have a significant effect on the time and magnitude of the peak dose within 1 million years. Although the general corrosion process is slow, tends to decrease with decreasing temperature, and may not lead to significant releases for the first 10,000 years (depending on DOE's design of the waste package), we believe this single FEP is significant enough over the long term to require inclusion in the assessment of performance during the time of geologic stability, regardless of the screening decision in the first 10,000 years. Further, consideration of the uncertainties involved in extrapolating general corrosion data for the proposed waste package materials supports the inclusion of this potentially highly significant process (“Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,” Docket No. EPA-HQ-OAR-2005-0083-0085, Section 5.4.1). Therefore, we believe that general corrosion, as well as those FEPs related to seismicity, igneous activity and climate change identified by NAS, require explicit inclusion in the assessments during the time of geologic stability

We did, as one commenter pointed out, consider providing NRC more latitude to identify FEPs if they would significantly affect the peak dose. After further consideration, we decided against this approach, believing the provisions outlined above and the specification of general corrosion would adequately address this situation, provide a reasonable test of disposal system performance, and give DOE the necessary assurance that the important factors have been explicitly identified in the rule. As we noted above, we identified general corrosion of engineered barriers as a FEP potentially significant to the peak dose, and specified its inclusion because it is likely to be a significant degradation process at later times. Similarly, consistent with the NAS recommendations, we have specified the inclusion of climate change, seismicity, and igneous scenarios. We view the requirement to include general corrosion, as well as the climate, seismic, and igneous scenarios identified by NAS, as leading to an effective and extensive assessment, which can fairly be represented as a reasonable test of the disposal system. As we discussed in our proposal, the search for additional FEPs that might be significant at some point beyond 10,000 years can rapidly become highly speculative and limited in benefit. Therefore, we continue to believe that our approach represents "informed judgment" and a reasonable test of repository performance over time frames as long as 1 million years.

We also note that DOE submitted, as part of its comments on the proposed rule, the results of analyses based on a simplified peak dose model (Docket No. EPA-HQ-OAR-2005-0083-0352, Appendix 1). DOE states that it had compiled a database of FEPs, independent of compliance period, and evaluated them for inclusion in a 10,000-year analysis. DOE "subsequently re-evaluated the FEPs over the period beyond 10,000 years" and concluded that those FEPs excluded on the basis of significance within 10,000 years would also not have significant effects on performance projections beyond 10,000 years. DOE reached its conclusion both for FEPs excluded "on a low consequence basis that is not affected by time" and for "gradual and continuing processes" that "are time dependent."

As part of its comments, DOE submitted an analysis that identified three reasons why gradual and/or infrequent FEPs excluded on the basis of significance within 10,000 years would also not have significant effects on performance projections beyond 10,000 years: (1) an excluded FEP was determined to be of secondary importance to the primary significant degradation FEP, which was included in the analysis; (2) the inclusion of the FEP would tend to lower the peak dose during the time of geologic stability because it resulted in earlier and more diffuse releases (hence the exclusion of the FEP would be conservative from a peak dose perspective); or (3) the FEP is correlated in some way with temperature (e.g., in the rate with which it operates), so it would be less significant at later times due to the lower temperature in the repository over time. (Docket No. EPA-HQ-OAR-2005-0083-0352, Appendix 1, Section 6.1 and Table 24) DOE considered FEPs of this nature associated with both the engineered and natural barrier systems. DOE concluded, for example, that some longer-term processes, such as general corrosion, may contribute to waste package failure, and disruptive seismic events may contribute to rockfall and other physical mechanisms leading to release

We also considered public comments on this topic. Most commenters who disagreed with our proposal cited the limited data available on various corrosion mechanisms that could affect the waste packages. Many of these commenters seem to believe that we have excluded all corrosion mechanisms except general corrosion. This is not the case. We have explicitly directed that general corrosion be considered because it is likely to be the most significant such process at longer times; however, other corrosion mechanisms (such as localized corrosion) are more likely in the early period after disposal when temperatures inside the repository are high. If DOE determines these processes to be insignificant within 10,000 years, they are not likely to be more significant than general corrosion at later times. If they are included in the 10,000-year analysis, they must be included in the longer-term assessments. One commenter highlighted our discussion of criticality as excluding one of the "most worrisome threats to the repository" over the long term. We cited an NRC technical study to support our conclusion that such an event is unlikely to be significant to the results of the assessments. Further, the DOE reference cited above concludes that all criticality scenarios fall below the probability screening threshold. An alternative view on the FEPs screening process was expressed in a report by the Electric Power Research Institute (EPRI): "Thus, the current EPA screening limit is very conservative compared to the [Negligible Incremental Dose] level suggested by [NAS]. It is likely that there are many FEPs that DOE has already included in their analysis using the EPA approach that would not have been included if the [NAS]-recommended approach had been followed. Given that many additional FEPs are already included, it should be unnecessary to include any additional FEPs if the regulatory compliance period is extended beyond 10,000 years." ("Yucca Mountain Licensing Standard Options for Very Long Time Frames," April 2005, pp. 3-5 and 3-6, Docket No. EPA-HQ-OAR-2005-0083-0087) Taking all of this information into account, we continue to believe it is reasonable that, with the exception of the specific FEPs identified in 197.36(c), a FEP determined to be insignificant in the first 10,000 years may continue to be excluded in the post 10,000-year analyses.

As we noted above, we are modifying the proposed rule regarding the provisions related to seismic events in §197.36(c). We noted in our proposal the NAS statement that "[w]ith respect to the effects of seismicity on the hydrologic regime, the possibility of adverse effects due to displacements along existing fractures cannot be overlooked" but that "such displacements have an equal probability of favorably changing the hydrologic regime." (NAS Report p. 93) We argued that these effects would likely be minimal given the many small-scale changes that would be possible in the connectivity of the fracture networks, and that these effects would likely be small compared to the effects of climate change on the hydrologic behavior of the disposal system We did not mean to imply that the seismic and climate events would involve the same hydrologic characteristics and processes or produce the same effects on the ground-water flow regime, but that the effects of one were likely to outweigh the effects of the other. While we still believe that is likely, we have concluded, after further consideration, that the issue of hydrologic effects resulting from seismic events needs to be examined in sufficient detail to address the point made by NAS. We believe the effects of fault displacement on the hydrologic regime will be adequately addressed by the variation in parameters such as hydraulic conductivity (i.e., evaluating reasonable variation in ground-water flow parameters, whether seismically-induced or not, will illustrate the range of effects that might result from seismicity). However, NAS also identified another seismic effect on hydrology, namely the potential for transient rise in the ground-water table. In this instance, NAS did not simply state that such potential could be bounded, but noted site-specific studies suggesting "a probable maximum transient rise on the order of 20 m or less" (NAS Report p. 94). Therefore, we now require that the effects of a rise in the ground-water table as a result of seismicity be considered. We are not specifying the extent of the rise to be considered, but leave that conclusion to be determined by NRC. In this case, however, we are also allowing NRC to make a judgment as to whether such a rise in ground water would be significant to the results of the performance assessment. If NRC determines that such a reasonably bounded scenario would not be significant, DOE would not be required to evaluate its effects.

We believe deferring to NRC on this point is the appropriate approach. The above quote from page 93 of the NAS Report makes it clear that changes to the hydrologic regime from seismic events would be equally likely to enhance or reduce transport of radionuclides. However, it would seem unlikely for changes to occur that would all combine to enhance transport to the saturated zone and then through the controlled area, such that concentrations of radionuclides at the RMEI location would be significantly increased. It seems more likely that localized changes would occur, which in sum would not significantly increase overall transport of radionuclides. Further, as noted above, we believe these seismically-induced changes are likely to be approximated by the normal variation in flow parameters. It may be that changes in the hydrologic system from climate change, including elevation of the ground-water table, may be quantitatively more significant than such changes resulting from seismic activity. We believe NRC is better positioned to make judgments regarding the significance and extent of such changes. We note that a dozen years of site characterization, scientific study, and performance assessments have been conducted since the NAS Report in 1995. NRC has conducted its own analyses as well as participated in ongoing technical exchanges with DOE over this period. We view deferring to NRC's judgment in this case as comparable to the approach we have taken with climate change. In that instance, we outlined the primary issues and overall approach, but specified that NRC would establish the details required to implement our standard.

Finally, we are retaining the provision related to climate change as it was proposed. We believe this is a reasonable approach, which allows NRC to characterize climate change beyond 10,000 years using constant conditions. This approach has the advantage of avoiding speculation regarding the timing and magnitude of climatic cycles, while addressing the important aspects of climate change. We received some comments that appear to have misinterpreted our proposal. Some comments suggested that our citation of the NAS statement to the effect that "climate changes on the time scale of hundreds of years would probably have little if any effect on repository performance" (NAS Report p. 92) as implying that we are "ignoring longer-term changes" such as "glacial periods covering thousands of years." This represents a fundamental misunderstanding of our proposal, which would allow the future climate to be represented by what is essentially a glacial transition period lasting 990,000 years, but in any event placed no limits on the duration of periods of increased precipitation. Similarly, some commenters expressed the view that we "required" the future climate to be represented by constant conditions, or that we were suggesting that a single climate be used in all realizations. On the contrary, we cited the NAS conclusion that "a doubling of the effective wetness" might be significant as one justification for stating that it would be reasonable to represent far-future climate by constant conditions. Today's final rule, consistent with our proposal, leaves it to NRC to determine the parameter values that would define the future climate, including influential parameters other than precipitation, such as temperature. Our specification of the outcome of "increased water flow through the repository" provides NRC with the flexibility to specify basic parameters, such as precipitation and temperature, that must be assumed by DOE, or to derive estimates of water flow directly. This is consistent with our current belief that the dominant mechanisms and flow paths for water to move from the surface through the repository and beyond should be determined by NRC rather than EPA. Further, we anticipated that "constant climate conditions" would be used as another parameter in the probabilistic assessment. That is, each realization would select its constant conditions from among a distribution of such conditions. This is exactly the approach that NRC has taken in its proposal, i.e., that a range of deep percolation values be used (70 FR 53313-53320, September 8, 2005).

Some commenters disagreed with the approach of specifying constant climate conditions leading to a higher rate of water flow through the repository, stating that the "non-linear" nature of the disposal system would be more sensitive to a dynamic, cyclical representation of climate. This is not necessarily true, as the effects on the disposal system would be highly affected by the timing of waste package failures (e.g., whether they fail during a wetter or drier cycle). Some comments cite recent climate research suggesting that anthropogenic climate influences will postpone the next glacial cycle by roughly 500,000 years, or that today's climate at Yucca Mountain will actually be more representative of future climates than would the wetter conditions known to have occurred in the past. We believe that our final rule's approach to climate change provides a reasonable approach to address a point of fundamental uncertainty regarding long-term climate change and its role in the performance assessments, an uncertainty that cannot be removed by additional research into past climate cycles or modeling of present or future climate behavior. We refer to NAS on this point: "Although the typical nature of past climate changes is well known, it is obviously *impossible to predict in detail either the nature or the timing of future climate change*." (NAS Report p. 77, emphasis added) Although continuing research will provide better understanding of past climate fluctuations, we believe that predicting with high confidence the timing and extent of climate fluctuations into the far future will remain an unrealistic goal. We believe that the understanding of past climate fluctuations and their potential effects on the Yucca Mountain hydrologic system is valuable information and should be applied to define the climate-related parameter values. As noted above, NRC has used such information to propose climate-related parameter values, which DOE will use to project the behavior of hydrologic processes at the site. We believe that this approach to treatment of a "residual, unquantifiable uncertainty" by the application of "informed judgment" is consistent with NAS guidance (NAS Report, p.80).

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 Federal Register 51735, October 4, 1993), this action is a "significant regulatory action" because it raises novel legal or policy issues arising out of the specific legal mandate of Section 801 of the Energy Policy Act of 1992. Accordingly, EPA submitted this action to the Office of Management and Budget for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. We have determined that this rule contains no information collection requirements within the scope of the Paperwork Reduction Act.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today’s final rule on small entities, I certify that this action will not have a significant economic impact upon a substantial number of small entities. This final rule will not impose any requirements on small entities. This final rule establishes requirements that apply only to DOE.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of UMRA) for State, local, or tribal governments or the private sector. This final rule implements requirements specifically set forth by the Congress in section 801 of the EnPA and establishes radiological protection standards applicable solely and exclusively to the Department of Energy’s potential storage and disposal facility at Yucca Mountain. The rule imposes no enforceable duty on any State, local or tribal governments or the private sector. Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. This final rule implements requirements specifically set forth by the Congress in section 801 of the EnPA and establishes radiological protection standards applicable solely and exclusively to the Department of Energy's potential storage and disposal facility at Yucca Mountain. The rule imposes no enforceable duty on any small governments. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This final rule implements requirements specifically set forth by the Congress in section 801 of the EnPA and establishes radiological protection standards applicable solely and exclusively to the Department of Energy's potential storage and disposal facility at Yucca Mountain. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This final rule does not have tribal implications, as specified in Executive Order 13175. This final rule will regulate only DOE on land owned by the Federal government. The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this rule. Although Executive Order 13175 does not apply to this rule, EPA specifically solicited additional comment on this proposed rule from tribal officials and consulted with tribal officials in developing this rule. EPA directly contacted more than 20 tribal governments and conducted three conference calls with members of tribal governments. In recognition of the importance of government-to-government consultation with tribes and the significance of tribal governments as sovereign nations, EPA extended the public comment period for tribal governments to December 31, 2005. Comments related to tribal issues, and our responses to them, may be found in Section 13 of the Response to Comments document associated with this final rule (docket ref).

G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. As discussed in our 2001 rulemaking (66 FR 32080-32081 and 32085-32086), the primary risk factor considered in our risk assessment is incidence of fatal cancer. We have derived a risk value for the onset of fatal cancer that considers children, since it is an overall average risk value (see Chapter 6 of the BID for more details) that includes all ages from birth onward, all exposure pathways, both genders, and most radionuclides. We do note that the risk factor does not include the fetus. However, we believe that the risk of fatal cancer per unit dose incurred by the unborn is similar to that for those who have been born, but the exposure period is very short compared to the rest of the individual's average lifetime, so the risk of fatal cancer to the unborn is proportionately lower and does not have a significant impact upon the overall risk of fatal cancer incurred by an individual over a lifetime. (See Chapter 6 of the BID for more discussion of the risk of fatal cancer resulting from in utero exposure.)

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This final rule will apply only to DOE. Construction, operation, and closure of the repository at Yucca Mountain would fulfill the Federal government's commitment to manage the final disposition of spent nuclear fuel from commercial power reactors. However, there is no direct link between operation of the repository and an increased use of nuclear power. Other economic, technical, and policy factors will influence the extent to which nuclear energy is utilized.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. Therefore, the Agency conducted a search to identify potentially applicable voluntary consensus standards. In our original proposal (64 FR 46976, August 27, 1999), we requested public comment on potentially applicable voluntary consensus standards that would be appropriate for inclusion in the Yucca Mountain rule. However, we identified no such standards, and none were brought to our attention in comments. Therefore, the standards promulgated in 2001 and today's final revisions are site-specific and developed solely for application to the Yucca Mountain disposal facility.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability. This final rule will apply only to DOE, and is issued by EPA in response to direction from Congress in the EnPA.

List of Subjects in 40 CFR Part 197

Environmental protection, Nuclear energy, Radiation protection, Radionuclides, Uranium, Waste treatment and disposal, Spent nuclear fuel, High-level radioactive waste.

Dated:

Stephen L. Johnson,

Administrator.

PART 197—PUBLIC HEALTH AND ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR YUCCA MOUNTAIN, NEVADA

1. The authority citation for part 197 continues to read as follows:

Authority: Sec. 801, Pub. L. 102–486, 106 Stat. 2921, 42 U.S.C. 10141n.

Subpart A—Public Health and Environmental Standards for Storage

2. Section 197.2 is amended by revising the definition of ''Effective dose equivalent'' to read as follows:

§ 197.2 What definitions apply in subpart A?

* * * * *

Effective dose equivalent means the sum of the products of the dose equivalent received by specified tissues following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. Annual committed effective dose equivalents shall be calculated using weighting factors in appendix A of this part, unless otherwise directed by NRC in accordance with the introduction to appendix A of this part.

* * * * *

Subpart B—Public Health and Environmental Standards for Disposal

3. Section 197.12 is amended by revising paragraph (1) of the definition of ''Performance assessment'' and the definition of ''Period of geologic stability'' to read as follows:

§ 197.12 What definitions apply in subpart B?

* * * * *

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;

* * * * *

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.

* * * * *

4. Section 197.13 is revised to read as follows:

§ 197.13 How is subpart B implemented?

The NRC implements this subpart B. The DOE must demonstrate to NRC that there is a reasonable expectation of compliance with this subpart before NRC may issue a license.

(a) The NRC will determine compliance, based upon the arithmetic mean of the projected doses from DOE's performance assessments for the period within 10,000 years after disposal, with:

(1) §197.20(a)(1) of this subpart; and

(2) §§197.25(b)(1) and 197.30 of this subpart, if performance assessment is used to demonstrate compliance with either or both of these sections.

(b) NRC will determine compliance, based upon the arithmetic mean of the projected doses from DOE's performance assessments for the period after 10,000 years of disposal and through the period of geologic stability. However, if the arithmetic mean exceeds the 75th percentile of the projected doses occurring at the time of peak mean dose during the period of geologic stability after 10,000 years, NRC will use the 75th percentile of the projected doses at the time of peak mean dose to determine compliance with:

(1) § 197.20(a)(2) of this subpart; and

(2) § 197.25(b)(2), if a performance assessment is used to demonstrate compliance.

5. Section 197.15 is revised to read as follows:

§ 197.15 How must DOE take into account the changes that will occur during the period of geologic stability?

The DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at the time of license application submission to NRC. However, 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 § 197.36.

6. Section 197.20 is revised to read as follows:

§ 197.20 What standard must DOE meet?

(a) The 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 committed effective dose equivalent from releases from the undisturbed Yucca Mountain disposal system:

(1) 150 microsieverts (15 millirems) for 10,000 years following disposal; and

(2) 3.5 millisieverts (350 millirems) after 10,000 years, but within the period of geologic stability.

(b) The DOE's performance assessment must include all potential pathways of radionuclide transport and exposure.

7. Section 197.25 is revised to read as follows:

§ 197.25 What standard must DOE meet?

(a) The DOE must determine the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion (see §197.26) could occur without recognition by the drillers.

(b) The DOE must demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual will receive an annual committed effective dose equivalent, as a result of the human intrusion, of no more than:

(1) 150 microsieverts (15 millirems) for 10,000 years following disposal; and

(2) 3.5 millisieverts (350 millirems) after 10,000 years, but within the period of geologic stability.

(c) The analysis must include all potential environmental pathways of radionuclide transport and exposure.

8. Section 197.35 is removed and reserved.

§ 197.35 [Removed and Reserved]

9. Section 197.36 is revised to read as follows:

§ 197.36 Are there limits on what DOE must consider in the performance assessments?

(a) Yes, there are limits on what DOE must consider in the performance assessments.

(1) The DOE's performance assessments conducted to show compliance with §§197.20(a)(1), 197.25(b)(1), and 197.30 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. Features, events, and processes with a higher chance of occurring shall be considered for use in performance assessments conducted to show compliance with §§197.20(a)(1), 197.25(b)(1), and 197.30, except as stipulated in paragraph (b) of this section. In addition, unless otherwise specified in these standards or NRC regulations, DOE's performance assessments need not evaluate the impacts resulting from 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.

(2) The same features, events, and processes identified in paragraph (a)(1) of this section shall be used in performance assessments conducted to show compliance with §§197.20(a)(2) and 197.25(b)(2), with additional considerations as stipulated in paragraph (c) of this section.

(b) For performance assessments conducted to show compliance with §§197.25(b) and 197.30, DOE's performance assessments shall exclude unlikely features, events, or processes, or sequences of events and processes. The DOE should use the specific probability of the unlikely features, events, and processes as specified by NRC.

(c) For performance assessments conducted to show compliance with §§197.20(a)(2) and 197.25(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. The DOE must evaluate all of the features, events, or processes included in paragraph (a) of this section, and also:

(1) The DOE must assess the effects of seismic and igneous scenarios, subject to the probability limits in paragraph (a) of this section for very unlikely features, events, and processes. Performance assessments conducted to show compliance with §197.25(b)(2) are also subject to the probability limits for unlikely features, events, and processes as specified by NRC.

(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. The magnitude of the elevation of the water table rise and its significance on the results of the performance assessment will be determined by NRC. If NRC determines that the increased elevation of the water table does not significantly affect the results of the performance assessment, NRC may choose to not require its consideration in the performance assessment.

(ii) The igneous analysis may be limited to the effects of a volcanic event directly intersecting the repository. The igneous event may be limited to that causing damage to the waste packages directly, causing releases of radionuclides to the biosphere, atmosphere, or ground water.

(2) The DOE must assess the effects of climate change. The climate change analysis may be limited to the effects of increased water flow through the repository as a result of climate change, and the resulting transport and release of radionuclides to the accessible environment. The nature and degree of climate change may be represented by constant climate conditions. The analysis may commence at 10,000 years after disposal and shall extend to the period of geologic stability. The NRC shall specify in regulation the values to be used to represent climate change, such as temperature, precipitation, or infiltration rate of water.

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

10. Appendix A to part 197 is added to read as follows:

Appendix A to Part 197—Calculation of Annual Committed Effective Dose Equivalent

Unless otherwise directed by NRC, DOE shall use the radiation weighting factors and tissue weighting factors in this Appendix to calculate committed effective dose equivalent for compliance with §§197.20 and 197.25 of this part. NRC may allow DOE to use updated factors issued after the effective date of this regulation. Any such factors shall have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance in order to be considered generally accepted and eligible for this use. Further, they must be compatible with the effective dose equivalent dose calculation methodology established in ICRP 26 and 30, and continued in ICRP 60 and 72, and incorporated in this appendix.

I. Equivalent Dose

The calculation of the committed effective dose equivalent (CEDE) begins with the determination of the equivalent dose, H_T , to a tissue or organ, T, listed in Table A.2 below by using the equation:

$$H_T = \sum_R D_{T,R} \cdot w_R$$

where $D_{T,R}$ is the absorbed dose in rads (one gray, an SI unit, equals 100 rads) averaged over the tissue or organ, T, due to radiation type, R, and w_R is the radiation weighting factor which is given in Table A.1 below. The unit of equivalent dose is the rem (sievert, in SI units).

Table A.1 -- Radiation weighting factors, w_R [1]

Radiation type and energy range [2]		w_R value
Photons, all energies		1
Electrons and muons, all energies		1
Neutrons, energy	< 10 keV	5
	10 keV to 100 keV	10
	> 100 keV to 2 MeV	20
	>2 MeV to 20 MeV	10
	> 20 MeV	5
Protons, other than recoil protons, > 2 MeV		5
Alpha particles, fission fragments, heavy nuclei		20

[1]All values relate to the radiation incident on the body or, for internal sources, emitted from the source.
[2]See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

II. Effective Dose Equivalent

The next step is the calculation of the *effective dose equivalent,* E. The probability of occurrence of a stochastic effect in a tissue or organ is assumed to be proportional to the equivalent dose in the tissue or organ. The constant of proportionality differs for the various tissues of the body, but in assessing health detriment the total risk is required. This is taken into account using the tissue weighting factors, w_T in Table A.2, which represent the proportion of the stochastic risk resulting from irradiation of the tissue or organ to the total risk when the whole body is irradiated uniformly and H_T is the equivalent dose in the tissue or organ, T, in the equation:

$$E = \Sigma\, w_T \cdot H_{T.}$$

Table A.2 -- Tissue weighting factors, w_T

Tissue or organ	W_T value
Gonads	0.20
Bone marrow (red)	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Esophagus	0.05
Thyroid	0.05
Skin	0.01
Bone surface	0.01
Remainder	0.05[a,b]

[a]Remainder is composed of the following tissues: adrenals, brain, extrathoracic airways, small intestine, kidneys, muscle, pancreas, spleen, thymus, and uterus.
b The value 0.05 is applied to the mass-weighted average dose to the Remainder tissues group, except when the following "splitting rule" applies: If a tissue of Remainder receives a dose in excess of that received by any of the 12 tissues for which weighting factors are specified, a weighting factor of 0.025 (half of Remainder) is applied to that tissue or organ and 0.025 to the mass-averaged committed equivalent dose equivalent in the rest of the Remainder tissues.

III. Annual Committed Tissue or Organ Equivalent Dose

For internal irradiation from incorporated radionuclides, the total absorbed dose will be spread out in time, being gradually delivered as the radionuclide decays. The time distribution of the absorbed dose rate will vary with the radionuclide, its form, the mode of intake and the tissue within which it is incorporated. To take account of this distribution the quantity *committed equivalent dose,* $H_T(\tau)$ where τ is the integration time in years following an intake over any particular year, is used and is the integral over time of the equivalent dose rate in a particular tissue or organ that will be received by an individual following an intake of radioactive material into the body:

$$H_T(\tau) = \int_{t_0}^{t_0 + \tau} H_T(t)\, dt$$

for a single intake of activity at time t_0 where $H_T(\tau)$ is the relevant equivalent-dose rate in a tissue or organ at time t. For the purposes of this rule, the previously mentioned single intake may be considered to be an annual intake.

IV. Annual Committed Effective Dose Equivalent

If the annual committed equivalent doses to the individual tissues or organs resulting from an annual intake are multiplied by the appropriate weighting factors, w_T, from table A.2, and then summed, the result will be the annual committed effective dose equivalent $E(\tau)$:

$$E(\tau) = \sum_T w_T \cdot H_T(\tau).$$