6560-50-P

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. Congress directed us to develop these standards and 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. Originally, these standards were promulgated on June 13, 2001 (66 FR 32074) (the 2001 standards).

On July 9, 2004, the U.S. Court of Appeals for the District of Columbia Circuit vacated portions of the 2001 standards concerning 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 EPA for revision. These remanded provisions are the subject of this action.

This final rule incorporates 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 (CEDE) at times up to 10,000 years after disposal and against a standard of 1 millisievert per year (mSv/yr) (100 mrem/yr) CEDE at times after 10,000 years and up to 1 million years after disposal. This final rule also includes several supporting provisions affecting the projections of expected disposal system performance prepared by the Department of Energy (DOE).

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 Headquarters West Building, 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 Air and Radiation Docket is (202) 566-1742.

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: 202-343-9360; fax number: 202-343-2305; e-mail address: clark.ray@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

DOE is the only entity regulated by these standards. Our standards affect NRC only to the extent that, 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 and eventually close the repository, DOE must obtain authorization for these activities 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. 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 and Thursday (9 a.m.-7 p.m.); Tuesday, Wednesday, and 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 "Advanced Docket Search" under "More Search Options." In the Docket 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 This 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)

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

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

0383 "Geological Disposal of Radioactive Waste," International Atomic Energy Agency Final Safety Requirements (WS-R-4), 2006

0417 "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste," International Commission on Radiological Protection Publication 81, 2000

0408 "Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," OECD Nuclear Energy Agency, NEA-6182, 2007

0421 "1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication 60

0423 "2007 Recommendations of the International Commission on Radiological Protection," ICRP Publication 103

0431 Response to Comments Document for Final Rule, EPA-402-R-08-008, June 2007

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

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

IAEA-International Atomic Energy Agency

ICRP-International Commission on Radiological Protection

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, as amended

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

TRU-transuranic

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 This Action

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, while Public Law 107-200 approved the site at Yucca Mountain for the development of a repository for the disposal of spent nuclear fuel and high-level radioactive waste, no licensing decision has been made regarding the acceptability of the proposed Yucca Mountain facility 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.

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 radioactive 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 for disposal in the repository.

In the United States, SNF and HLW have been produced since the 1940s, mainly as a result of commercial power production and national 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, as amended (NWPA, 42 U.S.C. Chapter 108) sets forth the framework for the disposal of SNF and HLW. In general, DOE is responsible for siting, constructing, and operating an underground geologic repository for the disposal of SNF and HLW and the Nuclear Regulatory Commission (NRC) is responsible for licensing the construction and operation of this repository, including permanent closure and decommissioning of the surface facilities. In making this licensing decision for the Yucca Mountain repository, NRC must utilize radiation protection standards that EPA establishes pursuant to Section

801(a) of the Energy Policy Act of 1992 (EnPA, Public Law 102-486).[1] Thus, today we are promulgating amendments to our public health protection standards at 40 CFR part 197 (which, pursuant to EnPA Section 801(a), apply only to releases of radioactive material stored or disposed of at the Yucca Mountain site, rather than generally applicable). NRC will amend its regulations to be consistent with these standards.

On June 3, 2008, pursuant to the NWPA, as amended, DOE submitted a license application to NRC seeking a license to construct the repository. NRC will determine whether DOE has met NRC's requirements, including those implementing 40 CFR part 197, and whether to grant or deny authorization to construct the repository and a license to receive radioactive material at the Yucca Mountain site.

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 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)). We later amended and reissued those 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 geologic repository for SNF and HLW. In October 1992, Congress enacted the EnPA and the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA, Public Law 102-579). These statutes changed our obligations concerning radiation standards for the Yucca Mountain candidate repository. The WIPP LWA:

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

(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 set forth our responsibilities as they relate to Yucca Mountain and 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. EPA-HQ-OAR-2005-0083-0076).

A. Promulgation of 40 CFR part 197 in 2001

Pursuant to 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 considered the NAS Report, our generic standards in 40 CFR part 191, and other relevant information, precedents, and analyses.

We evaluated 40 CFR part 191 because those standards were developed to apply to sites selected for storage and disposal of SNF and HLW. 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, since not all of the conditions found among all potential sites are present at Yucca Mountain. See 66 FR 32076-32078, June 13, 2001 (Docket No. EPA-HQ-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, 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. For more detailed descriptions of Yucca Mountain's geologic and hydrologic characteristics, and the disposal system, please see Chapter 7 of the 2001 Background Information Document (BID) (Docket No. EPA-HQ-OAR-2005-0083-0050) and the preamble to the proposed rule (64 FR 46979-46980, August 27, 1999, Docket No. EPA-HQ-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. EPA-HQ-OAR-2005-0083-0043).

The final 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 from releases from the undisturbed disposal system;
- 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;
- 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. These challenges and the Court's subsequent ruling 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 petitioners challenged various 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 numerical standards that applied for 10,000 years after disposal violated the EnPA because such standards were 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." (NAS Report p. 55) The Nuclear Energy Institute (NEI) challenged the ground-water protection standards as unnecessary to protect public health and safety, contrary to recommendations of the NAS, and outside our authority under the EnPA.

The D.C. Circuit Court's July 9, 2004decision dismissed NEI's challenge, and all of the challenges by Nevada and NRDC, except one. 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 on policy grounds its decision to apply compliance standards only to the first 10,000 years after disposal. Nuclear Energy Institute v. Environmental Protection Agency, 373 F.3d 1251 (D.C. Cir. 2004) (NEI).

The Court concluded that "we vacate 40 CFR part 197 to the extent that it incorporates a 10,000-year compliance period…." (Id. at 1315) 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 15 mrem/yr standard challenged. It ruled only that the compliance period was not 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) Today's action addresses this recommendation and the D.C. Circuit ruling.

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

The primary goal of our proposal issued in 2005 was to gather public comment on the appropriate response to the Court decision and NAS recommendation to assess compliance at the time of maximum dose (risk). Therefore, our proposed amendments centered on extending 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) Of course, establishing a radiological protection standard to apply at the time of peak dose is a uniquely challenging task. Only a small number of countries have established standards of any kind for the geologic disposal of SNF and HLW. Of these, only Switzerland has established a quantitative standard applicable for as long as 1 million years, although we are aware that other regulatory bodies outside the U.S. are contemplating the need to establish some type of regulation addressing these extremely long time frames. Comments received in the course of this rulemaking have been helpful given the extraordinary technical complexity of this task.

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

We considered carefully the language and reasoning of the Court's decision in revising 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 Yucca Mountain 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 applicable to the disposal standards. Therefore, the storage standard, which is applicable only for the period before disposal, is not affected by the 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 1282)). Therefore, we concluded that the Court's vacature of the 10,000-year compliance period, which was explicitly tied to recommendations concerning the individual-protection standard, 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 (70 FR 49014, August 22, 2005). 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 (hereafter,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 (hereafter, 350 mrem/yr) CEDE for the period between 10,000 years and 1 million years;
- Clarify that the arithmetic mean of the distribution of projected results will be compared to the dose standard for the initial 10,000 years, and specify use of the median of the distribution 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 with a probability of occurring 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 Publications 60 and 72 of the International Commission on Radiation Protection (ICRP), to calculate dose for comparison with the storage, individual-protection, and human-intrusion standards.

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

Of great 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 incurred by 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 compliance projections for the next 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 dose projections are given less weight in decision-making at longer times.[2] 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 supplemented that 10,000-year compliance period by requiring DOE to continue projections through the time of peak dose, consistent with the approach favored by the international community. However, while we believed this approach was consistent with 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 NAS recommendation. We concluded that the most direct way to address the Court's ruling would be to establish a numeric 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)

In establishing our final standards, we have considered that the level of uncertainty increases as the time period covered by DOE's performance assessment increases.[3] Therefore, it is reasonable for us to consider how the compliance standard

---

[2]For example, the ICRP's most recent recommendations note that "both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered." (Publication 103, 2007, Docket No. EPA-HQ-OAR-2005-0083-0423, Paragraph 222)

[3] "We recognize that there are significant uncertainties in the calculations and that these uncertainties increase as the time at which peak risk occurs increases." (NAS Report p. 56)

itself might also need to change. Specifically, 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 or represents a reasonable test of the disposal system (more extensive discussion of uncertainty in performance assessments is in Section III.A.4 of this document, "How Did We Consider Uncertainty and Reasonable Expectation?"); see also 66 FR 32098. We turned back to the international technical 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. In exploring this approach further, we 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 a widely-cited estimate of 300 mrem/yr for the national average background radiation exposure (NAS Report Table 2-1), 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 would also provide 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. Today's final rule adopts a more stringent standard that is not derived from an analysis of background radiation, as explained in Sections III.A.1 ("What is the Peak Dose Standard Between 10,000 and 1 Million Years After Disposal?") and III.A.5 ("How Did We Consider Background Radiation in Developing The Peak Dose Standard?") of this document.

Uncertainty in long-term projections also influenced our proposal. Given the probabilistic nature of performance assessments, it is possible that some combinations of parameter values will result in very high doses, even if such combinations have an extremely low probability of occurring. 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 all performance projections. This possibility may be increased by the introduction of additional, and possible excessive, 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 being most representative 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 for a period up to 1 million years, we believed the median might also provide a reasonable test of long-term performance. Today's final rule departs from the proposal by adopting the arithmetic mean as the statistical measure of compliance to be applied at all times, as explained in Section III.A.9 of this document ("How Will NRC Judge Compliance?").

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 reasonably be included in assessments: seismic events, igneous events, and climate change. (NAS Report p. 91) We developed provisions addressing these FEPs that incorporated the views expressed by the NAS. 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 the 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 reflecting precipitation levels that differ from current conditions, which eliminates unresolvable speculation regarding the timing, magnitude, and duration of climatic cycles over this time frame. We also directed that NRC establish the exact nature of future climate characteristics to be used in performance assessments. NRC subsequently issued a proposal to specify a range of values for deep percolation into the repository, which DOE would use as another parameter in its probabilistic performance assessments. (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 ICRP Publications 26 and 30 (Docket Nos. EPA-HQ-OAR-2005-0083-0425 and 0428, respectively). Since we issued 40 CFR part 191, ICRP has modified the models and associated organ-weighting factors to more accurately calculate dose. See ICRP Publications 60 and 72 (Docket Nos. EPA-HQ-OAR-2005-0083-0421 and 0427, respectively). 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.[4]

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. 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.[5] 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)

[4] ICRP published its most recent recommendations in Publication 103, issued in 2007 (Docket No. EPA-HQ-OAR-2005-0083-0423). EPA has not determined the impact of these recommendations on its current dose and risk estimates, but may decide to adopt them in the future. Today's final rule will incorporate the ICRP 60 recommendations as consistent with EPA's current federal guidance; however, we have provided some flexibility for use of newer dosimetry in the future if deemed appropriate by NRC.

[5] 5 U.S.C. 553

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-2005-0083-0431). 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 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 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 concerning the assessment of 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 further disagreed 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 of this document and in the Response to Comments document associated with this action (Docket No. EPA-HQ-OAR-2005-0083-0431).

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 1270 and 1273, 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. We believe that the approach we are taking is the most appropriate way to address the concerns raised by the Court's decision, particularly given the weight accorded by the Court to the NAS 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, today's final rule implements the NAS technical recommendation with regard to the length of time for the compliance period while still accommodating our policy concerns in the provisions related to the peak dose standard, 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, comments suggested 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 commenters supported our role in setting standards for Yucca Mountain. Other commenters 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. For example, several commenters simply expressed their support for, or opposition to, the Yucca Mountain repository. Other 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. Also, 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. These comments all raise considerations that are outside the scope of our authority and this rulemaking.

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, our rationale, and our response to 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.

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. The post-10,000-year public health protection standard limits the long-term peak dose to the RMEI from the Yucca Mountain disposal system to 1 mSv/yr (100 mrem/yr) committed effective dose equivalent (CEDE). This post-10,000-year (also referred to as the "peak dose") standard addresses and responds to the D.C. Circuit ruling that our 2001 standards, with the compliance period limited to 10,000 years, were inconsistent with the recommendations of the NAS. The post-10,000-year standard was the focus of our proposal and will apply after 10,000 years through the period of geologic stability, up to 1 million years after disposal. The other part of the individual-protection standard, which will apply over the initial 10,000 years after disposal, consists of the 150 μSv/yr (15 mrem/yr) CEDE individual-protection standard promulgated in 2001 as 40 CFR 197.20. We believe this approach maintains an appropriate emphasis on the initial condition of the repository and its critical early evolution, including the period when thermal stresses will be most significant.[6] As the disposal system evolves, today's final rule establishes a peak dose standard for the period up to 1 million years that is responsive to the Court's ruling, consistent with the NAS recommendation to establish a compliance standard for the time of peak risk, and satisfies our statutory mandate to protect public health and safety. The final rule also provides a reasonable test of disposal system performance by appropriately recognizing the relatively more difficult challenge in treating the uncertainties associated with projecting performance to such distant times, and the resulting lessened level of confidence that can be derived from such performance projections.

[6] We noted in our 2001 rule: "Focusing upon a 10,000-year compliance period forces more emphasis upon those features over which humans can exert some control, such as repository design and engineered barriers. Those features, the geologic barriers, and their interactions define the waste isolation capability of the disposal system. By focusing upon an analysis of the features that humans can influence or dictate at the site, it may be possible to influence the timing and magnitude of the peak dose, even over times longer than 10,000 years." (66 FR 32099)

As we noted in our proposal, there was no legal challenge to, 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. We believe that promulgating the post-10,000-year peak dose standard to protect public health and safety while retaining a separate individual-protection standard that focuses attention on the early evolution of the repository in the pre-10,000-year period enhances the overall protectiveness of our rule and is consistent with the findings and recommendations of the NAS committee. 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 1281), but does not restrict us from issuing additional standards. Thus, as long as we address the NAS recommendation regarding peak dose, as we are doing today by issuing the post-10,000-year standard, 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 our decision to retain a separate standard applicable for the first 10,000 years after disposal during this period, along with "at least one…EDE-based, individual protection standard" applying to the peak dose during the period of geologic stability between 10,000 years and 1 million years, protects public health and safety pursuant to the EnPA, complies with the Court's decision, 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.4 of this document ("How Did We Consider Uncertainty and Reasonable Expectation?").

The NAS Report recognized the possible outcome of a rulemaking establishing separate standards that apply over different time periods. As discussed in more detail in Section III.A.6 ("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) The committee also recognized, as we have just explained, that "the scientific basis for analysis changes with time" in potentially significant ways as the time to peak dose increases. (NAS Report pp. 30-31) We also find it useful to consider the testimony of Mr. Robert Fri, chair of the NAS committee, before the Senate Environment and Public Works Committee on March 1, 2006, in his personal capacity, whereinhe 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 explained that retaining the RMEI as the receptor (which the NAS committee recognized as more conservative than, but "broadly consistent" with, its preferred probabilistic critical group[7]) 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

[7] In discussing an alternative subsistence-farmer receptor, the committee noted that "it makes the most conservative assumption that wherever and whenever the maximum concentration of radionuclides occurs in a ground water plume accessible from the surface, a farmer will be there to access it." (NAS Report p. 102) We have defined the RMEI to incorporate this same assumption.

committee had considered and rejected such an approach. (See 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 (like the NAS committee itself) 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 be closer to the committee's overall goal than would applying the 15 mrem/yr standard to the 1 million-year compliance period. 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) See the hearing transcript at Docket No. EPA-HQ-OAR-2005-0083-0380 and Mr. Fri's prepared testimony at Docket No. EPA-HQ-OAR-2005-0083-0402. We believe the decision to establish two 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, which were also not addressed by NAS recommendations.

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

In establishing a public health and safety standard applicable at the time of peak dose, as required by the EnPA and recommended by the NAS, and after considering public comments on the issue, today's final rule adopts a more stringent standard than the proposed 3.5 mSv/yr (350 mrem/yr) standard. Specifically, we are today establishing an individual-protection standard of 1 mSv/yr (100 mrem/yr) to apply beyond 10,000 years and up to 1 million years after disposal.

As discussed in more detail later in this section, NAS expressly refrained from recommending any specific dose or risk limit for the compliance standard, but instead described "the spectrum of regulations already promulgated that imply a level of risk, all of which are consistent with recommendations from authoritative radiation protection bodies" for EPA's consideration. (NAS Report p. 49) Further, while NAS stated that a single standard "could be specified to apply uniformly over time and generations," it also recognized that other approaches are possible as "a matter for social judgment." (NAS Report pp. 56-57) NAS also recognized that the level of protection was a matter best left to EPA to establish through rulemaking: "We do not directly recommend a level of acceptable risk." (NAS Report p. 49) NAS further noted that, while "there is a considerable body of analysis and informed judgment from which to draw in formulating a standard for the proposed Yucca Mountain repository," "EPA's process for setting the Yucca Mountain standard is presumably not bound by this experience." (NAS Report p. 39) Thus, the NAS Report contains no finding or recommendation as to the dose limit at the time of peak dose in our Yucca Mountain standards.

In selecting this final standard, we started with a range of annual fatal cancer risk (10^{-5} to 10^{-6}) that encompassed the 15 mrem/yr standard established in 2001 for the initial 10,000 years after disposal. We also considered the "starting range" identified by NAS in determining the appropriate level for the individual-protection standard to apply in the time period beyond 10,000 years. (NAS Report p. 49 and Tables 2-3 and 2-4) For the reasons discussed below, we determined that it would not be reasonable to apply a standard within that starting range for the entire million-year compliance period. Rather, we identified dose levels that are protective of public health and safety and that reasonably accommodate our policy concerns regarding the implementation of a compliance standard for 1 million years. For the same reasons, the Agency has determined that it is not reasonable to apply its traditional risk-management policies when establishing a compliance standard applicable for periods beyond 10,000 years and up to 1 million years (see Section III.A.3, "How Do Our Standards Protect Public Health and Safety?"). EPA does not believe it is realistic to demand that projections for such complex systems over this far future time frame be readily distinguishable at the level of incremental risk customarily addressed by the Agency in situations where results can be confirmed, modeling is utilized on a more limited scale, or institutional controls are more applicable.

In selecting 100 mrem/yr as the peak dose standard for the period beyond 10,000 years, we took particular note of the NAS's discusson of that dose level: "Consistent with the current understanding of the related consequences, ICRP, NCRP, IAEA, UNSCEAR, and others have recommended that radiation doses above background levels to members of the public not exceed 1 mSv/yr (100 mrem/yr) effective dose for continuous or frequent exposure from radiation sources other than medical exposures. Countries that have considered national radiation protection standards in this area have endorsed the ICRP recommendation of 1 mSv per year radiation dose limit above natural background radiation for members of the public." (NAS Report pp. 40-41) We also note that the 100 mrem/yr level is included in the range of regulations offered by NAS for EPA's consideration. (NAS Report Table 2-3)

Therefore, as we discussed in our proposal, a dose level of 100 mrem/yr level is well-established as protective of public health under current dose limits, and, as such, represents a robust public health protection standard in the extreme far future. (70 FR 49040) As noted by NAS, international organizations such as ICRP, IAEA, and NEA recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Although it had used the concept of public dose limits previously, ICRP first described its recommendations for a comprehensive system of radiation protection in Publication 60 ("1990 Recommendations of the ICRP") (Docket No. EPA-HQ-OAR-2005-0083-0421). ICRP considered two referents in recommending a public dose limit: health detriment and "variation in the existing level of dose from natural sources." ICRP concluded that estimates of health detriment "suggest a value of the annual dose limit not much above 1 mSv." Similarly, "[e]xcluding the very variable exposures to radon, the annual effective dose from natural sources is about 1 mSv, with values at high altitudes above sea level and in some geological areas of at least twice this. On the basis of all these considerations, the Commission recommends an annual limit on effective dose of 1 mSv." (Paragraphs 190-191) ICRP re-affirmed this position in its most recent recommendations: "For public exposure in planned exposure situations, the Commission continues to recommend that the limit should be expressed as an effective dose of 1 mSv in a year." (Publication 103, Paragraph 245, Docket No. EPA-HQ-OAR-2005-0083-0423)

This recommendation as to a 100 mrem/yr public dose limit was adopted in the 1996 "International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources," which was jointly sponsored by IAEA, NEA, the Food and Agriculture Organization of the United Nations, the International Labor Organization, the Pan American Health Organization, and the World Health Organization. (IAEA Safety Series 115, Schedule II, Docket No. EPA-HQ-OAR-2005-0083-0409) It should also be noted that the European Union requires its Member States to incorporate this 100 mrem/yr public dose limit into national law or regulation (Council Directive 96/29/EURATOM of 13 May 1996, Docket No. EPA-HQ-OAR-2005-0083-0410). Non-EU countries such as Argentina, Australia, Canada, and Japan also incorporate this public dose limit into their systems of regulation, as shown by their national reports under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (see http://www-ns.iaea.org/conventions/waste-jointconvention.htm). The United States is also a Contracting Party to the Joint Convention (Docket No. EPA-HQ-OAR-2005-0083-0393).

Domestically, both NRC and DOE incorporate the 100 mrem/yr level into their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," Docket No. EPA-HQ-OAR-2005-0083-0407). In setting today's peak dose standard, EPA acknowledges and concurs in the broad consensus in the protectiveness of the 100 mrem/yr level and, furthermore, considers it especially suitable for application to the extreme far future, when planning for and projecting public exposures is much less certain.

For all these reasons, we conclude that the 100 mrem/yr peak dose standard we are establishing today for the period beyond 10,000 years will protect public health and safety. By considering international guidance and examples, we have derived a final peak dose limit that balances the competing factors highlighted by NAS and acknowledged by us as important: the dual objectives of promulgating a standard that is protective of the health and interests of future generations, and also effectively addressing the effects of uncertainty on compliance assessment. Moreover, the 100 mrem/yr level is comparable to the domestic and international standards NAS suggested that EPA consider. (NAS Report p. 49 and Tables 2-3 and 2-4)

Our selection of a 100 mrem/yr standard is therefore protective and reasonable in that it effectively addresses the factors it is necessary to consider when projecting exposures very far into the future. By applying this standard over the entire period of geologic stability beyond 10,000 years (up to 1 million years), our approach is consistent with the NAS recommendation to have a standard with compliance measured "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)

Although we have not used specific estimates of background radiation in determining our final peak dose standard, as we had proposed, we note that the 100 mrem/yr level reasonably comports with such an analysis as well. For example, it is comparable to outdoor (unshielded) measurements of cosmic and terrestrial radiation in Amargosa Valley. When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally.[8] Within the State of Nevada, the difference in average

---

[8] NAS cited an estimate of 300 mrem/yr as the national average for natural background radiation (cosmic, terrestrial, radon, and radioactive isotopes internal to the human body). (NAS Report Table 2-1) This is

estimates of background radiation for counties is greater than 100 mrem/yr. (Docket No. EPA-HQ-OAR-2005-0083-0387) This suggests that 100 mrem/yr can be considered to be a level such that the total potential doses incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain will remain below doses incurred by residents of other parts of the country from natural sources alone. See Section III.A.5 of this document for more discussion of background radiation ("How Did We Consider Background Radiation in Developing the Peak Dose Standard?").

Our proposal 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 also have considered how the role of quantitative projections in making compliance decisions must change as the time covered by those projections increases to the extreme far future. 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, which may rest equally on other lines of evidence, such as confidence in the long-term stability of the site or reference to natural analogues. In our view, in order to provide a reasonable test

---

the best-known estimate of average natural background in the U.S., but does not use the more conservative radon dose conversion factor provided by public comments.

of the disposal system, 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 compliance criteria. In fact, international organizations have treated such numerical criteria in a more flexible way and supported their application in conjunction with other qualitative considerations in applying them to regulatory determinations over very long time frames.[9] Further, we agree that confidence in the way the projections were performed, and the consideration of supporting qualitative information, may be more important to an overall judgment of safety at longer

[9] The 2007 NEA document on "Consideration of Timescales in Post-Closure Safety of Geological Disposal of Radioactive Waste," which is based on surveys of NEA Member Countries, states "Calculated values of dose and risk are therefore viewed in regulations not as predictions but rather as indicators or measures of protection that are used to test the capability of the system to provide isolation of the waste and containment of radionuclides (the 'dose' that is being calculated is what radio-protectionists refer to as 'potential dose'). These indicators are to be evaluated on the basis of models that include certain stylized assumptions, in particular regarding the biosphere and human lifestyle or actions." (Docket No. EPA-HQ-OAR-2005-0083-0411, p. 38) NEA also notes: "There is agreement that calculations of dose and risk in the future are illustrations of possible system behaviour rather than predictions of outcomes, and there is consensus that, in the long term, numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than as absolute limits in a legal context." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, Docket No. EPA-HQ-OAR-2005-0083-0408, p. 24) Similarly, ICRP Publication 81 contrasts the approach of "consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years" with "consideration of quantitative calculations further into the future making increasing use of stylized approaches and considering the time periods when judging the calculated results. Qualitative arguments could provide additional information to this judgmental process." (Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraph 71) The IAEA consensus document for geologic disposal ("Safety Requirements for Geological Disposal of Radioactive Waste," WS-R-4, 2006) states: "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Care needs to be exercised in using the criteria beyond the time when the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decisionmaking." (Docket No. EPA-HQ-OAR-2005-0083-0383, Paragraph 2.12)

times.[10] However, our task is to establish a numerical compliance limit, rather than a qualitative standard or dose target. Therefore, we believe it is appropriate in setting that limit to evaluate and apply the considerations that have led the international radiation protection community to view long-term projections in a more qualitative manner.

We conclude that a peak dose standard of 100 mrem/yr for the Yucca Mountain disposal system for the period between 10,000 and 1 million years protects public health and safety. Setting the standard as we have is also consistent with the NAS committee's decision not to recommend a level for the final peak standard and EPA's broad discretion to establish standards that are protective while accommodating technical and policy concerns inherent in projecting and evaluating potential events hundreds of thousands of years into the future. See Section III.A.3 of this document for more discussion of the protectiveness of our standards ("How Does Our Final Rule Protect Public Health and Safety?").

The ICRP recommendation for a public dose limit of 100 mrem/yr relates to the total exposure to members of the public from all manmade sources (excluding occupational, accidental, and medical, which can be significantly higher). A number of comments took issue with our approach and suggestion that it might be reasonable to "apportion" the entire 100 mrem/yr to the Yucca Mountain disposal system because of the lack of other potential sources in the region, and that this could be considered consistent with the NAS recommendation to rely on current conditions and present knowledge. The comments expressed the view that such an approach would be entirely

[10] Such considerations are not unusual in other applications. For example, in making plans based on weather forecasts, one can expect the next-day forecast to be fairly accurate. However, one has to recognize that the same degree of accuracy cannot be expected from longer-range forecasts. In that case, one would want to have confidence that the forecast is based upon the most current scientific understanding of weather patterns.

contrary to the NAS recommendation to apply apportionment, as well as to the principle of apportionment itself, which recognizes the potential for new or additional sources of exposure to be developed.

NAS made no recommendation or finding regarding apportionment. In its discussion of apportionment, NAS noted that the concept had been widely adopted (NAS Report pp. 40-41). NAS also noted that "guidance to date has been for expected exposures from routine practices. There is little guidance on potential exposures in the far distant future." (NAS Report p. 41). NAS made no specific recommendation that EPA apply the concept to Yucca Mountain, let alone how the concept should be applied.

Further, given our statutory obligation under the EnPA to establish a site-specific standard, allocating 100 mrem/yr to a single source at the time of peak dose is reasonable because other contributors currently in the Yucca Mountain area are negligible by comparison (FEIS, DOE/EIS-0250, Section 8.3.2, Docket No. EPA-HQ-OAR-2005-0083-0086). By relying on current conditions, as recommended by NAS, rather than speculating on potential future sources of exposure to the local population, it is reasonable for EPA to allocate the entire 100 mrem/yr to the Yucca Mountain disposal system. By assuming that current conditions will apply in the future, we are applying an approach routinely applied internationally, as well as by EPA in its WIPP compliance criteria (the "future states" assumption at 40 CFR 194.25).[11]

---

[11] For example, IAEA notes that in modeling over longer time frames, "The emphasis of assessment should therefore be changed so that the calculations relating to the near-surface zone and human activity are simplified by assuming present day communities under present conditions." (TECDOC-767, Docket No. EPA-HQ-OAR-2005-0083-0044, p. 19) The French Basic Safety Rule III.2.f specifies that "The characteristics of man will be considered to be constant (sensitivity to radiation, nature of food, contingency of life, and general knowledge without assuming scientific progress, particularly in the technical and medical fields)." (Docket No. EPA-HQ-OAR-2005-0083-0389, Section 3.2)

EPA's application of the concept of apportionment is, moreover, reasonable. We addressed the apportionment approach in conjunction with our 10,000-year standard of 15 mrem/yr as consistent with EPA's overall risk management approach and past actions. However, we do not agree that it is either required or reasonable to follow the apportionment approach over hundreds of thousands of years, when the level of uncertainty in dose projections is significantly increased and the ability to project the performance of engineered barriers and the overall disposal system with a high degree of certainty decreases. This position is consistent with general international practice and guidance, in which regulatory judgments rely less on compliance with quantitative standards and more on other qualitative factors supporting the overall safety case. Thus, for example, IAEA recognizes in the consensus document "Safety Requirements for Geological Disposal of Radioactive Waste" (WS-R-4, Docket No. EPA-HQ-OAR-2005-0083-0383) the general agreement of the geologic disposal community that, while apportionment is pertinent to geologic disposal, it cannot be assumed to apply indefinitely.[12] Moreover, IAEA reaches this conclusion on the basis of uncertainty in projecting exposure from a specific long-term source, without regard to the presumed knowledge, or lack thereof, of other potential sources of exposure. We believe our approach is consistent with the long-held international view of 10,000 years generally as a demarcation point prior to which quantitative dose projections can be reasonably well-

[12] In describing criteria relevant to apportionment, IAEA states: "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. *Care needs to be exercised in using the criteria beyond the time when the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making."* (Paragraph 2.12, emphasis added) Similarly, NEA cites IAEA and ICRP in noting that "Generally speaking, these documents recommend that the same criteria should be used as are applied for radiation protection from current practices. These documents also recognise, however, that *such criteria cannot be applied in the same way for the distant future as they are for current practices*." (NEA-6182, Docket No. EPA-HQ-OAR-2005-0083-0408, p. 19, emphasis added)

managed, but beyond which those projections become progressively more uncertain and less valuable.[13] In our view, it is preferable to follow this well-established precedent rather than to attempt to define a different transition point based on the level and timing of uncertainty in dose projections. As discussed in more detail later in this section, countries that have established dose or risk standards for geologic disposal have typically applied them for 10,000 years or less, suggesting that this is a period of time within which standards comparable to those applied to current practices can "serve as a reasonable basis for decision making." Beyond that time, the initial "criteria," or dose standards, are viewed more qualitatively or entirely different criteria that are not expressed in terms of risk or dose are applied.[14]

Moreover, we note that under 10 CFR 20.1301, NRC requires that licensees conduct operations so that the total effective dose equivalent to individual members of the public from "the licensed operation" does not exceed 100 mrem/yr. Thus, this

[13] ICRP clearly expresses this view in Publication 81: "To evaluate the performance of waste disposal systems over long time scales, one approach is the consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years. This approach focuses on that period when the calculation of doses most directly relates to health detriment and also recognises the possibility that over longer time frames the risks associated with cataclysmic geologic changes such as glaciation and tectonic movements may obscure risks associated with the disposal system. Another approach is the consideration of quantitative calculations further into the future making increased use of stylised approaches and considering the time periods when judging the calculated results. Qualitative arguments could provide additional information to this judgmental process." (Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraph 71) Similarly, IAEA suggests that within 10,000 years, "While it is recognized that considerable uncertainty can exist during this time period, it is still reasonable to attempt to make quantitative estimates of the indicators to be used." However, beyond that time, "While it may be possible to make general predictions about geological conditions, the range of possible biospheric conditions and human behaviour is too wide to allow reliable modeling…Such calculations can therefore only be viewed as illustrative and the 'doses' as indicative." ("Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," TECDOC-767, Docket No. EPA-HQ-OAR-2005-0083-0044, pp. 18-19)

[14] France applies a dose standard for the first 10,000 years that "will be applied for determining the acceptability of the radiological consequences." However, at later times, "the same [25 mrem/yr] limit shall be used *as a reference value*." (Basic Safety Rule III.2.f, Section 3.2.1, Docket No. EPA-HQ-OAR-2005-0083-0389, emphasis added) Sweden specifies quantitative analyses to be judged against a numerical standard for the first 1,000 years, but requires examination of "various possible sequences for the development of the repository's properties, its environment and the biosphere" after that time. (SSI FS 1998:1, Docket EPA-HQ-OAR-2005-0083-0047) Similarly, Finland applies a dose standard for "at least several thousands of years," but when "human exposure" is no longer "adequately predictable," an activity release standard is in place. (YVL 8.4, Docket EPA-HQ-OAR-2005-0083-0392)

regulatory limit applies to individual licensees operating today, without reference to other potential sources of exposure to the public. Of course, some types of NRC licensees, such as fuel cycle facilities subject to our standards in 40 CFR part 190, must meet dose constraints lower than the 100 mrem/yr limit. Nonetheless, 100 mrem/yr is the public dose limit from licensed operations imposed in NRC regulations.

We disagree with those comments generally questioning both the legality and the protectiveness of our proposal to establish a long-term standard higher than 15 mrem/yr. As described previously in Section III.A ("What Dose Standards Will Apply?"), 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 proposed level was well above the range identified by NAS as a starting point for our rulemaking, 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 NAS identified a range of risks represented by current national and international standards, "all of which are consistent with recommendations from authoritative radiation protection bodies," suggested 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 <u>the final rule could differ markedly from any of them</u>." (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. As stated earlier, we find that the annual risk associated with the final peak dose standard of 100 mrem/yr is protective of public health and comparable to the domestic and international standards NAS suggested that EPA consider, particularly when considering the extended time frames under consideration for this rulemaking. (NAS Report p. 49 and Tables 2-3 and 2-4)

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?") (Docket Nos. EPA-HQ-OAR-2005-0083-0380 and 0402). 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 did not 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 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 provides direction independent of the NAS Report; rather, the decision requires only that we ensure that our standards are consistent with the NAS 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 establishing those generic standards, 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. (See 58 FR 66401, December 20, 1993)

We note that sites whose natural features alone did not provide total 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 that 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. Over time, the initial static system consisting of intact waste packages and other engineered barriers in the natural geologic setting gives way to a more dynamic system in which episodic and gradual processes combine to transport radionuclides to the accessible environment. The sequence and timing of barrier failures strongly influence, and introduce considerable uncertainty into, the timing and magnitude of projected doses over the 1 million-year period. The range of projected doses widens considerably as the containment capability of the engineered barriers diminishes. Interpreting the safety of the disposal system for regulatory purposes, in our judgment, involves more than comparison of projected doses to a regulatory standard, and a single standard applicable to the initial static system would not adequately capture the essential nature of a system that will evolve over 1 million years.

In developing our final standards, we have given much attention to guidance from international organizations and examples from specific national programs. In general, we find few similarities in the details of the international approaches that are directly applicable, and no clear 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 in our proposal 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 dose projections may be compared to dose or risk targets or reference levels, but are viewed more as qualitative indicators of performance than as "accurate predictions of the expected behavior of a geologic repository" (NAS Report p. 71), 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.[15] More detailed discussion of

[15] The standard issued by the Swedish Radiation Protection Authority (SSI, formerly the Swedish Radiation Protection Institute) (SSI FS 1998:1, "Regulations on the Protection of Human Health and the Environment in Connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste," Docket EPA-HQ-OAR-2005-0083-0047) includes a numerical standard during the initial period after disposal and adopts a more qualitative approach at later times. Specifically, for the first 1,000 years following closure of a repository, "the assessment of the repository's protective capability shall be based on quantitative analyses of the impact on human health and the environment." (Section 11) Thus, initially the performance projections may be used to make decisions regarding the protectiveness of the disposal system. However, beyond the first thousand years, "the assessment of the repository's protective capability shall be based on various possible sequences for the development of the repository's properties, its environment and the biosphere." (Section 12) Similarly, the Finnish Radiation and Nuclear Safety Authority's (STUK) regulations for "Long-term Safety of Disposal of Spent Nuclear Fuel" (YVL 8.4, May 2001, Docket EPA-HQ-OAR-2005-0083-0392) include two primary protection standards. The first is an individual-protection standard of 10 mrem/yr (0.1 mSv/yr), which applies to "an assessment period that is adequately predictable with respect to assessments of human exposure but that shall be extended to at least several thousands of years." (Section 2.2) The second protection standard, which is implied to cover periods beyond the time for which "human exposure" is "adequately predictable," is a radionuclide release standard similar to that included in 40 CFR part 191 and applied at WIPP. We also refer readers to the French standard (Basic Safety Rule No III.2.f, "Disposal of Radioactive Waste in Deep Geological Formations," 1991, Docket No. EPA-HQ-OAR-2005-0083-0389). For the initial period, which is to last "at least 10,000 years…The limit of [25 mrem/yr] will be applied for determining the acceptability of the radiological consequences."

specific international approaches may be found in Section 4 of the Response to Comments document for this final rule (Docket No. EPA-HQ-OAR-2005-0083-0431).

2. What is the Dose Standard for 10,000 Years After Disposal?

Section 801(a)(1) of the EnPA directs us to "promulgate, by rule, public health and safety standards" that "prescribe the maximum annual effective dose equivalent to individual members of the public" from releases of radioactive material from the Yucca Mountain repository. Promulgation of the standard described in Section III.A.1 of this document, which will apply beyond 10,000 years and up to 1 million years, fulfills this statutory direction. Today's final rule also 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. We believe this is an appropriate exercise of our policy discretion, protective of public health and safety, and consistent 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, this dose level is also within the range of risks identified by NAS as consistent with current national and international regulations. (NAS Report p. 49, Tables 2-3 and 2-3) Moreover, the 15 mrem/yr standard for 10,000 years is

---

However, "[b]eyond this period" when "uncertainty concerning the evolution of the repository increases progressively with time…Quantified estimates of the individual dose estimates must then be made. These may be supplemented, by more qualitative assessments of the results of these estimates, as regards the geological barrier evolution factors, so as to verify that the release of the radionuclides does not result in an unacceptable individual dose. In this verification, the same [25 mrem/yr] limit shall be used *as a reference value*." (Section 3.2.1, emphasis added) consistent with EPA's overall risk management policies[16] and serves as a logical foundation for us to incorporate concerns regarding far future projections (such as the specifications regarding seismic, igneous, and climatic events and processes discussed in Section III.B of this document).

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 NAS believed likely. (NAS Report p. 2) 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 post-10,000-year dose standard in excess of 15 mrem/yr would have greater consequences than would early failure of a system licensed against a 15 mrem/yr standard that applied at all times. We recognize that DOE's estimates of waste package integrity rely heavily on extrapolations of laboratory testing data, which involve 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

[16] The annual fatal cancer risk of 15 mrem is 8.6×10^{-6}, based on a conversion factor of 5.75×10^{-4} fatal cancers per rem.

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 during the relevant time period.

In fact, the reverse is true. The peak dose standard adds a new level of public health protection for the post-10,000-year period that was not defined in our 2001 standards. It may in fact be highly unlikely, if not impossible, for projected doses to exceed (or even approach) 15 mrem/yr within the first 10,000 years without also exceeding 100 mrem/yr at some other time during the compliance period (see Section III.A.4, "How Did We Consider Uncertainty and Reasonable Expectation?"). In that case, the peak dose standard of 100 mrem/yr alone would provide the necessary public health protection at all times during the compliance period. The 10,000-year standard would not, then, control projected doses during that period but would instead represent an explicit statement of the level of performance that is required to be achieved by the peak dose standard in that initial period. We believe it is important to structure our regulations to make it clear that the standard of protection at Yucca Mountain would not be less than that provided for WIPP or the Greater Confinement Disposal facility (GCD).[17]

3. How Do Our Standards Protect Public Health and Safety?

[17] GCD is a group of 120-feet deep boreholes, located within the Nevada Test Site, which contain disposed transuranic wastes.

The peak dose standard we are establishing today, 1 mSv/yr (100 mrem/yr), will protect public health and safety for the period beyond 10,000 years and up to 1 million years. This standard is consistent with the public dose limit recommended by ICRP and widely adopted internationally and nationally. Section 801(a)(1) of the EnPA directs us to "promulgate, by rule, public health and safety standards" that "prescribe the maximum annual effective dose equivalent to individual members of the public" from releases of radioactive material from the Yucca Mountain repository. In promulgating these standards, we have given special consideration to the EnPA mandate that our standards be "based upon and consistent with" the recommendations of the NAS, which included setting a "health-based individual standard" "that sets a limit on risk to individuals of adverse health effects." (NAS Report pp. 65 and 4) We understand this to mean that we should select the standard based, in part, on the level of risk, although NAS declined to recommend such a level. (NAS Report p. 49) We have chosen to express the standard in terms of dose, for the reasons described in our 2001 final rulemaking (66 FR 32085-32086). In that rulemaking, we did consider both the NAS views on risk and EPA policies and precedents in establishing the dose standard. The risk associated with the 15 mrem/yr standard applicable for the initial 10,000-year period is consistent with both the Agency's overall risk management policies and the suggested NAS "starting point" (NAS Report p. 49) The nominal annual risk associated with the final peak dose standard of 100 mrem/yr, 5.75×10^{-5}, is comparable to the range of risks represented by domestic and international standards that NAS suggested for EPA to consider.[18] This is a protective level of risk given the extremely long time frames contemplated for this standard, and

[18] This document focuses on annual risk rather than lifetime risk because NAS identified annual risk as the appropriate metric, although it did not recommend a particular risk level.

reasonable in that it effectively addresses the associated uncertainty in projecting doses for up to 1 million years. Given this fact and the broad consensus regarding 100 mrem/yr as a protective public dose limit, EPA finds that the dose standard of 100 mrem/yr, with its associated risk, is protective of the RMEI over the period from 10,000 years to 1 million years, as required by the EnPA.

The Agency believes it important to emphasize two aspects of this decision. First, modeling of a complex system such as the Yucca Mountain disposal system over such time frames involves significant uncertainties in both the knowledge of characteristics of the site and the conceptual representation of the processes contributing to release and transport of radionuclides. The NAS recommendation has extended the application of regulatory judgment beyond the period when substantially complete containment might reasonably be provided, and through a period during which complete loss of containment cannot be discounted. The sequence and timing of scenarios resulting in waste package failure are highly dependent on initial assumptions and are the most significant factors in estimating the timing and magnitude of doses to the RMEI. Dose projections involve extrapolation of assumptions, models, and data over time periods much longer than those considered in other regulatory contexts. Such projections therefore cannot be confirmed in the usual sense (i.e., through measurements or monitoring), nor is it expected that long-term maintenance of the repository will be performed. Such considerations lead us to conclude that it would not be realistic to demand that projections from such complex systems be readily distinguishable from one another at the level of incremental risk customarily addressed by the Agency in situations where results can be confirmed, modeling is utilized on a more limited scale, or institutional controls are more applicable.

The Agency's second concern is the correlation of risk with health detriment. NAS specifically framed its recommendation to establish a risk standard in the context of health effects. (NAS Report pp. 4 and 65) In doing so, it explicitly extended the traditional reliance on "present knowledge" in the framing of performance assessments to assume that future societies would not have eliminated radiation cancer risks.[19] (NAS Report p. 100) However, the reliance on risk to express the results of long-term safety assessments has been approached more cautiously, and it has primarily been viewed as a mechanism to incorporate the likelihood of scenarios affecting potential exposures, rather than as a direct measure of health impacts or as a firm compliance criterion.[20]

Risk correlations are highly dependent on population characteristics and baseline cancer rates, which change over time with dietary, lifestyle, medical, industrial, environmental, demographic, and other contributing factors. ICRP has expressed caution that "[d]oses and risks, as measures of health detriment, cannot be forecast with any

[19] Dose can be converted to risk by use of either radionuclide-specific or overall conversion factors. The NAS committee referred only to overall conversions (i.e., risk per rem), which is the typical approach applied to dose standards when the specific mix of radionuclides is not well-defined in advance. The committee saw the direct use of risk as an advantage if the relationship should change in the future through new research on low-dose health effects, because the underlying risk could be viewed as representing the level of societal acceptance of health impacts, which the committee saw as less likely to change, whereas dose could become further removed from this level of societal acceptance. (NAS Report p. 64) In fact, we use a conversion factor slightly higher than that cited by the NAS committee (5.75×10^{-4} fatal cancers per rem, compared to the committee's figure of 5×10^{-4} per rem). See 66 FR 32080-32081, for more discussion of health risks from ionizing radiation.

[20] For example, a 2007 NEA document on "Consideration of Timescales in Post-Closure Safety of Geological Disposal of Radioactive Waste" (NEA/RWMC/IGSC/(2006)3), which was based on surveys of Member Countries, points out that "In evaluating compliance with regulatory criteria, or in formulating these criteria, extreme scenarios or parameter distributions can generally be assigned less weight. This is, for example, inherent in criteria expressed in terms of risk." (Docket No. EPA-HQ-OAR-2005-0083-0411, p. 38) Similarly, the UK Environment Agency has stated: "In the 1995 White Paper, the Government stated that reliance cannot be placed exclusively on estimates of risk to determine whether the facility is safe. Whilst such calculations can inform a judgement on the safety of the facility, other technical factors, including some of a more qualitative nature, will also need to be considered. The Government therefore considers it inappropriate to rely on a specified risk limit or risk constraint as an acceptance criterion for a disposal facility after control is withdrawn. It is, however, considered appropriate to apply a risk target in the design process." (Guidelines for Authorisation of Disposal Facilities for Low- and Intermediate-Level Radioactive Waste, Docket No. EPA-HQ-OAR-2005-0083-0063, Paragraph 6.14)

certainty for periods beyond around several hundreds of years into the future…Such estimates must not be regarded as predictions of future health detriment." However, ICRP has also suggested that it is not unreasonable for shorter-term assessments to relate dose or risk to health effects: "To evaluate the performance of waste disposal systems over long time scales, one approach is the consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years. This approach focuses on that period when the calculation of doses most directly relates to health detriment…" (ICRP Publication 81, "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Radioactive Waste," Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraphs 41 and 71, respectively) Thus, the Agency finds that its requirements for the probabilistic calculation of doses effectively incorporates the issue of risk as it has customarily been considered in long-term safety assessments. Further, the Agency believes its decision to view the 10,000-year standard within its traditional risk-management framework is reasonable and consistent with views on shorter-term safety assessments.

The nominal annual risk level for fatal cancer associated with the 100 mrem/yr dose standard is 5.75×10^{-5}. This is comparable to the range of risks represented by national and international regulations identified by NAS for EPA to consider, and is premised on a dose level the NAS has addressed favorably as a matter of international regulatory consensus (NAS Report pp. 40-41, Tables 2-3 and 2-4). Considering that this standard will apply for up to 1 million years, we believe this represents a level of risk that will protect public health and safety in the far future. However, for the reasons described above, we do not believe it is appropriate to view the standard through a strict risk perspective, and caution against doing so. Further, even if the risk correlations could be assumed valid over such times, the nominal risk represented by projected doses may be a reflection of the uncertainties inherent in such projections, and therefore overstated. ICRP states, for example, that "as the time frame increases, some allowance should be made for assessed dose or risk exceeding the dose or risk constraint…This must not be misinterpreted as a reduction in the protection of future generations, and, hence, as a contradiction of the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results." (ICRP Publication 81, Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraph 77)

As a result of these considerations, for a standard covering periods up to 1 million years, the Agency believes it is more appropriate to view protectiveness from a broader perspective. This perspective must include consideration of the modeling issues discussed earlier, as well as be cognizant of the regulatory context in which dose projections will be presented. NRC's judgment of "reasonable expectation" will not rely on a simple comparison of the mean projected dose with the regulatory standard, but will encompass the data, assumptions, and models underlying those projections, including the sources and treatment of uncertainties and conservatisms. We are also mindful that the post-10,000-year peak dose standard covers an extremely wide time window, far beyond that for any previous regulatory situation in this country, and that a peak mean dose could be projected to occur at any point within that time span. Where the precision and predictive capabilities of performance assessment models diminish over such long times, we believe it is appropriate that NRC "weigh how the scientific basis for analysis changes with time" in reaching its judgment (NAS Report pp. 30-31).

In that context, the 100 mrem/yr public dose limit recommended by ICRP and widely adopted by national and international organizations and government agencies represents a key element of radiation protection practice that can be applied to the estimation of potential future exposures. It provides a standard for public protection today and, by extension in the far future. This judgment reflects our view that the selected level must take 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 (both in terms of their value as predictions of expected behavior of the disposal system and in their correlation with health effects), as well as the relative importance they should assume, in a regulatory context. Having considered these factors, we conclude that the post-10,000-year dose standard of 100 mrem/yr is protective of the RMEI. It must also be emphasized that the 100 mrem/yr level applies to the RMEI, who is described as a person whose location, lifestyle, and characteristics cause that person to be subject to doses at the high end of the local population. As a result, the RMEI is among the most highly exposed members of the public. 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.

Taken together, the dual standards provide a reasonable test of the disposal system that appropriately combines protectiveness with recognition of the limitations of modeling in predicting the evolution of that system over hundreds of thousands of years. The 10,000-year standard is solidly grounded in the Agency's risk-management framework and prior practice for geologic disposal facilities. The longer-term peak dose standard is widely-accepted domestically and internationally as protective of public health and safety, reasonable in its recognition of the regulatory context, and fulfills our EnPA mandate by extending to the time of peak dose up to 1 million years. However, the Agency also emphasizes the site-specific nature of this rulemaking, which should not be viewed as a precedent for other regulatory situations, but as a reasoned response to unique circumstances involving issuance of a compliance standard applicable for periods up to 1 million years after disposal.

4. How Did We Consider Uncertainty and Reasonable Expectation?

In establishing our final standards pursuant to the EnPA, we have considered two important statements from the NAS committee: (1) "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" and (2) "No analysis of compliance will ever constitute an absolute proof; the objective instead is a reasonable level of confidence in analyses that indicates whether limits established by the standard will be exceeded." (NAS Report pp. 56 and 71, respectively) We have been mindful of these statements, as well as the fact that NAS deferred to our judgment in setting the level of the final compliance standard, as indicating that there are limits to the ability of science to provide definitive answers. "When all reasonable steps have been taken to reduce technical uncertainty…there still remains a residual, unquantifiable uncertainty…The only defense against it is to rely on informed judgment." (NAS Report p. 80)

We believe we have appropriately considered the NAS views in establishing 1 mSv/yr (100 mrem/yr) as the individual-protection standard for the period beyond 10,000 years and up to 1 million years. In order to approve DOE's license application, NRC must determine, at a minimum, that there is a reasonable expectation that standard will be met (as well as determine compliance with other NRC requirements, such as a multiple-barrier system). The primary indicator of compliance with the individual-protection standard is the mean of the distribution of projected doses presented by DOE (see Section III.A.9 of this document, "How Will NRC Determine Compliance?"). However, NRC's compliance determination will consist of more than a simple comparison of the mean of projected doses with the dose standard. Rather, as stated in 40 CFR 197.14, NRC will reach its determination "based upon the full record before it." Regardless of whether the mean of projected doses is well below the dose standard or not, NRC will examine the assumptions, data, models, and other aspects of DOE's projections to ensure that it has an understanding of those projections sufficient to reach a "reasonable expectation" as to their compliance with the standard (40 CFR 197.13). While applying the principles of reasonable expectation at all times, NRC may also use its judgment as to whether it would apply the concept in exactly the same way for times as long as 1 million years as it would for much shorter times. A key element of reasonable expectation is that it "accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system" (§ 197.14(b)), we would consider it logical as well as practical for NRC, in reaching its compliance decision, to evaluate the sources and effects of uncertainties in DOE's analyses, as well as DOE's treatment of them.[21]

[21] ICRP Publication 81: "Demonstration of compliance with the radiological criteria is not as simple as a straightforward comparison of calculated dose or risk with the constraints, but requires a certain latitude of judgement." (Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraph 86)

Uncertainties can influence performance assessments in a number of ways. Some sources of uncertainty can be addressed, or at least accounted for, while in other areas our knowledge may be too limited to even characterize the uncertainty, much less explicitly account for it. Sources of uncertainty are often discussed in broad categories such as "data" or "model" uncertainty, although these can take on various forms within those broader categories that create individual challenges.[22]

NAS supported the use of probabilistic modeling as one way to address the effects of uncertainty. However, NAS noted that this process itself can involve significant uncertainties in defining the parameter value distributions from which the probabilistic selections would be made. (NAS Report pp. 78-79) As a result, interpretation of probabilistic results, which illustrate uncertainty through the distribution of calculated values, may also be affected by this underlying uncertainty, which may not be fully appreciated or understood.

Selecting an appropriate dose limit for periods up to 1 million years 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. We have described the general view that the predictive capabilities of performance assessments diminish as the time periods covered by the assessments increase. It is also important to understand that, while mathematical calculations can result in very precise estimates of dose (to multiple

[22] For example, "data" uncertainty can cover broad issues such as whether sufficient data are available, whether the right kind of data are available, whether the data are of sufficient quality, and whether the available data adequately capture what NAS referred to as "the difficulties in spatial interpolation of site characteristics" which "will be present at all times" (NAS Report p. 72). Similarly, "model" uncertainty includes not only whether the processes acting on the site have been correctly represented mathematically and coupled with each other, but also whether the basic understanding of which processes operate, whether there are competing mechanisms that must be considered (e.g., for corrosion or ground-water flow), and the extent to which and conditions under which one mechanism is dominant.

significant digits), this precision is misleading in its presentation of the approximate outcomes of multiple interacting processes. We believe it is not appropriate to imply that there is a clear and immutable difference between two projections of dose, when it is understood that neither on its own is an unqualified representation of reality. Such representations may promise more than can be delivered by the model's ability to "slice it thin."[23] 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.[24]

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 as a result of variation in parameter values. To examine the long-term propagation of uncertainty in dose

---

[23] This problem is not specific to quantitative performance assessment. Similar issues have been identified in analysis of different policy options for energy or other areas associated with technological risk. It has been noted that "The results of individual risk assessment studies are often reported with formidable precision, expressed as discrete numbers (rather than ranges) and presented to two, three and even four significant figures. Yet...such precision seems entirely to misrepresent the accuracy of this style of appraisal taken as a whole…the problem does not tend to be driven by any single factor in analysis, nor is it a simple matter of some studies being more 'accurate' or 'reasonable' than others in any definitive sense. The manifest variability…is rather a simple reflection of…the adoption of different (but equally scientifically valid) assumptions and priorities concerning the multitude of different dimensions of risk. Where [different options cannot be clearly distinguished] in any absolute sense, then the value of appraisal lies in exposing the relationships between different assumptions in analysis and the associate pictures of the relative importance of different options. It is better to be *roughly accurate* in this task of mapping the social and methodological context-dependencies than it is to be *precisely wrong* in spurious aspirations to a one-dimensional quantitative expression of technological risk." ("On Science and Precaution in the Management of Technological Risk," Volume 1, Institute for Prospective Technical Studies, 1999, Docket No. EPA-HQ-OAR-2005-0083-0413, pp 13-16, emphasis in original)

[24] One might compare this situation to finding two proximate, but distinct, locations on a road map. In the first instance, the scale on the map is such that all individual roads and landmarks (e.g., schools, churches, libraries) can be seen. One can easily locate each site and circle it. Now consider a map of the same size, in which the scale is much smaller, showing only major thoroughfares and main local roads. One would still be able to approximate the desired location(s), but any attempt to circle them would likely encompass both (and may be deliberately larger to ensure that both are captured). Thus, the ability to distinguish the two locations hinges on the scale and detail of the map in question. The change in "scale" for our rulemaking is the extension of the compliance period to 1 million years.

projections, we used a simplified Yucca Mountain site performance assessment model and constructed a hypothetical disposal system that would 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 simplified site model and parameters used in the DOE model, and assumed some 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).[25] Further, upon "failure" of a waste package, the entire inventory of that package was assumed to be available for dissolution and transport, subject to solubility limits applied to each radionuclide.

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 hypothetical 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 within the initial 10,000 years, providing a basis for judging how the continuation of these processes would change the results over time. These analyses examined the

[25] Although it employed site parameter value distributions used by DOE, the model used in this analysis was simplified and "forced" to the boundary condition of a 15 mrem/yr mean dose at 10,000 years. This analysis should in no way be compared to the modeling conducted to support DOE's license application.

effects of uncertainties from the natural barrier portion of the disposal system, since additional waste package failures were not considered.[26] 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 with the mean at 15 mrem/yr.

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 5th and 95th 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. We believe this supports the premise, discussed earlier, that increasing uncertainty in dose projections over very long time periods lessens the ability of performance assessment modeling to meaningfully distinguish among alternative (and equally "likely") "futures" represented by individual model simulations, and ultimately to distinguish among alternate models and assumptions for site performance assessments. 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 No. EPA-HQ-OAR-2005-0083-0386).

NRC must reach a determination of compliance based on the specific case presented by DOE. In order to conclude that there is a reasonable expectation that the Yucca Mountain disposal system will comply with our standard of 100 mrem/yr, NRC

[26] We considered release of radionuclides from the waste form as a natural process dependent on solubility parameters. The waste form itself (spent fuel assemblies or vitrified HLW) is often considered part of the engineered barrier system.

must understand the technical basis for DOE's projections, including the inherent uncertainties. We believe it is appropriate for NRC to examine uncertainty in its licensing review in order to achieve the necessary level of confidence in DOE's understanding and depiction of the disposal system. Ultimately, in reaching its compliance determination, it is incumbent upon NRC to clearly state what it can or cannot conclude from the performance assessment results, within the limits of science.

5. How Did We Consider Background Radiation In Developing the Peak Dose Standard?

We are not adopting the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of specific background radiation estimates) to the selection of the 100 mrem/yr level. We received significant comment on this aspect of our proposal, much of it taking issue with the concept of using background radiation as an indicator of "safe" levels of exposure from an engineered facility. We also received additional information that provided insights into and refined our consideration of background radiation. For example, commenters referred to monitoring data collected by the Desert Research Institute indicating that the unshielded (outdoor) background radiation from cosmic and terrestrial sources in Amargosa Valley is roughly 110 mrem/yr. Commenters also informed us that roughly 90% of the population in Amargosa Valley lives in mobile homes, which has implications for indoor radon exposures. Other commenters supported the use of a different factor for converting radon concentrations into dose.

In considering these comments, as well as those taking issue with the overall premise described in the proposal, we found the relatively simple approach used in the proposal evolving into a more complex undertaking requiring numerous decisions where science did not provide a definitive answer. Addressing indoor radon estimates presented the greatest challenge, as indoor radon represented the highest proportion of overall background radiation. Complicating factors included multiple ways of calculating radon dose, the prevalence of mobile homes in Amargosa Valley, limited data sets primarily from the early 1990s, and data for individual counties in a different format than state-wide data. We concluded that there was no generally agreed-upon approach in the context of Amargosa Valley for incorporating indoor radon exposures into an analysis of background radiation that would lead to a regulatory standard, particularly given the fact that many commenters viewed the entire concept as arbitrary. Accordingly, we have decided not to adopt a standard derived from an analysis of background radiation estimates at specific locations or the differences between background radiation estimates at different locations.

We continue to believe that references to natural sources of radiation can provide useful insights. IAEA has observed 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". (IAEA WS-R-4, Docket No. EPA-HQ-OAR-2005-0083-0383, Paragraph A.8) We note that the 100 mrem/yr level reasonably comports with such an analysis as well. For example, as noted above, 100 mrem/yr is roughly the value reported by the Desert Research Institute for cosmic and terrestrial radiation at Amargosa Valley (unshielded). When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally. Within the State of Nevada, the difference in average estimates of background radiation for counties is greater than 100 mrem/yr. (Docket No. EPA-HQ-OAR-2005-0083-0387) As previously stated, this suggests that 100 mrem/yr can be considered to be a level such that the total potential doses incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain will remain below doses incurred by residents of other parts of the country from natural sources alone.[27] It may also be noted that the 100 mrem/yr public dose limit recommended by ICRP is itself related to background radiation, so indirectly our peak dose standard does incorporate the concept of variations in background radiation.[28] However, in the absence of compelling reasons for selecting specific background radiation estimates and points of comparison, we conclude that comparing background radiation estimates from specific locations does not provide a clear or sufficient basis for a regulatory compliance standard applicable to the Yucca Mountain disposal system. Discussion of specific issues raised in public comments is in Section 3 of the Response to Comments document.

---

[27] It could also be considered consistent with the NEA statement that "[w]hat can be aimed at, however, is to leave future generations an environment that is protected to a degree acceptable to our own generation. It is also relevant to observe that this level of protection will ensure that any radiological impacts due to disposal will not raise levels of radiation above the range that typically occurs naturally." ("The Handling of Timescales in Assessing Post-Closure Safety: Lessons Learnt from the April 2002 Workshop in Paris, France," p. 9, Docket No. EPA-HQ-OAR-2005-0083-0046)

[28] "This natural background may not be harmless…but the variations from place to place (excluding the large variations in the dose from radon in dwellings) can hardly be called unacceptable…Excluding the very variable exposures to radon, the annual effective dose from natural sources is about 1 mSv, with values at high altitudes above sea level and in some geological areas of at least twice this. On the basis of all these considerations, the Commission recommends an annual limit on effective dose of 1 mSv." (ICRP Publication 60, Docket No. EPA-HQ-OAR-2005-0083-0421, Paragraphs 190-191)

6. How Does Our Rule Protect Future Generations?

Because of its long lifetime, high hazard, and potential for misuse, SNF and HLW present special challenges to those charged with protecting the health, safety, and security of the public and the environment. Geologic disposal has long been viewed by policy-makers as the management option that best addresses all of these concerns.[29] In the United States, geologic disposal was first endorsed by the NAS in 1957 ("The Disposal of Radioactive Waste on Land") and established as national policy in the Nuclear Waste Policy Act of 1982.

However, the fact that geologic disposal has potentially significant impacts over times far in excess of recorded human history naturally raises concerns as to how the welfare of people living far in the future can and should be taken into account when societal institutions may no longer exist to provide oversight of a disposal facility.[30]

---

[29]In its 1995 Collective Opinion, the NEA Radioactive Waste Management Committee concludes that "from an ethical standpoint, including long-term safety considerations, our responsibilities to future generations are better discharged by a strategy of final disposal than by reliance on stores which require surveillance, bequeath long-term responsibilities of care, and may in due course be neglected by future societies whose structural stability should not be presumed" and "after consideration of the options for achieving the required degree of isolation of such wastes from the biosphere, geological disposal is currently the most favoured strategy," whereby "it is justified, both environmentally and ethically, to continue development of geological repositories for those long-lived radioactive wastes which should be isolated from the biosphere for more than a few hundred years." ("The Environmental and Ethical Basis of Geological Disposal of Long-Lived Radioactive Wastes," Docket No. EPA-HQ-OAR-2005-0083-0412, pp. 5-6) Similarly, the NAS Board on Radioactive Waste Management stated: "There is a strong worldwide consensus that the best, safest long-term option for dealing with HLW is geological isolation." ("Rethinking High-Level Radioactive Waste Disposal: A Position Statement of the Board on Radioactive Waste Management," 1990, Docket No. EPA-HQ-OAR-2005-0083-0420, p. 2)

[30] NEA states: "The design and implementation of a repository involves balancing of risks and responsibilities between generations. The obligations of the present generation toward the future are complex, involving not only issues of safety and protection but also of freedom of choice and of the accompanying burden of responsibility, and of the need to transfer knowledge and resources. Our capacity to deliver these obligations diminishes with distance in time, which complicates the setting of criteria to be used today in order to demonstrate that obligations to the future will be met." NEA-6182, Docket No. EPA-HQ-OAR-2005-0083-0408, p. 25)

In considering how our standards reflect these intergenerational issues, we considered the guidance offered by the NAS committee. (See 70 FR 49036) In citing NRC and IAEA sources on the question of intergenerational equity, 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 <u>or some other expression of the principle of intergenerational equity</u> 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 a close reading of the principle of intergenerational equity as stated by NAS. However, 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 it may not be reasonable to apply the same dose standard at all times because of the extremely long compliance period. We believe establishing a peak dose standard for the Yucca Mountain disposal system is a situation in which "some other expression of intergenerational equity" is more appropriate than is applying a single dose standard of 15 mrem/yr throughout the compliance period. The rulemaking process we are following is the accepted way for "social judgment" to be incorporated into regulations.

NAS made no recommendation regarding the appropriate expression of intergenerational equity, just as it made no recommendation regarding the level of the final peak compliance standard. Rather, NAS acknowledged EPA's wide latitude to exercise its policy judgment.

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 applied to current activities for periods approximating 10,000 years, which is a very long time. It also is generally accepted that engineered barriers cannot be relied upon indefinitely, and that projected doses may eventually exceed the initial regulatory levels. The question of equity is also raised by the fact that the repository is part of a passive disposal system that may provide complete containment for hundreds of generations without their knowledge, but present the greatest risks to equally unsuspecting generations beyond that time. However, it is unclear as to exactly how such long-term projected doses should be factored into a judgment of facility safety, if we are not confident they can be interpreted in the same way at all times.[31] We are establishing today a standard consistent with a public dose limit of 100 mrem/yr that is deemed protective today as a matter of international consensus, which would not affect the quality of life for future generations, even those hundreds of thousands of years distant. 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

[31] NEA-6182: "National programmes which have already established such criteria have generally found it possible to make cautious, but reasonable assumptions to extend the use of radiological limits already applied to contemporary activities for several thousands of years. The greater challenge lies in setting criteria for very long time frames, extending to a million year and beyond, for which safety analyses must account for high uncertainty and for which the understanding of the needs and impacts on future generations become increasingly speculative." (Docket No, EPA-HQ-OAR-2005-0083-0408, pp. 20-21)

compliance, not a soft target or reference level that could be exceeded for unspecified reasons and by unspecified amounts.

In conclusion, EPA acknowledges and remains committed to the principles of intergenerational equity. However, we do not interpret these principles as requiring that the same compliance standard must apply at all times. Such an approach is overly simplistic in the circumstances and ignores the complexities involved in establishing radiological protection standards for periods approaching 1 million years. We believe that peak dose limits over such periods 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. As a matter of public policy, a commitment to protect future generations over the next 10,000 years at levels consistent with standards applied for the current generation, and to protect more distant generations at levels consistent with the overall public dose limits deemed protective today and adopted nationally and internationally, protects public health and the environment across generations in a manner that comports with the objective of intergenerational equity. Under this approach, future generations will not face undue burdens or the irreversible loss of reasonable options arising from a decision by the current generation to pursue a policy of geologic disposal at Yucca Mountain, nor will the compliance demonstration demand more than can be provided by scientific analysis. The standards applicable to both time frames are protective of public health and safety and will offer comparable, if not identical, protections to the affected generations. See Section 9 of the Response to Comments document for more detailed discussion of these issues.

7. 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.8 ("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 geologic conditions could be bounded with reasonable confidence for periods “on the order of one million years.” (NAS Report p. 2)

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 potential expected conditions at the site over the regulatory compliance period. Parameter value 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.

8. Why is the Period of Geologic Stability 1 Million Years?

Today's final rule includes a compliance period of 1 million years, over which DOE must project performance and 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 the NAS recommendations, as the EnPA required. 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.7 (“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 believed that such changes could be bounded during the period of geologic stability of the site, i.e., as long as the conditions do not change significantly. (NAS Report pp. 72, 77) 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 constructive 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.[32] 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 post-10,000-year peak dose standard in today's final rule appropriately accommodates those considerations and is protective of public health, 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.

---

[32] 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-2005-0083-0383, 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-2005-0083-0388) 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," 1992 Documents of the NRPB, Volume 3, No. 3, p. 15, Docket No. EPA-HQ-OAR-2005-0083-0416)

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 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 for significant events to act on the waste packages and engineered barriers, and ultimately lead to release of radionuclides. 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 geologic history of the site, in the areas of igneous and seismic activity, also supports a 1 million year stability period. Information compiled by 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 and possibly to affect the quality of the information the assessment can provide 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 are 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)

9. How Will NRC Judge Compliance?

Today's final rule directs NRC to use the arithmetic mean of the distribution of projected doses to determine compliance with both the 150 μSv/yr (15 mrem/yr) dose standard applicable for the first 10,000 years after closure and the 1 mSv/yr (100 mrem/yr) peak dose standard applicable between 10,000 and 1 million years after closure. In reaching this decision, we considered comments raising legal, technical, and policy points. Foremost among these were comments focusing 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)

After considering public comments, the NAS Report, and the D.C. Circuit decision, we conclude that the use of the arithmetic mean to determine compliance at all times, without conditions or restrictions, is straightforward and clearly consistent with the NAS recommendation, pursuant to the EnPA. Consistent with our proposal, we are specifying that the "mean" to be used is the arithmetic mean, as this is consistent with the intent of 40 CFR part 191 and its implementation at WIPP. See Section 7 of the Response to Comments document for more discussion of the points raised in public comments.

10. 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 quality factor, Q, and the tissue weighting factor, W_T. In ICRP 60, the quality factor was replaced by the radiation weighting factor, W_R, with the same values assigned to alpha, beta, and gamma radiation. 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 (which could be modified in cases where scientific information was available to support using alternative factors), 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-2005-0083-0421, 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-2005-0083-0421, emphases 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 "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 comments 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.

B. How Will This 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 during the first 10,000 years after disposal). 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) is now stated as an annual probability of 1 in 100 million (10^{-8} per year).[33] 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), 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

[33] Only FEPs with an annual probability greater than or equal to 10^{-5} need to be considered in performance assessments to show compliance with §§197.25(b) and 197.30. FEPs below this probability threshold, but still above 10^{-8} per year, are defined by NRC as "unlikely".

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. We believe that approach remains reasonable for the site-specific Yucca Mountain standards, 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 in addition to "very unlikely" FEPs, "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 from 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 screening for FEPs is done for the 10,000-year performance assessment and then used with certain additions set forth in the rule for the 1 million-year peak dose performance assessment. 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 do not change over 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 individual-protection standard, 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 onehundredth 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 result in the inclusion of FEPs that are so speculative as to be unreasonable (70 FR 49052). Nor do we believe it would be consistent with 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 might have been present or occurred only 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 these FEPs may have less than a 50% chance of occurring within the entire history of the Earth. 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 2007 recommendations: "The use of probability assessment is limited by the extent that unlikely events can be forecast. In circumstances where accidents can occur as a result of a wide spectrum of initiating events, caution should be exercised over any estimate of overall probabilities because of the serious uncertainty of predicting the existence of all the unlikely initiating events." (Publication 103, Docket No. EPA-HQ-OAR-2005-0083-0423, paragraph 269) (Note that this discussion is in the context of "potential" exposures, which include releases that may occur in the far future from disposal facilities. Therefore, the term "accidents" should not be taken as limited to operational activities.) 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 probabilities for individual FEPs are determined once, and the same probabilities are used in both the 10,000-year and 1 million-year assessments.

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 demonstrate 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 believe that the use of the significance criterion of §197.36(a) would assure a reasonable test of disposal system performance through the period of geologic stability. 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 have directed that the effects of general corrosion on the engineered 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 it might be possible that 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 explicitly addressed general corrosion of the waste packages and other engineered barriers 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 FEP could be 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, in addition to those FEPs related to seismicity, igneous activity and climate change identified by NAS, requires 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 for the Yucca Mountain disposal system.

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."

Also 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 parameter values, 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. NRC may choose to estimate the magnitude of ground-water table rise itself, or require DOE to include such estimates in its license application. 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. Changes in the hydrologic system from climate change (e.g., increases in infiltration) are expected to 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 developed to reflect estimates of different future climate states. 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 <u>impossible to predict in detail either the nature or the timing of future climate change</u>." (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

<u>A. Executive Order 12866: Regulatory Planning and Review</u>

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. Burden is defined at 5 CFR 1320.3(b). We have determined that this rule contains no information collection requirements within the scope of the Paperwork Reduction Act. This final rule establishes requirements that apply only to DOE.

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

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.

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

This action is not a "significant energy action" as defined in Executive Order 13211 (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

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. 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 1999 proposal (64 FR 46976), 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. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this final rulemaking. 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. Section 801(a)(1) of the EnPA directs EPA to "promulgate, by rule, public health and safety standards" that " prescribe the maximum annual effective dose equivalent to individual members of the public" from releases of radioactive material from the Yucca Mountain repository. This final rule fulfills this statutory direction.

K. 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.

40 CFR part 197 is amended as follows:

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?

* * * * *

<u>Effective dose equivalent</u> 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) Sections197.20(a)(1) and 197.20(a)(2) of this subpart; and

(2) Sections197.25(b)(1), 197.25(b)(2), and 197.30 of this subpart, if performance assessment is used to demonstrate compliance with either or both of these sections.

(b) [Reserved]

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) 1 millisievert (100 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) 1 millisievert (100 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. NRC may determine the magnitude of the water table rise and its significance on the results of the performance assessment, or NRC may require DOE to demonstrate the magnitude of the water table rise and its significance in the license application. 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 through 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 the internal component of the annual 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, $\underline{H}_T$, to a tissue or organ, T, listed in Table A.2 below by using the equation:

$$\underline{H}_T = \sum_R \underline{D}_{T,R} \times \underline{w}_R$$

where $\underline{D}_{T,R}$ 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 $\underline{w}_R$ 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, $\underline{w}_R$ [1]

Radiation type and energy range [2]		$\underline{w}_R$ 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, $\underline{w}_T$ 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 $\underline{H}_T$ is the equivalent dose in the tissue or organ, T, in the equation:

$$E = \ni \underline{w}_T \cong \underline{H}_{T.}$$

Table A.2 -- Tissue weighting factors, $\underline{w}_T$

Tissue or organ	$\underline{W}_T$ 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 <u>committed equivalent dose</u>, $H_T(\tau)$ 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. Internal Component of the 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 internal component of the <u>annual committed effective dose equivalent</u> $E(\tau)$:

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

Billing Code 6560-50-P