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Part II

Environmental Protection Agency

40 CFR Part 197

Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 197

[OAR–2005–0083; FRL–7952–1]

RIN 2060–AN15

Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: We, the Environmental Protection Agency (EPA), are proposing to revise certain of our public health and safety standards for radioactive material stored or disposed of in the potential repository at Yucca Mountain, Nevada. Section 801(a) of the Energy Policy Act of 1992 (EnPA, Pub. L. 102–486) directed us to develop these standards. These standards (the 2001 standards) were originally promulgated on June 13, 2001 (66 FR 32074). Section 801 of the EnPA also required us to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. The health and safety standards promulgated by EPA are to be ''based upon and consistent with'' the findings and recommendations of NAS. On August 1, 1995, NAS released its report (the NAS Report), titled ''Technical Bases for Yucca Mountain Standards.'' In promulgating our standards, we considered the NAS Report as the EnPA directs.

On July 9, 2004, in response to a legal challenge by the State of Nevada and the Natural Resources Defense Council, the U.S. Court of Appeals for the District of Columbia Circuit vacated portions of our standards that addressed the period of time for which compliance must be demonstrated. The Court ruled that the time frame for regulatory compliance was not ''based upon and consistent with'' the findings and recommendations of the NAS and remanded those portions of the standards to us for revision. These remanded provisions are the subject of today's action.

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

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

DATES: Comments must be received on or before October 21, 2005.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2005–0083, by one of the following methods:

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD–ROM you submit, and in any cover letter accompanying the disk or CD–ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case we cannot read your comment due to technical difficulties or we need further information on the substance of your comment. EPA's policy is that we will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, we may not be able to consider your comment.

i. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

ii *Agency Web site:* EPA's preferred method for receiving comments is via its website, EDOCKET. EDOCKET is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. Go directly to EDOCKET at *http://www.epa.gov/edocket*, or, from the EPA Internet Home Page (*www.epa.gov*), select ''Information Sources'' (in the left column), then ''Dockets,'' then ''EPA Dockets'' (in the first paragraph). For either route, then click on ''Quick Search'' (in the left column). In the search window, type in the docket identification number OAR–2005–0083. Please be patient, the search could take about 30 seconds. This will bring you to the ''Docket Search Results'' page. At that point, click on OAR–2005–0083. From the resulting page, you may submit a comment by clicking on the balloon icon in the ''Submit Comment'' column and following the subsequent directions.

iii. *E-mail:* Comments may be sent by electronic mail (e-mail) to *a-and-r-docket@epa.gov*, Attention Docket ID No. OAR–2005–0083. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

2. *Surface Mail.* Send your comments to: EPA Docket Center (EPA/DC), Air and Radiation Docket, Environmental Protection Agency, EPA West, Mail Code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Attention Docket ID No. OAR–2005–0083.

3. *Hand Delivery or Courier.* Deliver your comments to: Air and Radiation Docket, EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OAR–2005–0083. Such deliveries are only

accepted during the Docket Center's normal hours of operation.

4. *Facsimile.* Fax your comments to: 202–566–1741, Attention Docket ID. No. OAR–2005–0083.

Instructions for submitting information to EDOCKET: Direct your comments and information to Docket ID No. OAR–2005–0083. It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Certain types of information will not be placed in EDOCKET. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

The EPA EDOCKET and the federal regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or *regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

Docket: The official docket is the collection of materials that is available for public viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744. The telephone number for the Air and Radiation Docket is 202–566–1742. As provided in EPA's regulations at 40 CFR part 2, and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged.

All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available since it will not be placed in EDOCKET. That is, although a part of the official docket, EDOCKET does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's EDOCKET. In addition, EPA policy is that copyrighted material will not be placed in EPA's EDOCKET, but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's EDOCKET. When a document is selected from the index list in EDOCKET, the system will identify whether the document is available for viewing. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

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, DC 20460–0001; telephone number: 202–343–9601; fax number: 202–343–2305; e-mail address: *clark.ray@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* If you submit CBI, clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. Respond to specific questions from the Agency.

9. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response.

C. 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#desks*) and the Amargosa Valley, Nevada public library (*http://www.amargosavalley.com/Library.html*) to provide information files on this rulemaking. These files are not legal dockets, however every effort will be made to put the same material in them as in the official public docket in Washington, DC. The Lied Library information file is at the Research and Information Desk, Government Publications Section (702–895–2200). Hours vary based upon the academic calendar, so we suggest that you call ahead to be certain that the library will be open at the time you wish to visit (for a recorded message, call 702–895–2255). The other information file is in the Public Library in Amargosa Valley, Nevada (phone 775–372–5340). As of the date of publication, the hours are Monday, Wednesday, and Friday (9 a.m.–5 p.m.); Tuesday and Thursday (9 a.m.–7 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 EPA's electronic public docket and comment system, EPA Dockets (EDOCKET). You may use EDOCKET to submit or 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 either go directly to *http://www.epa.gov/edocket/* or, from the EPA Internet Home Page (*www.epa.gov*), select ''Information Sources'' (in the left column), then ''Dockets,'' then ''EPA Dockets'' (in the first paragraph). For either route, then click on ''Quick Search'' (in the left column). In the search window, type in the docket identification number OAR–2005–0083. Please be patient, the search could take about 30 seconds. This will bring you to the ''Docket Search Results'' page. At that point, click on OAR–2005–0083. From the resulting page, you may access the docket contents (*e.g.*, OAR–2005–0083–0002) by clicking on the icon in the ''Rendition'' column.

D. 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.* 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.

E. What Documents Are Referenced in Today's Proposal?

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

Item No. (OAR–2005–0083–xxxx)

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

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

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

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

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

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

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

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

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

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

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
DOE—U.S. Department of Energy
DOE/VA—DOE's Viability Assessment
EIS—Environmental Impact Statement
EnPA—Energy Policy Act of 1992
EPA—U.S. Environmental Protection Agency
FEIS—Final Environmental Impact Statement
FEPs—features, events, and processes
FR—**Federal Register**
GCD—greater confinement disposal
HLW—high-level radioactive waste
HSK—Swiss Federal Nuclear Safety Inspectorate
IAEA—International Atomic Energy Agency

ICRP—International Commission on Radiological Protection
KASAM—Swedish National Council for Nuclear Waste
LLW—low-level radioactive waste
MCL—maximum contaminant level
MTHM—metric tons of heavy metal
NAPA—National Academy of Public Administration
NAS—National Academy of Sciences
NEA—Nuclear Energy Agency
NEI—Nuclear Energy Institute
NRC—U.S. Nuclear Regulatory Commission
NRDC—Natural Resources Defense Council
NTS—Nevada Test Site
NTTAA—National Technology Transfer and Advancement Act
NWPA—Nuclear Waste Policy Act of 1982
NWPAA—Nuclear Waste Policy Amendments Act of 1987
OECD—Organization for Economic Cooperation and Development
OMB—Office of Management and Budget
RMEI—reasonably maximally exposed individual
SSI—Swedish Radiation Protection Authority
SNF—spent nuclear fuel
SR—Site recommendation
TRU—transuranic
TSPA—Total System Performance Assessment
UK—United Kingdom
UMRA—Unfunded Mandates Reform Act of 1995
U.S.C.—United States Code
WIPP LWA—Waste Isolation Pilot Plant Land Withdrawal Act of 1992

Outline of Today's Action

I. What Is the History of Today's Action?

Radioactive wastes result from the use of nuclear fuel and other radioactive materials. Today, we are proposing to revise certain standards pertaining to spent nuclear fuel (SNF), high-level radioactive waste (HLW), and other radioactive waste (we refer to these items collectively as ''radioactive materials'' or ''waste'') that may be stored or disposed of in the Yucca Mountain repository. (When we discuss storage or disposal in this document in reference to Yucca Mountain, we note that no decision has been made regarding the acceptability of Yucca Mountain for storage or disposal as of the date of this publication. To save space and to avoid excessive repetition, we will not describe Yucca Mountain as a ''potential'' repository; however, we intend this meaning to apply.) Pursuant to Section 801(a) of the Energy Policy Act of 1992 (EnPA, Pub. L. 102–486), these standards apply only to facilities at Yucca Mountain.

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

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

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

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

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

This general division of responsibilities continues for the Yucca Mountain repository. Thus, today we are proposing to establish or revise specific aspects of our public health protection standards at 40 CFR part 197 (which are, pursuant to EnPA Section 801(a), applicable only to Yucca Mountain, rather than generally applicable). The NRC will issue implementing regulations for these standards. The DOE plans to submit a license application to NRC. The NRC then will determine whether DOE has met NRC's regulations and whether to grant or deny a license for Yucca Mountain.

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

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

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

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

We issued the amended 40 CFR part 191 disposal standards, which addressed the judicial remand, on December 20, 1993 (58 FR 66398). The EnPA, enacted in 1992, set forth our responsibilities as they relate to Yucca Mountain. In the EnPA, Congress directed us to set public health and safety radiation standards for Yucca Mountain. Specifically, section 801(a)(1) of the EnPA directed us to ''promulgate, by rule, public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site.'' Section 801(a)(2) directed us to contract with the National Academy of Sciences (NAS) to conduct a study to provide us with its findings and recommendations on reasonable standards for protection of public health and safety from releases from the Yucca Mountain disposal system. Moreover, it provided that our standards shall be the only such standards applicable to the Yucca Mountain site and are to be based upon and consistent with NAS's findings and recommendations. On August 1, 1995, NAS released its report, ''Technical Bases for Yucca Mountain Standards'' (the NAS Report) (Docket No. OAR–2005–0083–0076).

A. Promulgation of 40 CFR Part 197 in 2001

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

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

We also considered the findings and recommendations of the NAS in developing standards for Yucca Mountain. In some cases, provisions of 40 CFR part 191 were already consistent with NAS's analysis (*e.g.*, level of protection for the individual). In other cases, we used the NAS Report to modify or draw out parts of 40 CFR part 191 to apply more directly to Yucca Mountain (*e.g.*, the stylized drilling scenario for human intrusion). See the NAS Report for a complete description of findings and recommendations.

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

We proposed 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

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

comments (Docket No. OAR–2005–0083–0043).

1. What Are the Elements of EPA's 2001 Standards?

We are issuing today's proposal to respond to a ruling by the U.S. Court of Appeals for the District of Columbia Circuit (''the Court'') that vacated portions of 40 CFR part 197. Sections I.B (''Legal Challenges to 40 CFR part 197'') and I.C (''Ruling by U.S. Court of Appeals for the District of Columbia Circuit'') discuss aspects of the legal challenges on which the Court ruled. This section summarizes some of the key provisions and concepts in 40 CFR part 197 to provide a context to better understand the basis for the legal actions and today's proposed action, which is described in Section II of this document (''How Will EPA Address the Decision by the Court of Appeals?'').

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

- A standard to protect the public during storage operations at the Yucca Mountain site;
- An individual-protection standard to protect the public after disposal from releases from the undisturbed repository;
- A human-intrusion standard to protect the public after disposal from releases caused by a drilling penetration into the repository;
- A set of standards to protect ground water from radionuclide contamination caused by releases from the repository after disposal;
- The requirement that compliance with the disposal standards be shown for 10,000 years;
- The requirement that DOE continue its projections for the individual-protection and human-intrusion standards beyond 10,000 years to the time of peak (maximum) dose, and place those projections in the Environmental Impact Statement (EIS);
- The concept of the Reasonably Maximally Exposed Individual (RMEI), defined as a hypothetical person whose lifestyle is representative of the local population, 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.

We emphasize that today's proposal is narrowly focused to respond to the Court ruling. Most sections of our 2001 rule are unaffected by the Court's ruling and are not implicated in today's proposal. We are requesting and will respond to comments only on those provisions we are proposing to change today.

a. What Is the Standard for Storage of the Waste? (Subpart A, §§ 197.1 Through 197.5)

Section 801(a)(1) of the EnPA calls for EPA's public health and safety standards to apply to radioactive materials ''stored or disposed of in the repository at the Yucca Mountain site.'' The repository is the excavated portion of the facility constructed underground within the Yucca Mountain site. The storage standard, therefore, applies to waste inside the repository, prior to disposal.

The DOE also will handle, and might store, radioactive material outside the repository prior to subsurface emplacement. Therefore, our standards will provide public health and safety protection for surface management and storage activities on the surface of the Yucca Mountain site and in the Yucca Mountain repository. The combined doses incurred by any individual in the general environment from these activities must not exceed 150 µSv (15 mrem) committed effective dose equivalent per year (CEDE/yr).

b. What Are the Standards for Disposal? (Subpart B, §§ 197.11 Through 197.36)

Subpart B of our 2001 rule consisted of three separate standards (or sets of standards) that apply after disposal, which are discussed in more detail in the appropriate sections of this document (*e.g.*, Section II.A, ''How Will Elements of the Disposal Standards be Affected?''). For additional detail, see the preamble to the June 2001 rulemaking (66 FR 32074, June 13, 2001). The disposal standards are:

- An individual-protection standard;
- A human-intrusion standard; and
- Ground-water protection standards.

i. What Is the Standard for Protection of Individuals? (§§ 197.20 Through 197.21)

The first standard is an individual-protection standard. It specifies the maximum dose that a reasonably maximally exposed individual (RMEI) may receive from releases from the Yucca Mountain repository.

Our individual-protection standard set a limit of 150 µSv (15 mrem) CEDE/yr. This limit corresponds to an annual risk of fatal cancer within the range that NAS suggested as a ''reasonable starting point for EPA's rulemaking'' (NAS Report p. 5, Docket No. OAR–2005–0083–0076). The NAS s suggested risk range corresponds to approximately 2 to 20 mrem CEDE/yr.

The standard described above applies for a period of 10,000 years after disposal, and is to be measured against exposures to the RMEI at a location outside the controlled area (in the ''accessible environment'').

aa. Who Represents the Exposed Population?

To determine whether the Yucca Mountain disposal system complies with our standard, DOE must calculate the dose received by some individual or group of individuals exposed to releases from the repository and compare the calculated dose with the limit established in the standard. The standard specifies, therefore, the representative individual for whom DOE must make the dose calculation as the RMEI. It was left to NRC to define the details, beyond those which we specified, necessary for the dose calculation. NRC has further defined the RMEI as an adult (10 CFR 63.312(e)) and specified that the average concentration of radionuclides in well water ingested by the RMEI be based on a water demand of 3,000 acre-feet per year (10 CFR 63.312(c)).

The Reasonably Maximally Exposed Individual (RMEI)

The approach we chose (the RMEI) embodies the intent of the internationally-accepted concept to protect those individuals most at risk from the proposed repository but specifies one or a few site-specific parameters at their maximum values. The characteristics of the RMEI are defined from consideration of current population distribution and ground-water usage, and average food consumption patterns for the population downgradient from Yucca Mountain in Amargosa Valley, Nevada.

Our RMEI is a theoretical individual representative of a future population group or community termed ''rural-residential'' (see Chapter 8 of the 2001 BID for a description of this concept, Docket No. OAR–2005–0083–0050). We assume that the rural-residential RMEI is exposed through the same general pathways as a subsistence farmer. However, this RMEI would not be a full-time farmer. Rather, the RMEI might do personal gardening and earn income from other sources of work in the area. Under our standard, the RMEI will have food and water intake rates, diet, and physiology similar to those of individuals living in Amargosa Valley, Nevada. We assume that all of the drinking water and some of the food (based upon surveys) consumed by the RMEI is from the local area. Similarly, we assume that local food production will use water contaminated with radionuclides released from the disposal system. We believe this lifestyle is conservative but similar to that of most people living in Amargosa Valley today.

Location of the RMEI. The location of the RMEI is a basic part of the exposure scenario. We require that the RMEI be located in the accessible environment (*i.e.*, outside the controlled area) above the highest concentration of radionuclides in the plume of contamination. Based upon a review of available site-specific information (see Chapter 8 of the 2001 BID, Docket No. OAR–2005–0083–0050), we identified the southern edge of the Nevada Test Site as the southernmost extent of the controlled area. The actual compliance point will be determined through the licensing process. (Even if the RMEI were to be located north of this line of latitude, the RMEI must still have the characteristics described in § 197.21.) As discussed in Section I.B (''Legal Challenges to 40 CFR part 197'') and I.C (''Ruling by the U.S. Court of Appeals for the District of Columbia Circuit''), the location of the RMEI was a subject of the Court decision, was upheld, and is not a subject of today's proposal.

bb. How Far Into the Future Must Performance Be Assessed?

In 2001, we established a compliance period of 10,000 years. Under the 2001 standards, the peak dose within 10,000 years after disposal would be required to comply with the individual-protection standard. In addition, we required calculation of the peak dose beyond 10,000 years, but within the period of geologic stability. We required DOE to include the results and bases of the additional analyses in the EIS for Yucca Mountain as an indicator of the future performance of the disposal system. The rule did not, however, require that DOE meet a specific dose limit after 10,000 years. The compliance period was a subject of the Court decision and is the primary subject of today's proposal.

ii. What Is the Standard for Human Intrusion? (§§ 197.25 Through 197.26)

We adopted NAS's suggested starting point for a human-intrusion scenario. As NAS recommended, our standard required a single-borehole intrusion scenario based upon Yucca Mountain-specific conditions. The intended purpose of analyzing this scenario ''* * * is to examine the site- and design-related aspects of repository performance under an assumed intrusion scenario to inform a qualitative judgment'' (NAS Report p. 111). The assessment would result in a calculated RMEI dose arriving through the pathway created by the assumed borehole (with no other releases included). Consistent with the NAS Report, we also required ''that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed-repository case'' (NAS Report p. 113). We interpreted NAS's term ''undisturbed'' to mean that the Yucca Mountain disposal system is not disturbed by human intrusion but that other processes or events that are likely to occur could disturb the system.

The DOE is not required to use probabilistic performance assessment for the human-intrusion analysis, as it is for the individual-protection standard. However, if it chooses to do so, we required that the human-intrusion analysis of disposal system performance use the same methods and RMEI characteristics for the performance assessment as those required for the individual-protection standard, with the exception that the human-intrusion analysis would exclude unlikely natural features, events, and processes (FEPs).

The DOE must determine when the intrusion would occur based upon the earliest time that current technology and practices could lead to waste package penetration without the drillers noticing the canister penetration. In general, we believe that the time frame for the drilling intrusion should be within the period that a small percentage of the waste packages have failed but before significant migration of radionuclides from the engineered barrier system has occurred because, based upon our understanding of drilling practices, this period would be about the earliest time that a driller would not recognize an impact with a waste package.

The compliance standard for human intrusion parallels that for the individual-protection scenario. If the intrusion were to occur at or earlier than 10,000 years after disposal, DOE must demonstrate a reasonable expectation that annual exposures incurred by the RMEI within 10,000 years as a result of the intrusion event would not exceed 150 μSv (15 mrem) CEDE. However, if the intrusion occurred after 10,000 years, or when earlier intrusions result in exposures projected to occur after 10,000 years, DOE would not have to compare its results against a numerical standard, but would have to include those results in its EIS.

iii. What Are the Standards To Protect Ground Water? (§§ 197.30 Through 197.31)

We established separate ground-water standards as a means to protect the aquifer as both a resource for current users and a potential resource for larger numbers of future users either near the repository or farther away in communities comprised of a substantially larger number of people than presently exist in the vicinity of Yucca Mountain. The standards DOE must meet are equivalent to the radionuclide Maximum Contaminant Levels (MCLs) established for drinking water.

To implement the ground-water protection standards in § 197.30, we required that DOE use the concept of a ''representative volume'' of ground water (§ 197.31). Under this approach, DOE must project the concentration of radionuclides or the resultant doses within a ''representative volume'' of ground water for comparison against the standards. We selected a value of 3,000 acre-ft/yr as a ''cautious, but reasonable'' figure for the representative volume. Section 197.31 also describes two methods by which DOE may calculate radionuclide concentrations in ground water. See the preamble to the 2001 rulemaking for more discussion of the representative volume and approaches for calculating radionuclide concentrations for compliance purposes.

As with the individual-protection standard, compliance with the ground-water protection standards must be determined at the point of highest concentration in the plume of contamination in the accessible environment. The controlled area was defined in the same way as for the individual-protection standard. The ground-water protection standards were a subject of the Court decision, were upheld, and are not a subject of today's proposal.

c. What Is ''Reasonable Expectation''? (§ 197.14)

An important provision of our standards is the establishment of the principle of ''reasonable expectation'' to guide implementation of our standards and provide context for evaluating projections against the numerical compliance standards discussed above. It is a critical element in implementing our standards, but its importance might easily be overlooked or misunderstood. We use the concept of ''reasonable expectation'' in these standards to reflect our intent regarding the level of ''proof'' necessary for NRC to determine whether the projected performance of the Yucca Mountain disposal system complies with the standards (see §§ 197.20, 197.25, and 197.30). In issuing our 2001 standards, we noted that this term is meant to convey our position that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained for geologic disposal systems. We believe unequivocal proof is not possible because of the extremely long time periods involved and because disposal system performance assessments require extrapolations of conditions and the actions of processes that govern disposal system performance over those long time periods.

The primary means for demonstrating compliance with the standards is the use of computer modeling to project the performance of the disposal system under the range of expected conditions. These modeling calculations involve the extrapolation of site conditions and the interactions of important processes over long time periods, extrapolations that involve inherent uncertainties in the necessarily limited amount of information that can be collected through field and laboratory studies and the unavoidable uncertainties involved in simulating the complex and time-variable processes and events involved in long-term disposal system performance. Overly conservative assumptions made in developing performance scenarios can bias the analyses in the direction of unrealistically extreme situations, which in reality may be highly improbable, and can deflect attention from questions critical to developing an adequate understanding of the expected features, events, and processes (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Sections 11 and 12, July 2005, Docket No. OAR–2005–0083–0085). The reasonable expectation approach focuses attention on understanding the uncertainties in projecting disposal system performance so that regulatory decision making will be done with a full understanding of the uncertainties involved. Thus, realistic analyses are preferred over conservative and bounding assumptions, to the extent practical.

B. Legal Challenges to 40 CFR Part 197

Various aspects of our standards were challenged in lawsuits filed with the U.S. Court of Appeals for the District of Columbia Circuit in July 2001. Oral arguments were conducted on January 14, 2004. These challenges and the outcome are described in the following sections.

1. Challenges by the State of Nevada and Natural Resources Defense Council

The State of Nevada, the Natural Resources Defense Council (NRDC), and several other environmental and public interest groups challenged several aspects of our final standards on the grounds that they were insufficiently protective and had not been adequately justified. Specifically, they claimed that:

- EPA's promulgation of standards that apply for 10,000 years after disposal violates the EnPA because such standards are not ''based upon and consistent with'' the findings and recommendations of the NAS. NAS recommended standards that would apply to the time of maximum risk and stated that there is ''no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value.''
- The size of the controlled area defined by EPA, which represents the maximum extent of the disposal system and inside which DOE need not demonstrate compliance with the EPA standards, rests on inappropriate assumptions regarding the ability of people to live closer to the repository and violates the Safe Drinking Water Act provisions against endangering sources of drinking water.
- EPA's definition of ''disposal'' in 40 CFR 197.12 deviates from the definition in the NWPA by inserting the qualifying phrase ''for as long as reasonably possible,'' suggesting that the Yucca Mountain disposal system would be held to a lesser standard of protection because it would not have to provide ''permanent isolation.''

2. Challenge by the Nuclear Energy Institute

The Nuclear Energy Institute (NEI) is a trade organization representing nuclear power producers, who collect a surcharge from ratepayers for the Nuclear Waste Fund (established by the NWPA, *see* 42 U.S.C. 10222). NEI challenged the ground-water protection provisions in 40 CFR 197.30 on several grounds, including that:

- They conflict with the direction in the EnPA that EPA issue standards ''based upon and consistent with the findings and recommendations of'' NAS and that EPA's ''standards shall prescribe the maximum annual effective dose equivalent * * * from releases * * * from radioactive materials stored or disposed of in the repository.'' NEI argued that EPA's ground-water standards: (1) were in a form other than effective dose equivalent (EDE); (2) were not recommended by NAS, which stated that such standards were not ''necessary to limit risks to individuals'' (NAS Report p. 121); and (3) were not limited to releases from the repository because they require that DOE consider natural background when determining compliance.
- The science underlying the ground-water standards uses the outdated ''critical organ'' methodology, which results in inconsistent risk estimates and is inconsistent with other radiation-protection standards.
- EPA justified its ground-water standards on cost grounds without conducting a thorough cost-benefit analysis; NEI believes such an analysis would show that the ground-water standards provide no benefit to public health but will increase the cost and slow the construction of the repository.
- EPA is inappropriately applying drinking water standards, which were derived to apply to customers of public water supplies (*i.e.*, ''at the tap'') to ground water.

C. Ruling by the U.S. Court of Appeals for the District of Columbia Circuit

Oral arguments for the challenges described above were heard on January 14, 2004. The challenges to EPA's standards were consolidated with challenges to NRC's licensing requirements, DOE's siting guidelines, and the Presidential recommendation of the Yucca Mountain site and the subsequent Congressional resolution. The Court's ruling was handed down on July 9, 2004. The Court upheld EPA's Yucca Mountain rule in all respects, save for the regulatory compliance period.

1. What Did the Court of Appeals Rule on the Issue of Compliance Period?

The Court upheld the challenge to EPA's 10,000-year compliance period, ruling that EPA's action was not ''based upon and consistent with'' the NAS Report, and that EPA had not sufficiently justified its decision to apply compliance standards only to the first 10,000 years after disposal on policy grounds. *Nuclear Energy Institute* v. *Environmental Protection Agency*, 373 F.3d 1 (D.C. Cir. 2004) (*NEI*) (Docket No. OAR–2005–0083–0080). On that point, the Court stated that:

> NAS's conclusion that EPA ''might choose to establish consistent policies'' is of little importance * * * And although our case law makes clear that a phrase like ''based upon and consistent with'' does not require EPA to hew rigidly to NAS's findings, EnPA Section 801(a) cannot reasonably be read to allow a regulation wholly inconsistent with NAS recommendations. (*NEI*, 373 F.3d at 30.)

Similarly, the Court rejected EPA's reasoning that the requirement of 40

CFR 197.35 that DOE project performance to the time of peak dose and place those projections in the Environmental Impact Statement (EIS) addressed the intent of the NAS recommendation by ensuring that assessments would not be arbitrarily cut off at some earlier time:

> Although EPA's addition of this provision might well represent a nod to NAS, it hardly makes the agency's regulation consistent with the Academy's findings. NAS recommended that the compliance period extend to the time of peak risk, yet EPA's rule requires only that DOE *calculate* peak doses and expressly provides that ''[n]o regulatory standard applies to the results of this analysis.'' (*Id.* at 31, emphasis in original)

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

> In sum, because EPA's chosen compliance period sharply differs from NAS's findings and recommendations, it represents an unreasonable construction of section 801(a) of the Energy Policy Act. Although EnPA's ''based upon and consistent with'' mandate leaves EPA with some flexibility in crafting standards in light of NAS's findings, EPA may not stretch this flexibility to cover standards that are inconsistent with the NAS Report. Had EPA begun with the Academy's recommendation to base the compliance period on peak dosage and then made adjustments to accommodate policy considerations not considered by NAS, this might be a very different case. But as the foregoing discussion demonstrates, EPA wholly rejected the Academy's recommendations. We will thus vacate part 197 to the extent that it requires DOE to show compliance for only 10,000 years following disposal. (*Id.* at 31.)

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

a. What Were NAS's Findings (''Conclusions'') and Recommendations on the Issue of Compliance Period?

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

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

2. What Did the Court of Appeals Rule on Other Issues Related to EPA's Standards?

The Court did not sustain any of the other challenges lodged by Nevada, NRDC, or NEI. Instead, the Court found that:

- In defining the controlled area, EPA's conclusions regarding the likely extent of the future population and their exposures were reasonable. Further, the provisions of the Safe Drinking Water Act do not apply at Yucca Mountain (by virtue of the EnPA statement that EPA's standards ''shall be the only standards applicable to the Yucca Mountain site''). (*NEI*, 373 F. 3d at 32–38.)
- EPA is not bound to follow the NWPA definition of ''disposal'' because the enabling authority for this action is the EnPA, which does not require that NWPA definitions be used and does not itself define ''disposal.'' Therefore, EPA acted reasonably ''in filling that statutory gap.'' (*Id.* at 38–39.)
- EPA's interpretation of the EnPA as permitting separate ground-water standards is reasonable because: (1) The EnPA does not restrict EPA to establish *only* EDE standards, but requires that EPA ''establish a set of health and safety standards, at least one of which must include an EDE-based, individual-protection standard''; (2) NAS made no ''finding or recommendation'' either for or against a ground-water standard, so consistency with NAS is not at issue; and (3) ''Part 197 * * * does not regulate background radiation * * * the rule requires only that DOE take background levels into account when measuring permissible releases of radionuclides from the repository. Therefore, part 197 could not possibly run afoul of EnPA's focus on released radiation.'' (*Id.* at 43–48.)
- NEI's arbitrary and capricious arguments in *NEI* were the same as the arguments that NEI had raised in a challenge to EPA's radionuclide MCLs under the Safe Drinking Water Act, which the Court had rejected only one year previously in *City of Waukesha* v. *EPA*. (*Id.* at 48–49.)
- EPA ''unremarkably'' concluded that ground-water protection standards represent sound pollution prevention policy and will encourage a more robust repository design. This reasoning prevailed with the Court on both the cost-effectiveness and ''at the tap'' challenges. (*Id.* at 49–50.)

II. How Will EPA Address the Decision by the Court of Appeals?

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

In today's action, we are not proposing to revise all of these standards, only those affected by the Court decision. Therefore, we are proposing to revise only the individual-protection and human-intrusion standards, along with certain supporting provisions related to the way DOE must consider features, events, and processes (FEPs) in its compliance analyses. In addition, we are proposing to adopt updated scientific factors for calculating doses to show compliance with the storage, individual-protection, and human-intrusion standards, as described in more detail in Section II.C.6. We are not proposing to change any aspect of the ground-water protection standards. We are providing notice and requesting public comment only on our proposed revisions to 40 CFR part 197. With the exception of the updated factors for calculating doses for the storage standard, we are not requesting and will not consider public comment on either the storage or ground-water protection standards. Furthermore, we are not requesting, nor will we consider, comments on those aspects of the individual-protection and human-intrusion standards to which no changes are proposed.

We are proposing to address the Court's decision by revising elements of our standards to incorporate the time of peak dose into the determination of compliance. We are also proposing to further delineate how DOE should incorporate features, events, and processes that may take place over very long times into its calculation of peak dose, consistent with our ''reasonable expectation'' standard.

A. How Will Elements of the Disposal Standards be Affected?

The Court's ruling vacated only one aspect of 40 CFR part 197, the 10,000-year compliance period. Thus, we considered the language and reasoning of the Court's decision to determine its applicability to each element of the disposal standards. The three main components of the standards are discussed in the following sections. We also considered the need to modify certain other aspects that would influence how DOE would conduct its performance assessments beyond 10,000 years. These aspects are discussed in more detail in Section II.D (''How Will Today's Proposal Affect the Way DOE Conducts Performance Assessments?'').

1. Individual-Protection Standard

The Court's decision clearly affects the compliance period for the individual-protection standard, which is the primary standard for public health and safety called for by the EnPA. The legal challenge and the Court's response left no doubt that the compliance period for the individual-protection standard was at issue and the decision centered on the NAS's recommendation regarding the compliance period for the individual-protection standard. Therefore, as described in Section II.C, we are proposing today to modify the individual-protection standard to incorporate a compliance measure effective at the time of peak dose, in addition to the 15 mrem/yr standard applicable for the first 10,000 years after disposal, which we are retaining.

Section I.A.1.b.i discusses other elements of the individual-protection standard, specifically the definition of the controlled area and the use of the RMEI as the representative exposed person. We are not modifying the definition of the controlled area, which was upheld by the Court. We have described the maximum extent of the area, using current conditions and relatively near-term plans for development. The actual compliance point will be determined through the licensing process, and DOE will have to justify its reasons for selecting a particular location to NRC.

Similarly, we are not proposing to alter the description of the RMEI as a person having a ''rural-residential'' lifestyle as reflected in today's population. We have described at length our reasons for using current characteristics as an appropriate means to avoid excessive speculation about which of the infinite number of possible future lifestyles would be most representative over very long periods (*see* 66 FR 32088–32094 (Docket No. OAR–2005–0083–0042) and Section 4 of the Response to Comments document for the 2001 rulemaking (Docket No. OAR–2005–0083–0050)). Some comments on our 1999 proposal disagreed with our reasoning and choice of RMEI. We recognize that interested parties may see an extension of the compliance period as justifying a different description for the RMEI, at least for time frames well beyond 10,000 years. They may point to climate change scenarios as potentially making the ''rural-residential'' lifestyle as it is defined in our 2001 rule incompatible with climate change assumptions. It may be argued that climate change could significantly affect the types of locally grown food in the RMEI's diet, as well as the use of contaminated ground water for irrigation or watering livestock, which would ultimately influence exposures. NAS alluded to such a possibility, noting that one effect of climate change could be ''a shift in the distribution and activities of human populations'' (NAS Report p. 92). However, NAS also concluded that ''there is no simple relation between future climatic conditions and future population'' (NAS Report p. 92). We agree that it is difficult to predict exactly how climate change, or other evolutionary scenarios, would influence lifestyles, nor can we predict the viability or distribution of agricultural activities compared with those pursued today. In fact, we believe that the RMEI as a current ''rural-residential'' individual may be among the more conservative possibilities. Given the importance of irrigation and other uses of ground water in the Amargosa Valley region, it is likely that potential exposures to contaminated ground water would be lower under many wetter climate change scenarios where greater precipitation could reduce the use of ground water for irrigation and other practices.

Some commenters might question whether it is important to have internal consistency between climate/biosphere characteristics and RMEI lifestyle and characteristics. We believe that it would be highly speculative to select RMEI characteristics to correspond to some future climate state. We require that DOE consider climate change within 10,000 years, and are proposing today also to require consideration of climate change for much longer times (*see* Section II.D.2.d, ''Consideration of Climatological FEPs''). As noted above, we believe the present-day RMEI represents a conservative choice if, as seems likely, future climate in the Yucca Mountain region tends to be cooler and wetter. Under wetter conditions, agricultural activities around the site area would rely less on irrigation using well water. With less use of contaminated ground water for irrigation, the contribution to the RMEI dose from contaminated food would presumably be lowered or perhaps eliminated. In counterpoint, under wetter conditions, it is possible to speculate that individuals could live closer to the repository than is considered for present-day conditions and potentially tap contaminated ground waters closer to Yucca Mountain than at the RMEI location. We believe that the RMEI, as presently defined for present-day conditions, is a reasonably conservative approach for the dose assessments, and is appropriate for wetter climate conditions. Assumptions regarding the possible uses of ground water are quite speculative and have been avoided to the extent possible in the setting of the standards (66 FR 32111). Therefore we are not redefining the RMEI characteristics in any attempt to correlate them with climatic variations, primarily due to speculation regarding the uses of ground water by man. As noted above, this approach is consistent with the NAS's conclusion that there is no exact correlation between potential climate changes and shifts in the distribution and activities of human populations. Comments on the definition of the controlled area and specification of the RMEI are outside the scope of today's proposal. We will not consider or respond to comments on these topics.

2. Human-Intrusion Standard

While the Court did not specifically address the human-intrusion standard, we believe it is logical and defensible to modify it to parallel the individual-protection standard. Like the individual-protection standard, our provisions for human intrusion envisioned some consideration of performance beyond 10,000 years. The 2001 standard required that DOE determine when an intrusion by drilling would be possible and assess the consequences. The resulting exposures were then subject to the same compliance standard as the individual-protection standard (15 mrem/yr at 10,000 years or earlier and dose projections beyond 10,000 years to be compiled in the EIS). In proposing revisions to the human-intrusion standard to conform to changes we are proposing to make to the individual-protection provisions, we are adhering to the NAS recommendation that ''EPA require that the estimated risk calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case'' (NAS Report p. 12). In light of this recommendation, and the Court's interpretation of how closely we must align with the NAS recommendations to be deemed ''based upon and consistent,'' we believe it is both prudent and reasonable to propose to revise the human-intrusion standards to incorporate peak dose compliance measures that conform to the proposed revisions for individual protection.

Aside from the application of dose standards at both 10,000 years and the time of peak dose, the foundation of the proposed revised human-intrusion standard is unchanged. DOE must determine the earliest time at which it would be possible to penetrate waste packages by drilling. The scenario described in § 197.26 would still apply (*i.e.*, penetration of a single package, direct pathway to ground water, etc.). The decision to apply a regulatory standard for the period of geologic stability does not in any way affect the reasoning underlying the selection of this scenario. It remains fully consistent with the NAS conclusion that at Yucca Mountain ''there is no scientific basis for estimating the probability of intrusion at far-future times'' (NAS Report p. 106). Instead, NAS recommended that ''the result of the analysis should not be integrated into an assessment of repository performance based on risk, but rather should be considered separately. The purpose of this consequence analysis is to evaluate the resilience of the repository to intrusion'' (NAS Report p. 109). NAS further suggested that EPA describe a ''stylized'' intrusion scenario based on current drilling technologies, an approach we adopted in § 197.26 and which will remain unchanged by today's proposal.

The circumstances of the intrusion scenario in § 197.26 are required to be developed based on present-day practices, in accordance with the NAS recommendation. This approach was fully justified for the reasons given by NAS and unchallenged for the 10,000-year time frame. We find that maintaining the approach beyond 10,000 years is also fully justified and consistent with the NAS for the same reasons. If anything, it would be even more speculative to attempt to project changes to the circumstances of the intrusion at time frames potentially out to 1 million years. Furthermore, in keeping with the purpose of the human-intrusion analysis as a test of repository resilience, it is appropriate to continue to exclude unlikely natural events and processes from the analysis.

The intrusion scenario requires consideration of package degradation, premised on the assumption that drillers encountering an intact package would cease drilling and releases would be avoided. We believe that this assumption is equally valid both within and beyond a 10,000-year time frame. In our 2001 rule, DOE would not have been required to demonstrate compliance with a dose limit if packages were determined not to degrade sufficiently within 10,000 years to permit intrusion (or, in any event, if the consequences of the intrusion were not calculated to occur within 10,000 years). We are proposing to modify our rule to require that DOE show compliance with a dose limit regardless of when the consequences of the intrusion occur. Consistent with the proposed revised individual-protection standard, DOE will have to show compliance with a peak dose standard beyond 10,000 years, in addition to a 150 μSv/yr (15 mrem/yr) standard applicable up to 10,000 years. The dose standard that applies to exposures to the RMEI through the period of geologic stability will be the same as for the individual-protection standard (*see* Section II.C.3, ''What Dose Level is EPA Proposing for Peak Dose?''). Overall, this scenario continues to represent a reasonable test that ''can provide useful insight into the degree to which the ability of a repository to protect public health would be degraded by intrusion'' (NAS Report p. 108). We are not soliciting, and will not consider, comments on the overall intrusion scenario or other aspects of the human-intrusion standard that are not proposed to be changed.

3. Ground-Water Protection Standards

The Court's decision does not affect the ground-water protection standards. The Court upheld our statutory reading of the EnPA as providing the authority to establish such standards as the Agency deemed necessary to supplement the individual-protection standard, as well as the scientific basis of those standards. (*See NEI*, 373 F.3d at 43–48, Docket No. OAR–2005–0083–0080.) The Court further concluded that our reasoning for including such a standard as a means to protect the ground-water resource was sound and consistent with the Agency's overall pollution prevention policies. Regarding consistency with the NAS recommendations, the Court stated that:

> Although we concluded earlier in this opinion that EPA violated section 801's ''based upon and consistent with'' requirement by adopting a 10,000-year compliance period, we reach the opposite conclusion here because NAS treated the compliance-period and ground-water issues quite differently. Whereas NAS expressly rejected a 10,000-year compliance period, it said nothing at all about the need to add a separate ground-water standard * * * Put another way, NAS made no ''finding'' or ''recommendation'' that EPA's regulation could fail to be ''based upon and consistent with.''

NEI, 373 F.3d at 46–47.

As a result, we do not believe the Court's ruling regarding the 10,000-year compliance period applies to the ground-water protection standards, which have the same compliance period. Further, unlike the individual-protection and human-intrusion standards, we never envisioned that DOE would project its compliance with the ground-water protection standards beyond 10,000 years, even for inclusion in the EIS. The Court decision leaves EPA with discretion in formulating the provisions for ground-water standards. We believe (and the Court agreed) that the application over 10,000 years of limits equivalent to MCLs is a conservative but reasonable regulatory scheme that represents sound pollution prevention policy. Furthermore, protection of public health from releases to ground water over times beyond 10,000 years will be provided by extending the individual-protection standard to the time of peak dose, which accounts for transport and exposure through all pathways. For these reasons, we are not proposing to modify the ground-water protection standards, either by extending the period of compliance or in any other respect. We are not requesting, and will not consider, comments regarding any aspect of the ground-water protection standards.

4. Reasonable Expectation

''Reasonable expectation'' is the compliance concept underlying our disposal standards. That is, we require that DOE show a ''reasonable expectation'' that the standards will be met. As discussed extensively in our 2001 Yucca Mountain rulemaking, ''proof'' of disposal system performance in the traditional sense of the word cannot be attained for periods extending into the thousands or hundreds of thousands of years (66 FR 32101–32103, June 13, 2001, Docket No. OAR–2005–0083–0042). In such situations, it is a natural tendency to give greater emphasis to aspects that may not be the most likely to occur, but have the potential to significantly affect performance. This may be particularly true in areas where physical data are limited. However, assessments that are built around conservative assumptions at every decision point may in fact result in highly unrealistic performance projections. Simplifications and assumptions are involved out of necessity because of the complexity and time frames involved, and the choices made will determine the extent to which modeling simulations realistically simulate the disposal system's performance. If choices are made that make the simulations very unrealistic, the confidence that can be placed on modeling results is very limited. The uncertainties involved with these simplifications must be recognized. Overly conservative assumptions made in developing performance scenarios can bias the analyses in the direction of unrealistically extreme situations, which in reality may be highly improbable, and can deflect attention from questions critical to developing an adequate understanding of the expected features, events, and processes. ''Reasonable expectation'' encourages the use of ''cautious, but reasonable'' assumptions and discourages the reliance on highly conservative assumptions. It recognizes that projections of disposal system performance over very long times are best viewed as indicators of performance, rather than as firm predictions. It further requires the applicant and regulator to focus on the full range of outcomes and not to give greater weight to certain projections simply because they are more conservative.

The concept of ''reasonable expectation'' was a guiding principle in the formulation of our 2001 standards. We believe the concept is equally applicable for periods well beyond 10,000 years, and is in fact more important for very long time periods. In our view, it is ''reasonable'' to consider approaches for uncertainties in calculations at several hundred thousand years that may differ from the approach for uncertainties considered within 10,000 years after disposal. An approach applying standards ''acceptable today for the period of geologic stability would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard'' (66 FR 32098, June 13, 2001, Docket No. OAR–2005–0083–0042). We therefore emphasize the primacy of ''reasonable expectation'' in compliance with 40 CFR part 197 and retain it without change. However, we have considered how DOE and NRC might need to approach the concept to account for the much greater overall uncertainty in projections over periods as long as 1 million years. Section II.B describes the overall concept of ''reasonable expectation'' and our thoughts for today's proposal in more detail.

5. Effects of Uncertainty

We believe that the most problematic aspect of extending the compliance period to peak dose is the uncertainty involved in making projections over such long time frames, which we discussed in some detail in our proposed and final rulemakings in 1999 and 2001, respectively. This remains a critical factor in formulating today's proposal, which we feel must be emphasized and explored in detail. Although we refer generally to ''uncertainties'' throughout this document, it may not always be clear to readers exactly what we mean by this term, why their effects are difficult to manage, and why they should have an impact on the decision-making process. It may be useful to consider an analogous situation that will be readily familiar, such as the tracking of hurricanes.

The strength and path of hurricanes are functions of factors such as temperature, humidity, barometric pressure, and wind speed. There is natural variation in these parameters, and their variation can make the difference between a Category 5 storm (the most severe) striking a populated coastal area and a tropical storm that remains out in the ocean. When one views the projected path of a storm, the surrounding envelope of possible paths expands as one looks into the future and may spread over several hundred miles. The critical task in tracking the storm is identifying which populated areas are in the path of the storm, and whether they must be evacuated.

By this analogy, a 10,000-year dose projection might be comparable to selecting a single town to evacuate when the storm is still two hundred miles from landfall, while a peak dose projection might be more like pinpointing the correct location when a tropical depression first forms thousands of miles away, which may be weeks earlier. Regardless of the level of rigor that can be applied to the technical calculation, it is simply not possible to place the same level of confidence in the two selections. We see similar difficulties in ''predicting'' the ''true'' behavior of the Yucca Mountain disposal system, or the multiple engineered and natural components of that system, for periods on the order of hundreds of thousands of years.

We are aware that some stakeholders dispute our position that uncertainties increase significantly with time, and therefore believe that uncertainty offers little justification for placing less confidence in very long-term projections than can be placed in those that apply over the relatively near term. Some stakeholders, for example, suggest that uncertainty should have little impact on peak dose projections and that DOE should be required to identify where uncertainty, rather than reasonably expected performance, influences dose projections (Docket No. OAR–2005–0083–0029 and 0033). They have pointed to statements in the NAS Report to bolster this position, such as: ''analyses that are uncertain at one time might not be so uncertain at a later time; for example, the uncertainties about cumulative releases to the biosphere that depend on the rate of failure of the waste packages are large in the near term but are smaller later, when enough time has passed that all of the packages will have failed'' (NAS Report pp. 29–30); ''Because there is a continuing increase in uncertainty about most of the parameters describing the repository system farther in the distant future, it might be expected that compliance of the repository in the near term could be assessed with more confidence. This is not necessarily true'' (NAS Report p. 72); ''Detailed estimates of time for canister failure are less important for much longer-term estimates of individual dose or risk'' (NAS Report p. 85).

Although NAS pointed out that uncertainties associated with some disposal system components will decrease over time (*e.g.*, at some time all waste packages will be degraded), our view, and the view of many others (including NAS, as should be clear from the above citation: ''Because there is a continuing increase in uncertainty * * *''), is that uncertainties generally increase with time, at least to the time of peak dose. (*See*, for example, IAEA Draft Safety Requirements DS154, ''Geological Disposal of Radioactive Waste,'' Section A.7, page 37, April 2005 (Docket No. OAR–2005–0083–

0051), which states, ''It is recognized that radiation doses to people in the future can only be estimated and the uncertainties associated with these estimates will increase farther into the future''; the Nuclear Energy Agency report on ''The Handling of Timescales in Assessing Post-Closure Safety,'' pp. 13–14 (Docket No. OAR–2005–0083–0046), which states, ''These events and changes are subject to uncertainties, which generally increase with time and must be taken into account in safety assessments. Eventually, but at very different times for different parts of the system, uncertainties are so large that predictions regarding the evolution of the repository and its environment cannot meaningfully be made''; and the Swiss National Cooperative for the Disposal of Radioactive Waste (Nagra), which states, in Technical Report 02–05 (pp. 27–28) (Docket No. OAR–2005–0083–0075), ''HSK–R–21 [Swiss disposal regulation] acknowledges that there is inevitable uncertainty in model calculations and the further into the future predictions are made, the greater the uncertainty. The implementer has to show what processes and events could affect the repository over the course of time and then to derive and evaluate potential evolution scenarios from these.'') For some aspects of the system, such uncertainties can increase dramatically (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Section 12.3, July 2005, Docket No. OAR–2005–0083–0085). To repeat, we are in agreement with NAS that such projections can be performed and even ''bounded'' to some extent. However, the central question here is how the results of very long-term assessments can have sufficient meaning to provide an adequate basis for a licensing decision that the repository should or should not be approved.

NAS demonstrated some concern with this issue by recognizing that the level of confidence that could be placed in projections was of key importance, and offered constructive guidance in limiting or considering the effects of uncertainties. Unfortunately, the NAS statements on decreasing uncertainty regarding some disposal system components do not draw a clear relationship to the time of peak dose at which it recommended compliance be measured. While we generally agree with these statements, we find that they are most relevant to times after peak dose and, therefore, after the time frame most important from a regulatory perspective. Returning to our hurricane analogy, it is true that uncertainties eventually decrease; one might be able to predict with equal confidence both the storm's location in two hours and that in two weeks it will have completely dissipated. In this sense, one can agree with the NAS's conclusion that ''it is not necessarily true'' that long-term projections are more uncertain than near-term projections. Nevertheless, relatively high confidence about the endpoint of the hurricane has little impact on the ability to predict where and when it might cause the greatest damage along its path. Similarly, for Yucca Mountain, increasing confidence in certain aspects of the system's components (*e.g.*, the endpoint of the waste packages, much like the endpoint of the hurricane) does not necessarily inform estimates of peak dose.

NAS notes that ''uncertainties about cumulative releases'' that ''depend on the rate of failure of the waste packages'' will be lessened at far future times when ''all of the packages will have failed'' (NAS Report p. 28–29). The emphasis here on eventual failure cannot help us when the direction is to assess peak dose. It is self-evident and non-controversial that the engineered barrier system cannot be expected to last forever. However, assumptions regarding ''the rate of failure of waste packages'' are exactly the critical element in estimating the timing and magnitude of the peak dose (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Sections 12.3 and 12.4, July 2005, Docket No. OAR–2005–0083–0085). Thus, identifying factors that would decrease overall system uncertainty at times approaching 1 million years does not adequately support a conclusion that uncertainties can be equally well managed at the time of peak dose, even if that time is much less than 1 million years.

In addressing this larger question of how to consider long-term projections in a regulatory process, we have considered guidance and precedents from international programs. NAS provided important scientific and technical reasoning for evaluating compliance at peak dose, which we augment with guidance from sources who approached the problem of uncertainty from the regulatory perspective. For regulatory compliance over 10,000 years, we were able to identify several (albeit limited) analogous regulatory programs in the U.S., including those for the WIPP and EPA's underground injection control program (see the preamble to the 2001 rulemaking, 66 FR 32098, Docket No. OAR–2005–0083–0042). For time frames extending potentially to 1 million years, there are no precedents in U.S. regulation. In response to the Court decision, therefore, important sources for guidance and models for contemplating regulations at such long times were other international programs grappling with the same issues, namely disposal of highly radioactive and long-lived waste. Throughout this document, we quote extensively from a number of international sources, from both multinational organizations (such as IAEA) and individual countries (such as Sweden). We do this because we find ourselves in a situation that is, if not unique, shared by a rather small circle. We have found it useful to consult the ideas of those faced with a similar situation. In general, they reinforce two points we emphasize throughout this document. The first, which we have already discussed, is that uncertainties generally increase with time. The second point is that projections at those longer times cannot be viewed with the same level of confidence as shorter-term projections, and may in fact be viewed as more qualitative indicators of disposal system performance.

For example, the IAEA has stated that, for periods lasting from about 10,000 to 1 million years, ''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 modelling * * * Such calculations can therefore only be viewed as illustrative and the 'doses' as indicative'' (IAEA–TECDOC–767, ''Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories,'' p. 19, 1994, Docket No. OAR–2005–0083–0044). Also, ''[t]he utility of individual numerical indicators will vary greatly and, given the large uncertainties, considerable caution is needed to avoid any suggestion or expectation that any given indicator of disposal system performance can be an accurate estimate of future reality. Such an indicator typically provides only an estimate of what might happen under certain assumed conditions * * * The aim of the assessment is not to predict the actual performance of the disposal system * * * but rather to reach reasonable assurance that it will provide an adequate level of safety'' (IAEA–TECDOC–975, ''Regulatory Decision Making in the Presence of Uncertainty in the Context of the Disposal of Long Lived Radioactive Wastes,'' pp. 22, 24, 1997, Docket No. OAR–2005–0083–0045). Finally, ''[c]are has to be exercised in applying the criteria for periods beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making'' (IAEA Draft Safety Requirements DS154, ''Geological Disposal of Radioactive Waste,'' Section A.7, p. 37, April 2005, Docket No. OAR–2005–0083–0051).

The Nuclear Energy Agency (NEA) states that ''[t]here is an increasing consensus among both implementers and regulators that, in carrying out safety assessments, calculations of dose and risk should not be extended to times beyond those for which the assumptions underlying the models and data can be justified * * * Eventually, but at very different times for different parts of the system, uncertainties are so large that predictions regarding the evolution of the repository and its environment cannot meaningfully be made'' (''The Handling of Timescales in Assessing Post-Closure Safety,'' pp. 10, 13, 2004, Docket No. OAR–2005–0083–0046). Similarly, the Swedish Radiation Protection Authority (SSI) has proposed draft guidance for the disposal of SNF, stating that ''[f]or very long periods * * * [t]he intention should be to shed light on the protective capability of the repository and to provide a qualitative picture of the risks'' (p. 7, Docket No. OAR–2005–0083–0048). This draft guidance is intended to supplement SSI's standards (SSI FS 1998:1, September 28, 1998, Docket No. OAR–2005–0083–0047), which require that ''[f]or the first thousand years after disposal, the assessment of the repository's protective capability shall be based on quantitative analyses of the impact on human health and the environment'' (§ 11), but do not specify quantitative analyses as the basis for longer-term assessments (''shall be based on various possible sequences for the development of the repository's properties, its environment and the biosphere,'' § 12).

We acknowledge that detailing the effects of uncertainty is itself uncertain. We recognize that knowledge is not absolute up to 10,000 years, with uncertainties burgeoning shortly beyond that time. We also recognize that there can be considerable uncertainty in measurements of current conditions. Further, we concur with NAS that uncertainties can be qualitatively different for different aspects of the assessment. For example, NAS points out that human behavior can be projected for a few decades at most, while the geologic record can be studied for evidence of processes that have occurred over millions of years (and are still occurring today). However, the assessment of Yucca Mountain's performance depends not only on the ability to project large-scale geologic processes, such as seismicity and volcanism, but also the gradual evolution of complex saturated and unsaturated zone characteristics, such as the chemistry of infiltrating water or the direction and connectivity of a fracture-flow system.

B. How Does the Application of ''Reasonable Expectation'' Influence Today's Proposal?

Under today's proposal, projecting disposal system performance involves the extrapolation of physical conditions and the interaction of natural processes with the wastes for unprecedented time frames in human experience, *i.e.*, possibly hundreds of thousands of years. In this sense, the projections of the disposal system's long-term performance cannot be confirmed. Not only is the projected performance of the disposal system not subject to confirmation, the natural conditions in and around the repository site will vary over time and these changes are also not subject to confirmation, making their use in performance assessments equally problematic over the long-term. In light of these fundamental limitations on assessing the disposal system's long-term performance, we believe that the approach used to evaluate disposal system performance must take into account the fundamental limitations involved and not hold out the prospect of a greater degree of ''proof'' than in reality can be obtained.

There are several fundamental components to be established in setting up and analyzing disposal system performance scenarios. A model must be created that translates the physical processes operating at the site into mathematical statements, such as ground-water flow equations, that can calculate the movement of radionuclides through the various components of the disposal system and into the accessible environment. A model may be very generic or highly sophisticated and tailored to capture distinct aspects of a particular site. Two additional steps are necessary in order to develop dose projections. First, the possible performance scenarios themselves and associated assumptions must be established, and second, the distribution of expected values for the parameters involved in the performance calculations must be determined. The scenarios are developed from an understanding of the natural processes, the engineered barrier design, and the interactions of the engineered barrier system with the repository environment. The range of expected parameter values for the analyses is based upon the results of site characterization studies, laboratory testing, and expert judgment. For both of these components, unrealistic and perhaps extreme choices can be made that would, in effect, give false expectations of disposal system performance, or hide important uncertainties that would, in reality, have important consequences on the performance projections (the model itself may also have conservatisms built into it, which may be even more difficult to identify). If extreme assumptions are made in defining the scenario, a de facto ''worst-case'' scenario is developed at the outset and analyses using the upper end of the range of parameter values result in performance projections that are in fact extreme cases, rather than representing the full range of expected performance. Effectively, such a restrictive approach results in emphasis on what would be the conservative extremes of the probability distributions for the performance assessments and analyses rather than if a realistic approach were taken. In such a case, the regulatory judgment would be focusing on extreme situations, rather than on evaluating safety under reasonably expected conditions. On the other hand, if the scenario were defined more realistically and the same distribution of parameter values used, the resultant distribution of doses would be closer to the actual expected performance and regulatory decisions could be made with confidence that the assessments represent a more realistic range of expected performance. Including multiple ''worst-case'' assumptions in setting up the performance scenarios, combined with selecting conservative values for site-related parameter distributions, actually corresponds to assessing very low-probability/high-consequence scenarios that can then easily be mistaken as expected-case analyses. Under the reasonable expectation approach, expected case as compared to conservative and worst-case assessments are more explicitly identified and the uncertainties presented more directly so that the reasoning behind regulatory decisions can be more easily understood and defended. We note that this approach was also recommended by a joint NEA–IAEA peer review of DOE's TSPA to support its site recommendation, which states in Section 4.1.3 (''Realism or conservatism''):

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

''An International Peer Review of the Yucca Mountain Project TSPA–SR,'' pp. 54–55, 2002, Docket No. OAR–2005–0083–0062, emphasis in original.

In making its decisions, the primary task for NRC is to examine the projections put forward by DOE to determine ''how much is enough'' in terms of the information and analyses presented, *i.e.*, how NRC determines when the analyses provide an acceptable level of confidence and the results can be interpreted in a way meaningful for regulatory compliance. In 40 CFR part 197 as originally promulgated, we did not have specific measures in our standards on how to make that judgment. NRC, as the implementing agency, must be satisfied with DOE's presentation; therefore, we concluded those specific measures of satisfaction were appropriate for NRC to determine. Neither did EPA specify: (1) Confidence measures for such judgments or numerical analyses; (2) analytical methods that must be used for performance assessments; (3) quality assurance measures that must be applied; (4) statistical measures that define the number or complexity of analyses that should be performed; or (5) any assurance measures in addition to the numerical limits in the standards. We specified only that the mean of the dose assessments must meet the exposure limit.

We anticipate that if these very long-range performance projections (beyond 10,000 years) indicate that repository performance would degrade dramatically under a wide range of conditions at some point in time, that this would become a concern in the licensing decision. If such a dramatic deterioration were projected to occur close to the regulatory time period it would be a more pressing concern for licensing decisions than if it were to occur many hundreds of thousands of years into the future (remembering that the uncertainty in performance projections increases with time). With the initial issuance of 40 CFR part 197, EPA elected to leave the handling of the very long-term projections of performance as an implementation decision for the regulatory authority, but to impose the requirement that such analyses be performed and reported in the EIS. The degree of ''weight'' that should be given to these very long-term assessments, we said, is an implementation decision that should be left to NRC to determine, by balancing the projected performance and the inherent uncertainties in these projections against the projected dose levels (2001 Response to Comments, p. 7–13, Docket No. OAR–2005–0083–0043).

We propose to continue this general approach of not specifying the bases or mechanisms for a compliance decision, except that the post-10,000-year analyses are now proposed to be part of the 40 CFR part 197 standards with a quantitative limit imposed.

As noted earlier, the conceptual framework of ''reasonable expectation'' as promulgated in our 2001 rulemaking is applicable even when extending the compliance period to peak dose. In fact, we believe it becomes even more important as the level of confidence that can be placed in numerical projections decreases over time. However, we are not proposing to expand or modify the definition in § 197.14 to account for the greater uncertainty between 10,000 years and the time of peak dose (within 1 million years of disposal). The existing definition describes principles that are applicable for both shorter and very long time frames (although the implications of these principles may be different, depending on the time frame). To provide insight into our interpretation of reasonable expectation at very long times, we provide additional information in the remainder of this section and throughout our discussion of the proposed changes for NRC to consider as it implements our peak dose standard. We believe such guidance will be useful, particularly in the context of handling long-term FEPs, as discussed in Section II.D of this document.

We emphasize that parameters and scenarios should be included in the performance assessment even if they are not among the more highly conservative approaches. There is a tendency in long-term assessment to introduce conservatisms and to focus on the higher-end dose projections, while discounting lower dose projections that may actually be just as probable or perhaps represent higher-probability scenarios. We stress that DOE should work to ensure that the results express the full range of possible outcomes within the bounds of credible scenarios and parameter values. Less conservative scenarios (*i.e.*, lower projected doses) should not be eliminated unless they are deemed to be highly improbable. Of course, the compliance measure will be expressed as a specific statistical measure of the results, not the entire range of results. The entire range of results is context to be used to assist the licensing authority in judging the likelihood of the facility to meet the standards. In that context, the results of the performance assessments are not to be biased by an overemphasis on low-probability scenarios at the expense of results for the entire spectrum of reasonably credible and supportable scenarios and parameter values. Our position is that the reasonable expectation approach accounts for the inherent uncertainties involved in projecting disposal system performance by taking into account a large spectrum of possible parameter values rather than making assumptions that reflect only conservative to very conservative values. We also emphasize that the uncertainties in site characteristics over long time frames, and how the long-term projections of expected performance of the disposal system were made, need to be well understood before regulatory decisions are made. We stress again the purpose of the assessments as expressed by IAEA: ''The aim of the assessment is not to predict the actual performance of the disposal system * * * but rather to reach reasonable assurance that it will provide an adequate level of safety'' (IAEA–TECDOC–975, p. 24, Docket No. OAR–2005–0083–0045). NAS agrees that ''[t]he results of compliance analysis should not, however, be interpreted as accurate predictions of the expected behavior of a geologic repository'' (NAS Report p. 71, Docket No. OAR–2005–0083–0076).

In Section II.D of this document (''How Will Today's Proposal Affect the Way DOE Conducts Performance Assessments?''), we propose to limit speculation over the long compliance period now being addressed by requiring compliance within a performance assessment that continues to emphasize the most significant features, events, and processes. The purpose is to provide a reasonable test of performance over a range of conditions. To do so, we propose to eliminate very unlikely features, events, and processes, and the scenarios including them, from consideration and specify this in the standards. We believe this is consistent with a finding of the NAS: ''It is always possible to conceive of some circumstance that, however unlikely it may be, will result in someone at some time being exposed to an unacceptable radiation dose * * * The challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events'' (NAS Report pp. 27–28). We have chosen to do this by continuing to place reasonable constraints on the scenarios that need to be examined. We believe this is consistent with another finding of the NAS: ''We conclude that the probabilities and consequences of modifications generated by climate change, seismic activity, and volcanic eruptions at Yucca Mountain are sufficiently boundable so that these factors can be included in performance assessments that extend over periods on the order of about 10^6 years'' (NAS Report p. 91). Typically, as we discuss elsewhere in this document, the term ''boundable'' implies a ''worst case'' approach (*i.e.*, a ''bounding analysis'') to assessing the limits of disposal system performance. We do not believe such an approach is appropriate and are not proposing to adopt it. Instead, in this context, we interpret ''boundable'' as referring to limits that may be placed on the scenarios so that they will represent a reasonable test of disposal system performance over the very long term, but not be driven by extreme assumptions or endless speculation. Thus, we view our treatment of these ''modifiers'' as comparable to our specification of a ''stylized'' scenario for human intrusion, and consistent with the NAS statement that ''[i]t is important that the 'rules' for the compliance assessment be established in advance of the licensing process'' (NAS Report p. 73).

In our 1999 preamble to proposed 40 CFR part 197, we said that if we were to regulate longer than 10,000 years, we would expect the licensing judgment to be less strict in relying on dose projections compared to 10,000 years (64 FR 46998, August 17, 1999, Docket No. OAR–2005–0083–0041): ''We note that if the compliance period for the individual-protection standard extended to the time of peak dose within the period of geologic stability (which NAS estimated to be 1 million years for the Yucca Mountain site), this [reasonable expectation] test would allow for decreasing confidence in the numerical results of the performance assessments as the compliance period increases beyond 10,000 years. For example, this means that the weight of evidence necessary, based upon reasonable expectation, for a compliance period of 10,000 years would be greater than that required for a compliance period of hundreds of thousands of years.'' Given the increased uncertainty that is unavoidable in the capabilities of science and technology to project and affect outcomes over the next 1 million years, the concept of reasonable expectation underlying our standards implies that a dose limit for that very long period that is higher than the 15 mrem/yr limit that applies in the relatively ''certain'' pre-10,000-year compliance period could still provide a comparable judgment of overall safety. See Section II.C.3 (''What Dose Level is EPA Proposing for Peak Dose?'') for a specific discussion of the dose limit in today's proposal.

In formulating an approach to compliance out to the time of peak dose, we have established 10,000 years as an indicator for times when uncertainties in projecting performance are more manageable and for which comparisons can be made with other regulated systems. We realize that uncertainties exist within the initial 10,000-year period and that 10,000 years does not represent a strict dividing point between periods over which projections can be made with certainty or not. Clearly, we believe that calculations beyond 10,000 years have value, or we would not have previously required DOE to include them in its EIS. However, we also believe that over the very long periods leading up to the time of the peak dose, the uncertainties in projecting climatic and geologic conditions become extremely difficult to reliably predict and a technical consensus about their effects on projected performance in a licensing process would be very difficult, or perhaps impossible, to achieve. This is one of the major reasons that the 10,000-year time frame was originally selected in the generic standard for land disposal of the types of waste intended for the Yucca Mountain repository (40 CFR part 191) (2001 Response to Comments, p. 7–17, Docket No. OAR–2005–0083–0043). In such a situation, one might conclude that little or no weight should be given to highly uncertain projections as a basis for a licensing decision. Conversely, others might conclude that the inability to produce highly reliable performance estimates should preclude the possibility of licensing at all. Such a conclusion would be inconsistent with any concept of permanent disposal, which necessarily requires examination of time frames and events that cannot be predicted with certainty. We believe that the performance projections at Yucca Mountain, if constructed and interpreted consistent with the concept of ''reasonable expectation,'' can provide useful information on the facility's performance and can form a key part of the basis for a licensing decision. Clearly NAS agreed, since it recognized that significant uncertainties exist, yet nonetheless recommended that projections to peak dose form the basis for EPA's standards to be used in judging compliance for licensing the Yucca Mountain disposal system. NAS further recognized that an approach akin to reasonable expectation is warranted: ''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 p. 71).

C. How Is EPA Proposing To Revise the Individual-Protection Standard (§ 197.20) To Address Peak Dose?

In considering how to revise the individual-protection standard, we have sought an approach that would be:

- Responsive to the Court ruling;
- Protective of public health and safety;
- Reflective of the best science and cognizant of the limits of long-term projections;
- Implementable by NRC in its licensing process; and
- Limited in scope and focused on aspects critical to accomplishing the above goals.

In balancing these goals, we have carefully examined the NAS recommendations and looked more broadly to international models and guidance on long-term radioactive waste disposal. We believe today's proposal satisfies these goals. We believe the first three are straightforward and our reasoning outlined in the next sections will clearly show how they influenced our proposal. The fourth point relates to an essential purpose of our action that can sometimes be overshadowed by emphasis on the NAS recommendations and the Court ruling. As NAS stated, ''standards are only useful if it is possible to make meaningful assessments of future repository performance with which the standards can be compared'' (NAS Report p. 34). Ultimately, NRC must be able to use our standards to judge whether DOE has provided sufficient evidence that the disposal system will be protective of public health and safety. While there are significant scientific aspects to this decision, regulatory judgment must bridge the gap between what science can show and the unprecedented time frames involved. The licensing process must consider the confidence that can be placed in performance assessments used to represent disposal system evolution and the information necessary to make a decision. Our ''reasonable expectation'' standard is critical to making this judgment.

The last point above refers to the legal status of our rule. Today's proposal is specifically targeted toward addressing the Court ruling regarding the compliance period. Many other aspects of our rule were either upheld by the Court or not challenged. As discussed in Section II.A, we are not revisiting those issues.

In a similar vein, when considering potential approaches to address the Court's decision, we did not feel constrained by our actions in the 2001 rulemaking. Nor do we believe that rejecting certain approaches in that rulemaking creates a legal barrier to incorporating them into today's proposal. Our preferred approach was rejected by the Court in favor of a compliance standard applicable at the time of peak dose, whenever it might occur within the period of geologic stability. In our 2001 rulemaking, we considered, discussed, and accepted comment on the length of the compliance period, including consideration of the time of peak dose. We ultimately chose not to establish a compliance period applicable throughout the period of geologic stability. Thus, it is difficult to see how we could satisfy the Court's ruling if we were not permitted to reconsider or revise our previous conclusions.

1. Multiple Dose Standards Applicable to Different Compliance Periods

In balancing the considerations described above, the central problem is to determine what is achievable in terms of the reliability of dose projections. Our task was clearly presented by the Court, and our starting position is to fulfill that task by proposing a compliance standard at the time of peak dose, whenever it might occur within the period of geologic stability. We have discussed at length our concerns regarding the quality of very long-term projections and their application in a licensing process; even in light of the Court decision, those concerns remain. However, we also believe it is clear that shorter-term projections do have sufficient reliability to serve as the basis for regulatory decision-making. On the one hand, we do not want to place more regulatory emphasis on peak dose projections than can be justified; on the other, a standard effective at relatively short times, where we believe such emphasis is warranted, is unlikely on its own to be responsive to the Court ruling. We have sought to reconcile these two extremes in order to satisfy all of the goals outlined earlier.

In what we see as the best solution to this difficulty, today we are proposing that the individual-protection standard consist of two parts, which will apply over different time frames. One part of the standard, which will apply over the initial 10,000 years after disposal, consists of the 15 mrem/yr individual-protection standard promulgated in 2001 as 40 CFR 197.20. The other part other part of the standard, which is being proposed today, will apply beyond 10,000 years to the time of peak dose up to a limit of 1 million years. We believe this approach appropriately recognizes the relative manageability of uncertainties at such disparate times, and the resulting level of confidence that can be derived from performance projections.

There is no disagreement internationally that quantitative projections are the most direct means of evaluating disposal system performance, or that comparison of such projections with an acceptable level of performance is a straightforward and transparent method of assessing disposal system safety. However, there is also a general consensus that reliance on quantitative projections to determine safety may be misleading and incomplete, becoming more so at times very far into the future. IAEA notes that ''[q]uantitative analysis is undertaken, at least over the time period for which regulatory compliance is required, but the results from detailed models of safety assessment are likely to be more uncertain for time periods in the far future'' (DS154, Section 3.48, p. 25, Docket No. OAR–2005–0083–0051). Also, ''an indication that calculated doses could exceed the dose constraint, in some unlikely circumstances, need not necessarily result in the rejection of a safety case * * * In general, when irreducible uncertainties make the results of calculations for the safety assessment less reliable, then comparisons with dose or risk constraints have to be treated with caution'' (DS154, Sections A.7, A.8, pp. 36–37, Docket No. OAR–2005–0083–0051). As suggested by the discussion of reasonable expectation in Section II.A.4, at longer time periods, the quantitative projections should be considered less for their strict numerical outcomes and more as one component in a qualitative evaluation of the overall safety case.

In their book ''Principles and Standards for the Disposal of Long-Lived Radioactive Wastes'' (2003, Docket No. OAR–2005–0083–0061), Chapman and McCombie state that ''[a]n approach commonly used is to calculate releases, doses or risks out to peak consequences—but to use different approaches to judging acceptability in different time frames. At far future times (>10 ka) [>10,000 years] * * * calculated doses may then be more appropriately compared with less stringent limits than the typical limits at shorter times'' (p. 79). They also present the concept of ''time-graded containment objectives'' in which the first 1,000 years or so is characterized by ''total containment of all activity in the repository.'' For the ''next one (or a few) hundred thousand years * * * doses * * * are below the range of natural background radiation.'' Finally, ''after this time * * * there is no further containment objective: doses may be envisaged in the range of those from natural background radiation.'' (p. 114)

Different countries have approached this situation in various ways, and many national regulations are still evolving. For example, as summarized by Chapman and McCombie in Table 5.1 (Docket No. OAR–2005–0083–0061): Canada at one time limited quantitative compliance to 10,000 years, to be followed by qualitative evaluation, with special attention to the rate of increase in projected risk; Germany takes a similar approach in official guidance, but does not specify a time frame in regulation; France requires quantitative compliance for 100,000 years, with the situation becoming ''hypothetical'' afterward; Switzerland requires numerical compliance at all times. The Swedish draft guidance referred to in Section II.A.5 states that ''[f]or long periods of time, thousands of years and even longer, the risk analysis should be successively regarded as an illustration of the protective capability of the repository assuming certain conditions'' (p. 7, Docket No. OAR–2005–0083–0048). We believe the approach proposed today, outlined in the paragraphs below, is consistent with that trend.

First, we are retaining the standard promulgated in 2001 as § 197.20, which requires that DOE demonstrate a reasonable expectation that the RMEI will not incur annual exposures greater than 150 μSv (15 mrem) (expressed as a committed effective dose equivalent) from releases of radionuclides from the Yucca Mountain disposal system for 10,000 years after disposal. DOE will make this demonstration using the arithmetic mean of performance assessment results (see Section II.C.5, ''How Will NRC Judge Compliance?'' for further discussion of the mean). We believe this is appropriate, protective, and will maintain consistency with our generic standards (now applied to the WIPP) and other precedents described earlier. Further, NAS stated that the ''range [of 10^{-5} to 10^{-6} per year for risk] could therefore be used as a reasonable *starting point* for EPA's rulemaking'' (NAS Report p. 49, emphasis in original). By maintaining the 15 mrem/yr standard for 10,000 years we clearly establish a ''starting point'' for assessing compliance that is consistent with both NAS and our overall risk management policies, and serves as a logical foundation for us to incorporate concerns regarding far future projections.

Because of the emphasis on peak dose as the key benchmark of safety in both the NAS Report and the Court decision, some commenters may question not only the need for a standard at such relatively short times, but also whether it is legally permissible, given the Court's decision. We believe there is ample justification for a separate 10,000-year standard on both counts. Taking the legal questions first, there was no legal challenge and the Court made no ruling on the protectiveness of our standard up to 10,000 years. Further, the Court ruled that we must address peak dose, but did not state, and we do not believe intended, that we could not have additional measures to bolster the overall protectiveness of the standard. As the Court noted, the EnPA requires that EPA ''establish a set of health and safety standards, at least one of which must include an EDE-based, individual protection standard'' (*NEI*, 373 F.3d at 45, Docket No. OAR–2005–0083–0080), but does not restrict us from issuing additional standards. Thus, as long as we issue ''at least one'' standard addressing the NAS recommendation regarding peak dose, we are not precluded from issuing other, complementary, standards to apply for a different compliance period. The Court's concern was whether we had been inconsistent with the NAS recommendation by not extending the period of compliance to times longer than 10,000 years. NAS itself did not address the idea of having separate standards to apply over different time periods. We believe such a decision falls well within our policy discretion and in that context the 10,000-year standard is analogous to our ground-water protection standards.

An important reason for retaining a standard applicable for the first 10,000 years is to address the possibility, however unlikely, that significant doses could occur within 10,000 years, even if the peak dose occurs significantly later, as DOE currently projects.

Examination of DOE's Total System Performance Assessments (TSPA) for the site shows that the time of peak dose occurs in the hundreds of thousands of years (FEIS, DOE/EIS–0250, Appendix I, Section 5.3, February 2002, Docket No. OAR–2005–0083–0086). The waste packages assessed in the TSPA are heavily engineered to provide corrosion resistance under the conditions expected in the repository, and are projected to remain essentially unbreached for periods well beyond 10,000 years. The scientific data that underlie these corrosion resistance projections are laboratory tests on the metals, under conditions intended to stress the metals and simulate their performance in the repository. These testing methods are typical ''state-of-the-art'' techniques for corrosion testing. However, it must be recognized that the extrapolation of laboratory test results in a predictive sense involves significant uncertainties, and our experience in verifying such projections is only for time frames of decades in the case of industrial applications (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Section 5, July 2005, Docket No. OAR–2005–0083–0085). While DOE projects, based upon the results of laboratory testing, that the waste containers will maintain their integrity for thousands to tens of thousands of years, 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. Although we believe that significant doses within 10,000 years are highly unlikely, we also believe it important to structure our regulations to preclude the chance that protection at Yucca Mountain would be less than that provided for WIPP or the Greater Confinement Disposal facility (GCD, which is a group of 120-feet deep boreholes, located within NTS, which contain disposed transuranic wastes). It would be inappropriate to apply a standard designed to accommodate the uncertainties in projections many tens to hundreds of thousands of years into the future to projections within 10,000 years, when uncertainties are much more manageable. The 15 mrem/yr dose limit is the measure against which compliance would be judged during the initial 10,000-year period.

In today's action, we are proposing to add a standard of compliance that would apply at the time of peak dose, if DOE determines that the peak occurs at any time beyond 10,000 years but within 1 million years (as recommended by NAS). Specifically, in addition to retaining the 15 mrem/yr standard applicable up to 10,000 years, we are proposing to establish a separate numerical compliance standard against which the median of peak dose projections would be compared (see Section II.C.3 for a discussion of the proposed dose limit and Section II.C.5 for a discussion of the arithmetic mean and median). As discussed earlier, we recognize that there is strong consensus in the international radioactive waste community that dose projections extending for periods into the many tens to hundreds of thousands of years can best be viewed as qualitative indicators of disposal system performance, rather than as firm predictions that can be compared against strict numerical criteria. The primary concern, which we have also expressed, is managing the uncertainties that become more prominent at longer time frames.

Nevertheless, we believe that the best way to address the Court decision is to establish a numerical compliance standard for the time of peak dose so that a clear test for compliance decision-making can be applied to the results of quantitative performance assessments. What we are proposing is unprecedented in our national regulatory schemes, and we remain greatly concerned about the ability of the implementing agencies to manage the uncertainties in very long-term projections in order to make comparisons with a numerical standard meaningful. We discuss elsewhere in this document (see Sections II.B and II.D.2, for example) ways in which NRC and DOE might temper the effects of uncertainty in dose projections, e.g., through the selection of parameter distributions or scenarios.

Some readers may note that we rejected similar approaches offered in comments on our 1999 proposed rule. One commenter in particular suggested that the dose standard could be increased over time, i.e., 15 mrem/yr up to 10,000 years, 150 mrem/yr from 10,000 to 100,000 years, and 1.5 rem/yr from 100,000 to 1 million years (Docket A–95–12, Item IV–D–35). As stated in our Response to Comments document published in conjunction with the 2001 final rulemaking (p. 3–8, Docket No. OAR–2005–0083–0043), we considered that our approach accomplished the same goal as that offered by the commenter. While we did state that ''no regulatory body that we are aware of considers doses of 150 mrem to be acceptable,'' we also stated that ''the uncertainties involved in very long-term assessments would make it more difficult to judge compliance with any numerical standard,'' which we still believe is true. It is clear that we struggled to reconcile the competing claims of confidence in projections and intergenerational equity. We sought an approach that would account for what we see as potentially unmanageable uncertainties, but did not depart from levels of risk that are considered protective today. Nevertheless, the Court's decision puts us in the position of establishing a quantitative standard at the time of peak dose. It is necessary for us to re-evaluate potential approaches to doing so, including whether and under what conditions a higher dose standard can be justified. We discuss an approach similar to that offered by the commenter in Section II.C.2.c (''Peak Dose Standard Varying Over Time'').

We are not requesting comment on the 15 mrem/yr standard or its applicability for the initial 10,000-year period. The public record reflects an exhaustive level of comment and consideration on these points (see our 1999 proposed and 2001 final rulemakings, as well as Sections 3 and 4 of the 2001 Response to Comments Document (Docket Nos. OAR–2005–0083–0041, 0042, 0043, respectively). The Court did not question the scientific basis of the 15 mrem/yr dose standard, the protective nature of that limit, or its well-established precedents in regulation for periods as long as 10,000 years (including its implementation at WIPP and GCD), nor indeed were any of these aspects of the rule challenged. Further, as noted above, the Court did not rule that the 10,000-year compliance period had no value, only that it was not by itself consistent with the NAS recommendation (''We will thus vacate part 197 to the extent that it requires DOE to show compliance for only 10,000 years following disposal,'' NEI, 373 F.3d at 31, Docket No. OAR–2005–0083–0080).

We are requesting comment on the combination of the 15 mrem/yr standard with a separate standard applicable beyond 10,000 years through the period of geologic stability. We believe we have provided a rational basis for taking this approach and that it is consistent with the Court's position that we could have ''taken the Academy's recommendations into account and then tailored a standard that accommodated the agency's policy concerns.'' *NEI*, 373 F.3d at 26, Docket No. OAR–2005–0083–0080.

2. What Other Options Did EPA Consider?

We considered a number of other approaches to respond to the Court's decision, each of which had attractive qualities, as well as disadvantages. These disadvantages generally relate to the difficulty of implementation given the increasing complexity and uncertainty of much longer-term projections.

a. Maintain the 10,000-Year Standard Alone Without Addressing Peak Dose

The Court suggested that, ''[h]ad EPA begun with the NAS recommendation to base the compliance period on peak dosage and then made adjustments to accommodate policy considerations not considered by NAS,'' the 40 CFR part 197 standards issued in 2001 might have been accorded more deference. *NEI*, 373 F.3d at 31, Docket No. OAR–2005–0083–0080. However, it is not clear how EPA's earlier explanation of its policy concerns might be reconciled with NAS's technical recommendation. In view of this, we believe that the most direct and responsive action to address the Court ruling is to revise our standards to include consideration of the time when peak dose occurs. Therefore, although we are retaining the previous 10,000-year provisions as one component of our revised standards, we are also proposing an additional measure to address the time of peak exposure within the period of geologic stability beyond 10,000 years. We believe that this approach, coupled with the selection of the dose standard to apply at the time of peak dose (see Section II.C.3) and specification of certain aspects of DOE's performance assessment (see Section II.D), will adequately address our policy concerns.

b. Dose Standard To Apply at Peak Dose Alone

The second option we considered is simply to replace the 10,000-year standard with one that applies at the time of peak dose, whenever it might occur. This approach is attractive primarily because it would be straightforward in responding to the Court decision. Although we believe that 10,000 years has value as a precedent for safety assessments, and are retaining that element of the standards, it is not intrinsically significant as a demarcation point for addressing a peak dose standard beyond 10,000 years. A peak dose standard alone (i.e., not in conjunction with the 10,000-year standard we are retaining) would remove confusion on that point, but introduces additional difficulties, as described in the following sections.

As discussed in Section II.C.4.a, we do not believe it is reasonable or justifiable simply to extend the application of a 15 mrem/year dose limit over the entire period up to the time of peak dose. Rather, at the time of peak dose, which could potentially occur hundreds of thousands of years into the future, we believe rising uncertainties justify adopting a different (higher) dose level. However, as discussed in Section II.C.3, this approach, while more cognizant of the effect of uncertainties and the dangers of relying on specific numerical indicators at very long times, departs from our previous standards of protectiveness in the event that peak doses occur within relatively short time periods. Specifically, if peak doses occur within 10,000 years, we would be in the position of measuring safety against a dose level that we have explicitly rejected as not sufficiently protective over that time frame, both in our generic standards and in our earlier Yucca Mountain rulemaking. Further, there would be a clear contrast between the level of protection offered to the population in the vicinity of the WIPP and that offered the population affected by Yucca Mountain. We recognize that our insistence on maintaining a 15 mrem/yr standard over the initial 10,000 years might appear inconsistent with our proposal, which could allow peak doses shortly after 10,000 years at levels well above 15 mrem. However, as discussed previously, we believe NRC has the authority, as part of its licensing process, to consider the timing and magnitude of peak dose in assessing the safety of Yucca Mountain. Furthermore, we do not believe it is prudent to disregard the usefulness of a stringent 10,000-year measure simply because uncertainties at longer time frames make it infeasible to conduct a performance assessment with the same level of rigor. Our view on this point is discussed in Section II.A.1.

c. Peak Dose Standard Varying Over Time

We also considered a variation on our proposed approach, in which the post-10,000-year dose level would rise incrementally as time and the effects of uncertainty increase. This approach would provide greater continuity with the 10,000-year standard and a gradual transition as the role of uncertainty increases. The difficulty in this approach is identifying criteria to define the timing and level of these transitions, which would have to incorporate some appraisal and comparison of the effects of uncertainty at various times. Some of the advantages of this approach are also captured by the statistical approach discussed in Section II.C.2.e. We have not identified a defensible way to derive transition levels or the times at which these dose level changes could be made.

d. Standard Expressed as a Dose Target, Rather Than Limit

Although we have chosen to add a standard extending the compliance period beyond 10,000 years, we believe that the most problematic aspect of doing so is the uncertainty involved in making projections over such long time frames, which we discussed in some detail in our proposed and final rulemakings for 40 CFR part 197 in 1999 and 2001, respectively (Docket Nos. OAR–2005–0083–0041 and 0042). To repeat, we are in agreement with NAS that such projections can be performed and even ''bounded'' to some extent. However, we remain concerned about whether and under what conditions results of very long-term assessments can have sufficient meaning to provide the basis for a licensing decision that the repository should or should not be approved.

One way to take these uncertainties into account is to establish a more flexible compliance benchmark for very long time periods, one that would represent a more qualitative ''target'' for dose assessments rather than a strict numerical limit. This approach would be generally consistent with several international programs. For example, the Swedish Radiation Protection Authority (SSI) has proposed draft guidance for the disposal of SNF, stating that ''[f]or very long periods * * * [t]he intention should be to shed light on the protective capability of the repository and to provide a qualitative picture of the risks'' (p. 7, Docket No. OAR–2005–0083–0048). The Swedish regulations themselves are not detailed regarding the way different time periods should be addressed, although it is clear that times beyond 1,000 years are seen differently than the period up to 1,000 years. For the first thousand years after closure, ''the assessment of the repository's protective capability shall be based on quantitative analyses of the impact on human health and the environment,'' but for longer periods that assessment ''shall be based on various possible sequences for the development of the repository's properties, its environment and the biosphere'' (Sections 11 and 12, respectively, Docket No. OAR–2005–0083–0047).

In some cases, this reasoning is also applied to near-surface disposal facilities involving much shorter time frames. For example, in the United Kingdom, ''[t]he 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. However, if the estimated risk is above the target, the Agency will need to be satisfied not only that an appropriate level of safety is assured, but also that any further improvements in safety could be achieved only at disproportionate cost * * * In the very long term, irreducible uncertainties about the geological, climatic and resulting geomorphological changes that may occur at a site provide a natural limit to the timescale over which it is sensible to attempt to make detailed calculations of disposal system performance. Simpler scoping calculations and qualitative information may be required to indicate the continuing safety of the facility at longer times'' (UK Environment Agencies, ''Disposal Facilities on Land for Low and Intermediate Level Radioactive Waste: Guidance on Requirements for Authorisation,'' sections 6.14 and 8.23, Docket No. OAR–2005–0083–0063). Thus, in the UK approach, estimated risks may be allowed to exceed the numerical target if it is determined that further restrictions in risk are impossible or impractical.

Our approach in the 2001 rulemaking, which required peak dose projections to be placed in the Environmental Impact Statement, was based on similar reasoning. It allowed NRC to evaluate those results qualitatively, but did not prescribe that they be compared against a dose limit. We also believe such an approach would be consistent with our ''reasonable expectation'' standard, which intends to avoid a narrow focus on numerical calculations and encourages consideration of the totality of the assessment in the context of the overall safety case (ICRP took the same view in its Publication 81, ''Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste,'' stating 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, a contradiction with the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results'' (Docket No. OAR–2005–0083–0087); similarly, IAEA states ''that calculated doses are less than the dose constraint is not in itself sufficient for acceptance of a safety case * * * Conversely, an indication that calculated doses could exceed the dose constraint * * * need not necessarily result in the rejection of a safety case,'' DS154, Section A.7, pp. 36–37, Docket No. OAR–2005–0083–0051). In considering how to address peak dose in this standard, however, we believe it is more implementable and will be viewed as more rigorous to set a specific dose limit and provide direction concerning assumptions and methodologies for peak dose calculations, and leave it to NRC to consider the quantitative projections of peak dose as a particularly important part of the ''full record before it'' that it will consider in determining whether there is a reasonable expectation that the dose limit will be achieved.

e. Standard Expressed as a Statistical Distribution

Finally, we considered a standard of compliance that would combine features of the qualitative and quantitative approaches described earlier. Rather than incorporating a specific numerical limit that must be met by a single compliance measure (such as the median or arithmetic mean of a distribution), this approach would be based upon the characteristics of the distribution itself. It would take into account the range of results for performance assessment by examining multiple representative dose estimates such as upper and lower percentile values. Under this formulation, DOE might have to show that some percentage of the peak dose projections would remain within a certain range of a reference dose level. For example, this standard might say that at least 10% of peak annual dose results must be 15 mrem or lower, and that no more than 10% of results can exceed some upper limit. Using these parameters and assuming that DOE ran 100 assessments of system performance using probabilistically-sampled input parameter values, each resulting in a separately calculated ''peak'' dose, at least ten of those results would have to be 15 mrem or lower and no more than ten could be above the ''upper limit''.

This approach seems to address some of our concerns. First, it recognizes growing uncertainties but constrains how much is acceptable by specifying characteristics of the distribution that must apply at all times without being overly affected by ''outliers.'' In fact, the value of the projected peak dose is considered only in determining where it falls in relation to the designated upper and lower percentile measures. In this example, no more than 10% of the results may exceed the ''upper limit'', but the amount by which they exceed that limit is not taken into account (and similarly for doses below 15 mrem/yr). Thus, projected doses of 1 rem/yr (1,000 mrem/yr) would carry the same significance as much lower projected doses, as long as both were higher than the ''upper limit''. As a result, this approach might provide additional flexibility in judging the level of conservatism appropriate to addressing uncertainties (and perhaps compensate for conservatism) across a range of scenarios because the results would not be disproportionately affected by low-probability scenarios resulting in very high doses, as the arithmetic mean would be. In addition, the lower dose threshold acts as a conservative performance requirement in that it requires that the disposal system provide a specified level of performance tied to the 15 mrem/yr dose standard applicable to performance up to 10,000 years.

A firm base of assessments at lower levels (*e.g.*, 15 mrem/yr) would tie DOE's results to, and provide continuity with, the 10,000-year projections. It could be reasonable to allow a small number of results to exceed the ''upper limit,'' so long as the ''expected'' performance remains within a given range (within about an order of magnitude of 15 mrem, if we were to use as the ''upper limit'' the value of 350 mrem/yr we are proposing today). It should be kept in mind that even using the mean of the distribution as the compliance measure allows for a percentage of results to exceed the limit, depending to some extent on how the distribution is skewed; this statistical approach offered for discussion is simply more precise in specifying the percentage.

Second, while accounting for uncertainties, it can be linked to the standards of safety established for geologic repositories at earlier time frames. Percentile curves could be compared against reference levels based upon well-established limits within the U.S. and internationally, such as 15 mrem/yr, 25 mrem/yr, 30 mrem/yr, or 100 mrem/yr, or the 350 mrem/yr we are proposing today. This could provide continuity with our approach at 10,000 years. It is reasonable to assume that uncertainties will tend to become less manageable as time increases, but there is no clear and predictable demarcation for when uncertainties become ''unmanageable.''

Third, this approach would be consistent with our ''reasonable expectation'' standard, which is intended to encourage DOE to focus on ''cautious, but reasonable'' scenarios and examine the full range of results to obtain the best possible understanding of the long-term behavior of the disposal system. In applying a standard that must address times from 10,000 years up to 1 million years, it might be more representative of system behavior to consider the entire distribution of results that may occur over those times than to focus on a single number as indicative of acceptable performance. Using this approach, NRC would be assured that the bulk of the results will fall within reasonable limits, may be better able to understand why results fall at certain points along the continuum, and would have additional flexibility to determine compliance within those limits.

We used a somewhat similar approach in developing the containment requirements in 40 CFR 191.13(a). In that section of our generic regulations, we required that calculations show that a disposal system have no more than one chance in ten of exceeding the release limits, and no more than one chance in 1,000 of exceeding ten times the release limits. In establishing those requirements, we explained that the release limits applied to ''those processes that are expected to occur as well as relatively likely disruptions.'' The release limits multiplied by ten applied to ''more likely natural disruptive events * * * [and the] range of probabilities was selected to include the anticipated uncertainties in predicting the likelihood of these natural phenomena. Greater releases are allowed for these circumstances because they are so unlikely to occur.'' In part 191, no release limits were applied to even lower-probability (*i.e.*, ''very unlikely'') events, analogous to our approach of screening out very unlikely events at Yucca Mountain: ''the Agency believes there is no benefit to public health or the environment from trying to regulate the consequences of such very unlikely events' (50 FR 38071, September 19, 1985, Docket No. OAR–2005–0083–0064). We have successfully implemented this regulation at WIPP.

While we see several potential positive aspects of this statistical approach, we also have concerns regarding both the overall approach and the ways in which it could give a misleading impression of disposal system performance in a compliance demonstration. First, there is a difficulty in defining exactly where percentile limits should be placed and how they should be justified. Second, while the criteria we have suggested would apply to the entire distribution of results, they would essentially give the ''tails'' of the distribution a strong role in determining whether the disposal system should be licensed. As we discuss later in Section II.C.5 (''How Will NRC Judge Compliance?''), we believe it is appropriate to consider an indicator of the ''central tendency'' of the results as demonstrative of performance.

Our second concern relates to the idea that the calculated peak dose values themselves are not explicitly incorporated into the compliance determination through calculation of a separate statistical measure, such as the mean. While this offers an advantage insofar as the overall measure is not overly influenced by very high results, for any defined set of cut-offs there is always the possibility that the distribution will fall just outside the acceptable criteria. While strictly speaking only the number of doses above the higher cut-off level enters into the compliance demonstration, the magnitude of those doses would also be important in the regulator's confidence in the overall acceptability of the disposal system. Similarly, a distribution that falls just outside the cut-offs could be judged ''better'' than a distribution that meets the criteria, if a different measure such as the mean or median were used for comparison. In considering a series of 100 realizations, for example, a distribution with 11 above, but only slightly above, the ''upper limit'' and only nine at 15 mrem/yr or lower (but with the next highest at only 16 mrem) would fail the test, even if the bulk of the results were relatively low (say, below 100 mrem). However, a distribution with ten realizations significantly higher than the ''upper limit'' (*e.g.*, 500 mrem/yr and higher), ten at 15 mrem/yr, and most of the remaining doses well above 100 mrem/yr, would pass the test, even though it is likely that the arithmetic mean would be noticeably higher in the second case. Such a disparity might also indicate the presence of high-dose scenarios in one distribution that were not included in the other.

Therefore, we have chosen not to propose this approach for Yucca Mountain. We are concerned that it will be less transparent to the public and not give a clear indication of the necessary level of performance. Further, upper and lower percentiles and dose limits must be selected, as in the example above; the selection of all these values would need to account for risk management and policy considerations. It is difficult to identify a specific set of criteria that would lead to the selection of one set of values over another.

3. What Dose Level is EPA Proposing for Peak Dose?

Having determined that it would be appropriate to propose a numerical peak dose standard for the period of geologic stability beyond 10,000 years, we must then determine the appropriate level for that standard. We considered several factors in selecting the level proposed today. First, and most significant, is the issue of uncertainty in long-term projections. Uncertainties are problematic not only because they are challenging to quantify, but also because their impact will differ depending on initial assumptions and the time at which peak dose is projected to occur. Further, the natural tendency in modeling long-term processes is to introduce additional conservatisms to help ensure that actual performance will be no worse than projected performance. Thus, excessive conservatism in addressing uncertainty drives assessments away from ''cautious, but reasonable'' assumptions and may result in an unrealistic, overly pessimistic view of disposal system performance. As we stated in our earlier rulemaking, ''[s]etting a strict numerical standard at a level of risk acceptable today would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard'' (66 FR 32098, June 13, 2001, Docket No. OAR–2005–0083–0042).

This raises a broader point regarding the significance of very-long term projections and how they should be considered in the context of repository safety. Leaving aside the uncertainties inherent in projecting geologic characteristics over such periods, even a well-characterized site will display natural variability in the parameters that influence radionuclide transport. This natural variability exists at every possible site and can be reduced (or at least better estimated) by site characterization, but can never be eliminated, no matter how stable the site. As assessments extend to longer time periods, this natural variability will lead to an increasing spread of results even if conditions do not change significantly (it may be useful again for the reader to refer to the hurricane analogy discussed in Section II.A.5, where the range of possible storm paths increases as forecasts look farther ahead in time). Therefore, given the difference in the level of confidence regarding the ''real'' performance of the disposal system for projections at 250,000 years as at 10,000 years, we believe that emphasizing incremental dose increases when such increases are overwhelmed by fundamental uncertainties inappropriately takes attention away from an evaluation of the overall safety of the disposal system and its ability to contain and isolate wastes or respond to disturbances. On that point, we have argued against viewing projections as ''predictions'' of disposal system performance and have emphasized that assessments should aim to provide a ''reasonable expectation'' that performance will be within acceptable limits (on this point, see the NAS Report, for example p. 71: ''The results of compliance analysis should not, however, be interpreted as accurate predictions of the expected behavior of a geologic repository''). While there is a body of experience in applying the ''reasonable expectation'' concept for 10,000 years, we are also considering its implications for time periods in the hundreds of thousands of years (see Section II.B, ''How Does the Application of ''Reasonable Expectation'' Influence Today's Proposal?'').

We have also considered the potential impacts to future generations that would be represented by a dose standard applied to periods up to 1 million years. Impacts on future generations could come in the form of economic cost, health impacts, or a reduction in the options available to make decisions to address the problems faced by those generations. A number of regulatory and scientific bodies suggest that it is appropriate to relate longer-term standards to background radiation levels. NEA, for example, suggests that consideration of future generations ''implies that the safety implications of a repository need to be assessed for as long as the waste presents a hazard'' but that such assessments need not focus on exposures: ''In view of the way in which uncertainties generally increase with time, or simply for practical reasons, some cut-off time is inevitably applied to calculations of dose or risk. There is, however, generally no cut-off time for the period to be addressed in some way in safety assessment, which is seen as a wider activity involving the development of a range of arguments for safety'' (''The Handling of Timescales in Assessing Post-Closure Safety,'' p. 39, 2004, Docket No. OAR–2005–0083–0046, emphasis in original). This reasoning supports the idea that dose projections should be given progressively less weight in the overall decision as time passes. We note that ICRP recently discussed a similar concept. Specifically, ICRP suggests that future projected doses can be weighted to take into account a variety of factors, and that ''[w]eights can also be assigned according to the time at which the exposure will occur'' (''The Optimisation of Radiological Protection,'' draft for consultation, p. 29, April 2005, Docket No. OAR–2005–0083–0052). Such an approach could involve giving doses in the far future less weight, either in a numeric sense or in the context of the overall safety case.

The National Academy of Public Administration (NAPA), in its 1997 report ''Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly Across Generations'' (Docket No. OAR–2005–0083–0087), recognizes that each generation must consider not only how its actions will affect future generations, but also the extent to which inaction will compromise its own interests and negatively affect those same future generations.

To inform decision-making, NAPA defined four basic principles:

• Trustee: Every generation has obligations as trustee to protect the interests of future generations;
• Sustainability: No generation should deprive future generations of the opportunity for a quality of life comparable to its own;
• Chain of Obligation: Each generation's primary obligation is to provide for the needs of the living and succeeding generations. Near-term concrete hazards have priority over long-term hypothetical hazards;
• Precautionary: Actions that pose a realistic threat of irreversible harm or catastrophic consequences should not be pursued unless there is some countervailing need to benefit either current or future generations.

Under NAPA's approach, there is no absolute freedom of succeeding generations to escape the effect of the preceding generations' decisions. Rather, it is the responsibility of each generation to consider those decisions and their consequences in the light of new knowledge, technology, societal attitudes, and economic or other factors. NAPA terms this the ''rolling present.'' As it relates to the management of spent nuclear fuel, there is no question that the next several generations may incur societal as well as economic costs, whether it involves continued development of the Yucca Mountain repository, development of interim storage facilities or expanded storage at reactor sites, or decisions regarding the future use of nuclear power. Application of the NAPA principles would lead each generation to an approach that would best address the problem without unduly limiting the options available to succeeding generations to modify that approach or to take other actions to address their needs.

In general, while there is wide agreement that future generations should not be unduly compromised by the decisions of the current generation, there is no clear consensus regarding the extent of the claims held by future generations on the current generation (*i.e.*, how many generations should be considered, how to compare their interests to those of the current generation, or what it means to ''compromise'' their ability to take action). The Swedish National Council for Nuclear Waste (KASAM) concludes that increasing uncertainties ''means that our capacity to assume responsibilities changes with time. In other words, our moral responsibility diminishes on a sliding scale over the course of time'' (Nuclear Waste State-of-the-Art Reports 1998, p. 27, Docket No. OAR–2005–0083–0056). KASAM suggests that for the next 5 or 6 generations (roughly 150 years), we can apply a ''Strong Principle of Justice'' so that these generations can be expected to achieve a quality of life equivalent to that of the current generation. For a further 5 or 6 generations, we may only be able to apply a ''Weak Principle of Justice'' to ensure that these generations can at least satisfy their basic needs. Beyond that point, the best we can do is conduct ourselves today so as not to jeopardize future generations' possibilities for life (the ''Minimal Principle of Justice''). In the case of spent fuel disposal, these considerations lead to the idea that a repository must provide reasonable protection and security for the very far future, but this may not necessarily be at levels deemed protective (and controllable) for the current or succeeding generations.[2]

In any case, it is clear that quantitative regulatory limits cannot be applied indefinitely. There is general agreement that assessments (and corresponding regulatory safety limits or reference points) for periods longer than 1 million years are of limited value in any case (*e.g.*, IAEA states that ''little credibility can be attached to assessments beyond 10^6 years. Even qualitative assessments will contribute little to the decision making process'' (''Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories,'' IAEA–TECDOC–767, p. 19, 1994, Docket No. OAR–2005–0083–0044), and Sweden's draft guidance states that ''[n]o account need be given for periods beyond a million years after closure, even if'' peak exposures would be expected after that time (p. 7, Docket OAR–2005–0083–0048).

In addition to examining international guidance and precedents, we also reviewed the NAS's statements on the subject. As discussed in detail later in this section, NAS refrained from recommending any specific dose or risk limit for regulations, but instead suggested a range of risks as a ''starting point'' for EPA's consideration. Further, while NAS stated that a standard that ''could * * * apply uniformly over time and generations * * * would be consistent with the principle of intergenerational equity,'' it also recognized that other approaches are possible: ''Whether to adopt this or some other expression of the principle of intergenerational equity is a matter for social judgment'' (NAS Report pp. 56–57).

In determining an appropriate level of protection for periods up to 1 million years, we believe it is appropriate to consider potential exposures from the Yucca Mountain disposal system in the context of exposures incurred by residents of other areas of the United States from natural sources. Specifically, we believe it is reasonable to set a standard that would represent a level of incremental radiation exposure such that the total annual exposure of the RMEI could be comparable to the total natural radiation exposures incurred now by current residents of well-populated areas. Given the large uncertainties surrounding the outcomes at these unprecedented time frames, we believe such an action is justifiable and protective. Using this approach, we are proposing to establish a standard of 350 mrem (3.5 mSv) per year, which will limit total radiation exposures of the RMEI to levels comparable to those incurred today from natural sources by residents of a nearby western State.

We believe this level of protection appropriately blends the concerns outlined above with current and historical thinking regarding the acceptability of risks associated with background radiation, while recognizing the conceptual difficulties inherent in regulating at times potentially hundreds of thousands of years into the future. NAS 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). Thus, the NAS Report does not bind us to apply any particular dose limit in our Yucca Mountain standards.

We note that a number of international scientific and regulatory bodies and programs suggest natural sources of radioactivity serve as a point of comparison when uncertainties become significant. For example, the IAEA has stated that, for time frames extending from about 10,000 to 1 million years, ''it may be appropriate to use quantitative and qualitative assessments based on comparisons with natural radioactivity and naturally occurring toxic substances'' (''Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories,'' IAEA–TECDOC–767, p. 19, 1994, Docket No. OAR–2005–0083–0044). IAEA also suggests that ''[i]n very long time frames * * * uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases'' (''Geological Disposal of Radioactive Waste,'' DS154, Section A.7, p. 37, April 2005, Docket No. OAR–2005–0083–0051). Similarly, in summarizing the results of a workshop to assess long-term assessments, the NEA suggests that at time frames when the ''system [is] responding to external change,'' a key performance indicator could be ''comparison with background radiation levels.'' At that workshop, the idea was presented that up to 100,000 years, ''a dose constraint derived from natural background levels is prescribed'' and beyond that point ''the eventual redistribution of the residual activity by natural processes remains indistinguishable from natural regional variations in radiation levels'' (''The

[2] This sentiment, however, is not universal. Chapman and McCombie point out that the Swiss radiation protection regulations make the argument ''that since the current generation is the beneficiary of nuclear power future doses should be less'' (p. 53). They then acknowledge, however, that such arguments are complex, noting that ''it has been pointed out that future generations do indeed benefit from nuclear technology through the technical advances made, the conservation of fossil reserves, the reduction in greenhouse gases, etc.'' Further, they go on to write:

In addition, the inability to guarantee long-term or effectively permanent institutional control over long-lived uranium mining wastes disposed of at the earth's surface or over historical ''legacy wastes'' in countries where defence programmes have resulted in large-scale contamination, means that we are implicitly accepting (for this type of waste, and some NORM wastes) that future generations may have lower levels of protection than today. This is causing re-examination of the appropriate balance of radiological protection standards for the future for these materials. The most commonly accepted principle today for disposal of nuclear fuel cycle wastes is that future generations must be protected for very long times (at least 10,000 years) to at least reach the level of protection expected by today's generations; for extremely long times the growing tendency is to then make comparisons with natural sources of radiation, such as ore bodies.

''Principles and Standards for the Disposal of Long-Lived Radioactive Wastes,'' pp. 53–54, 2003, Docket No. OAR–2005–0083–0061.

Handling of Timescales in Assessing Post-Closure Safety: Lessons Learnt from the April 2002 Workshop in Paris, France,'' pp. 33, 35, 2004, Docket No. OAR–2005–0083–0046). Further, as regards low- and intermediate-level waste disposal, the UK Environment Agencies (consisting of the Environment Agency of England and Wales, the Scottish Environment Protection Agency, and the Department of the Environment for Northern Ireland) state that ''At times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed * * * Comparisons with the ambient levels of radioactivity in the environment may also be appropriate'' (''Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation,'' section 6.22, 1996, Docket No. OAR–2005–0083–0063).

We therefore considered which natural sources of radioactivity in the United States might provide similar reference points for a dose standard beyond 10,000 years. Natural background radiation in the U.S. averages roughly 300 mrem/yr, but varies significantly across the country, from a low of about 100 mrem/yr in coastal areas to above 1 rem/yr (1,000 mrem/yr) in certain localized regions. For purposes of this discussion, natural background radiation consists of external exposures from cosmic and terrestrial sources, and internal exposures from indoor exposures to naturally-occurring radon. Altitude and geology are two of the primary variables accounting for regional variations; however, there can be tremendous fluctuation even within a city or county, primarily due to variations in radon emissions. These fluctuations introduce some uncertainty in estimates of localized background radiation levels, which are also affected by factors such as the number and distribution of samples within a geographic area, whether the samples are short-term or averaged over a longer period, the structure of the building, the location of the sampling point(s) within a building, and assumptions in translating measured concentrations to estimated doses.

In order to assess total exposures and derive a dose limit, it is necessary to establish levels of natural background radiation already experienced in the vicinity of Yucca Mountain. We selected Amargosa Valley as the point of comparison for this analysis. We believe this is an appropriate approach, as the RMEI is defined as having a lifestyle and diet representative of current residents of Amargosa Valley. It is reasonable to consider total exposures in light of exposures already incurred by people in the immediate vicinity of Yucca Mountain. However, there are varying estimates of exposures from natural background sources in that area. DOE estimates that the natural background in Amargosa Valley is equivalent to the average across the U.S., or 300 mrem/yr (FEIS, DOE/EIS–0250, Table 3–28, Docket No. OAR–2005–0083–0086). However, that overall figure is highly dependent on the radon contribution, which DOE also assumes is equivalent to the average across the U.S., or 200 mrem/yr. Based on EPA radon studies, we believe it is reasonable and somewhat conservative to assume that radon exposures to residents of Amargosa Valley would be slightly higher (say 25%) than the national average (and possibly as much as 100 mrem/yr higher than the statewide average), resulting in a radon contribution to those residents of about 250 mrem/yr. Thus, combined with the cosmic and terrestrial exposures estimated by DOE, we estimate total annual natural background radiation at Amargosa Valley to be approximately 350 mrem/yr.[3]

To make the comparison with total exposures, it is also necessary to consider what total exposures provide a reasonable reference point for limiting releases from Yucca Mountain. As noted above, our goal is to ensure that releases from Yucca Mountain will not cause total exposures to the RMEI to exceed natural background levels with which other populations live routinely. We selected the State of Colorado as the reference point in meeting this goal. We considered several factors in this selection. First, we must recognize that some incremental exposure will be allowed; that is, it is a foregone conclusion that even the most protective standard cannot be expected to reduce natural background exposures, and clearly we cannot establish a negative standard. Thus, the reference point would have to have a higher level of background than does the area near Yucca Mountain. In addition, because of the aforementioned complications in estimating localized background radiation (due primarily to the radon component), we chose to examine statewide averages, which are less uncertain. Of the states with sufficient data, 32 have average background radiation levels higher than Nevada. In selecting among these, we considered characteristics such as geographic location and population. Our preference is to choose a state in the western part of the country that is fairly well-populated and might otherwise have characteristics considered reasonably comparable to Nevada (such as radon potential, surface water/coastal features, or size of major cities). We find that Colorado best fits those criteria. According to the population data (U.S. Census Bureau Statistical Abstract of the United States, July 1, 2004, *http://www.census.gov/statab/ranks/rank01.html*), Colorado ranks 22nd among all states in total population (Nevada is 35th). Colorado's average annual background radiation is estimated at 700 mrem/yr (see ''Assessment of Variations in Radiation Exposure in the United States,'' 2005, Docket No. OAR–2005–0083–0077, for both background radiation and population information). Other states have comparable or higher radon potential and higher background levels with which people live routinely (background levels in North Dakota, South Dakota, and Iowa, for example, are 789 mrem/yr, 963 mrem/yr, and 784 mrem/yr, respectively), and might also be used for comparison. However, we believe Colorado is more representative of the characteristics exhibited by Nevada (and Amargosa Valley).

In view of these factors, we selected Colorado as our point of reference. Thus, comparing Colorado's estimated average annual background radiation of 700 mrem/yr to our estimate for Amargosa Valley, we derive an incremental exposure level of 350 mrem/yr, which we are proposing to establish today as the dose limit to

[3] Data from EPA studies in 1993 indicate that the total average natural background exposure in the State of Nevada is 222 mrem/yr (''Assessment of Variations in Radiation Exposure in the United States,'' 2005, Docket No. OAR–2005–0083–0077), which is roughly 75% of the national average. Because data were not available specifically for Amargosa Valley, we used the statewide average as a starting point to estimate background radiation at Amargosa Valley. The overall statewide average is significantly affected by estimated exposures in Clark County (where Las Vegas is located), and not necessarily representative of exposures closer to Yucca Mountain. Clark County accounts for roughly two-thirds of the state's population (Census Bureau, Nevada State Data Center, *http://dmla.clan.lib.nv.us/docs/nsla/sdc/*). As outlined above, data support the conclusion that average exposures in Clark County would be significantly lower than in the rest of the state, primarily because of indoor radon exposures. EPA's map of radon zones developed in the early 1990s found Clark County to be the only county in Nevada placed into the lowest emission category, in which average exposure potential is less than 200 mrem/yr (''EPA Map of Radon Zones,'' EPA–402–R–93–071, Docket No. OAR–2005–0083–0065). Most of the other counties, including Nye County (where Yucca Mountain and Amargosa Valley are located), fell into the intermediate category, in which average exposure potential is estimated in the range between 200 and 400 mrem/yr.

apply to the time of peak dose beyond 10,000 years.

The limit we are proposing today is somewhat higher than the average natural background level of 300 mrem/yr across the U.S., which places it above two other options we considered (see Sections II.C.4.b and II.C.4.c). One option is the limit of 100 mrem/yr based on international guidance for all sources of exposure except natural, accidental, and medical. The other is 200 mrem/yr, which we derived through a somewhat different way of looking at total background levels nationwide. In our view, the 350 mrem/yr level and these other values are within a range of values for which projections might well be indistinguishable after several hundred thousand years. That is, when taking increasing uncertainties into account in the very long term, the effects of factors that would distinguish projections of 100, 200, and 350 mrem/yr within a 10,000-year time frame are more difficult to identify clearly at very long times, so that such projections may be qualitatively identical to each other and to the level of performance represented by projections of 15 mrem/yr at 10,000 years. That is, modest differences in basic modeling assumptions regarding such factors as temperature inside the repository over the first few hundred years after disposal can lead to differences in projected doses. Such differences reflect uncertainties and changes in models, and should not be interpreted as representing meaningful differences in the level of safety that can be expected to be achieved. Given the difficulty in estimating performance in the very far future, we would also view 350 mrem/yr as representing a satisfactory level of performance should it be the ''true'' value at such long times.

We recognize that a standard based on variations in natural background radiation would be higher than previous non-occupational standards in the U.S. In our 2001 rulemaking, we justified the dose limit of 15 mrem/yr and the 10,000-year compliance period in part because they were consistent with other EPA policies. In particular, a peak dose standard of 350 mrem/yr (and the time frame of up to 1 million years over which that standard could apply) may appear to some to be a departure from the risk-management policies EPA has adopted and applied in a variety of Agency programs, most notably in the Superfund cleanup program. We believe the circumstances involved in today's proposal are significantly different from the situations addressed under Superfund or any other existing U.S. regulatory program, and that it should be clear that comparisons between the two are inappropriate.

It should be clear that we are not arguing that most people take into account levels of background radiation when deciding where to live or work, or that it in any way plays a major role in their decision-making. Rather, in establishing a standard to apply to the RMEI over unprecedented times, we believe it is reasonable to consider exposures incurred routinely today by people in other locations, which in our view do not ''pose a realistic threat of irreversible harm or catastrophic consequences'' to those people.

In that context, we note that EPA does not consider the risks from such exposures to be excessive in the context of radon occurrence in residences. As described earlier, radon exposures can vary widely even in localized areas for a number of reasons. While average radon doses are estimated to be roughly 200 mrem/yr, measurements indicate that some exposures could be more than ten times that level in unique situations. The concentration at which EPA recommends action be taken to mitigate exposures is 4 pCi/l, which translates roughly to 800 mrem/yr. The Agency further recommends that homeowners consider taking action only if the measured concentration is between 2 and 4 pCi/l (*i.e.*, above 400 mrem/yr) (''A Citizen's Guide to Radon: The Guide to Protecting Yourself and Your Family from Radon,'' EPA 402–K–02–006, May 2004, Docket No. OAR–2005–0083–0058). It should be understood that this recommendation is not based solely on risk, but considers factors such as the voluntary nature of the exposure, the application to private property, and the capabilities of mitigation technology. The dose limit proposed today is well below the ''action level'' recommended for radon.

One way to provide context for comparisons with natural radioactivity is to evaluate the radiotoxicity of the waste itself. In particular, it has been suggested that assessment time frames could be tied to the time necessary for the waste to decay to levels roughly comparable to the uranium ore from which the fuel was derived, which is often on the order of several hundred thousand years. For example, IAEA states that ''[r]adiotoxicity indices are useful in putting the potential hazards of radioactive waste disposal into perspective * * * they are qualitative indicators of the time-scales of interest for safety analysis'' (''Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories,'' TECDOC–767, p. 15, 2004, Docket No. OAR–2005–0083–0044). NEA takes a similar position: ''radiological toxicity and comparison with natural systems such as uranium ores offer a basis for a safety indicator that can usefully complement dose and risk'' (''The Handling of Timescales in Assessing Post-Closure Safety,'' p. 30, 2004, Docket No. OAR–2005–0083–0046). Standards developed in Finland explicitly incorporate this comparison by defining the ''farthest future'' for assessments as the period when the activity in spent fuel becomes less than that in the natural uranium from which the fuel was fabricated (NEA, p. 34, Docket No. OAR–2005–0083–0046). Draft guidance for the Swedish program states that assessments ''need not be extended beyond the point in time when the initial content of the radioactive substances in the repository has decayed to a level at which the potential of causing harmful effects or other environmental consequences has decreased to insignificant levels'' (p. 7, Docket No. OAR–2005–0083–0048). One technical paper presented in the U.S. concludes that ''regardless of the assumptions used, the risk to public health from a HLW or spent fuel waste repository will always become less than that of the original uranium ore deposit'' and that ''[c]onsidering the nature of the many barriers to release that are included in the repository design, [it] should easily be the case'' that this ''crossover time'' (the time at which the radiotoxicity, or overall hazard, of the remaining waste will be equivalent to that of the original ore used to make the fuel) will be less than 10,000 years (''An Assessment of Issues Related to Determination of Time Periods Required for Isolation of High Level Waste,'' Proceedings of the Symposium on Waste Management at Tucson, Arizona, February 26–March 2, 1989, Docket No. OAR–2005–0083–0049).

While it is clear that consideration of natural radioactivity is a widely accepted concept for supporting safety assessments over very long times, it should also be clear that we believe regulatory standards for the Yucca Mountain disposal system based on background exposures can be reconciled with considerations of impacts on future generations, as outlined earlier in this section. Some international statements regarding natural radioactivity reflect the lack of consensus on what constitutes an undue burden. For example, NEA notes that when ''the repository has become comparable to a natural system in certain important aspects, this does not necessarily indicate a return to unconditionally safe conditions'' (NEA, p. 30, Docket No. OAR–2005–0083–0046).

However, Chapman and McCombie directly address this question, stating that, at these very long times, ''There is no logical or ethical reason for trying to provide more protection than the population already has from Earth's natural radiation environment, in which it lives and evolves * * * it must be recognized that man cannot be expected over infinite times to do much better than nature. The potential exists for natural uranium ore deposits, or spent fuel or HLW repositories, to give rise locally to doses that are higher than the global average for natural radiation, particularly if they are eventually eroded in the near-surface environment. However people exist today in many locations where doses are tens, even up to a hundred times higher than the average. Thus, a repository is not providing, globally, a novel source of exposure and does not at these long times represent any unusual anomaly in the global environment'' (''Principles and Standards for Disposal of Long-Lived Radioactive Wastes,'' pp. 114–115, 2003, Docket No. OAR–2005–0083–0061).

We do not mean to suggest that uranium ore bodies are benign entities, and there is certainly a difference between exposures incurred by direct contact with the material and those incurred at a distance after environmental transport of material has provided some lowering of potential exposures by natural retardation processes. These comparisons are relevant in the sense that exposures from longer-term releases from the Yucca Mountain disposal system would not be expected to be worse than those from natural features that are fairly common in parts of the country. The exposures that might result from ore body releases are highly dependent on the characteristics of the ore body and surrounding environment, as well as the other assumptions applied (measurements of releases from unmined ore bodies are limited; however, some surficial radiation measurements from unmined ore bodies suggest that a person at the site could easily receive several hundred mrem/yr (''The Uranium District of the Texas Gulf Coastal Plain'', U.S. Department of Energy Symposium Proceedings, CONF–780422, Vol. 2, 1978, Docket No. OAR–2005–0083–0081). On this point, we stated in our 1985 final rulemaking for 40 CFR part 191 that ''estimates of the risks from unmined ore bodies ranged from about 10 to more than 100,000 excess cancer deaths over 10,000 years. Thus, leaving the ore unmined appears to present a risk to future generations comparable to the risks from disposal of wastes covered by these standards'' (50 FR 38083, September 19, 1985, Docket No. OAR–2005–0083–0064). In the terms of the Precautionary Principle as presented by NAPA, exposures of this magnitude that are projected to occur several hundred thousand years into the future should not be considered to ''pose a realistic threat of irreversible harm or catastrophic consequences'' (Docket No. OAR–2005–0083–0087).

We recognize that meaningful distinctions are made today between natural background radiation and additional incremental (and involuntary) exposures caused by human activity. However, at long time frames (potentially as long as 1 million years into the future), such distinctions are less meaningful, and natural radiation levels can serve as a reasonable and logical reference point for assessing radiological impacts. We agree with NEA that a reasonable overall aim ''is to leave future generations an environment that is protected to a degree acceptable to our own generation * * * 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'' (NEA, p. 9, Docket No. OAR–2005–0083–0046). Our proposed approach limits doses from the Yucca Mountain disposal system in the far future to levels that represent variations in natural background and are far below doses that can be projected from uranium ore bodies or natural radiation in some locations in the U.S. and worldwide. Our proposed limit is somewhat higher than the annual average background radiation in the U.S. Using the reasoning described above, under this standard the additional radiation exposure at the time of peak dose to a resident of Amargosa Valley from the Yucca Mountain disposal system would be no greater than what would be incurred if that person moved today from the vicinity of Yucca Mountain to a nearby state. Using the NAS suggestions as a starting point, and considering international guidance and examples, we have derived the proposed dose limit to balance competing factors highlighted by NAS and acknowledged by us as important: the dual objectives to effectively address the effects of uncertainty on compliance assessment and to adhere as closely as possible to the relevant ethical principles, including a consideration of impacts on future generations. We believe that our selection of a 350 mrem standard is reasonable and effectively addresses the factors it is necessary to consider when projecting exposures very far into the future. By applying over the entire period of geologic stability beyond 10,000 years (up to 1 million years), it will capture the peak dose during that period. By doing so, our proposal 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).

In all of our discussion of potential dose standards, we have emphasized the importance of perspective in evaluating dose projections at very long times. It is important to distinguish between effects that are meaningful in assuring public health and safety and those that simply illustrate a modeling exercise. We are proposing an approach to setting a dose level derived from variations in current natural background radiation in the U.S. that would relate potential exposures to the RMEI to exposures incurred today by people in other locations from sources of natural background radiation. Given the long times involved in dose projections, and the significant uncertainties, we believe that comparisons with natural sources of radiation are appropriate.

Finally, from a regulatory perspective, we have also considered that the peak dose limit would apply at any time after 10,000 years. The limit we select must be credible both at times close to 10,000 years and times much further into the future. Readers may also question whether a 350 mrem/yr standard can be considered credible at times beyond but closer to 10,000 years. (We have acknowledged that uncertainties are not immediately overwhelming and unmanageable for a period up to 10,000 years.) We think it unlikely that the peak would occur at a relatively early time beyond 10,000 years. However, should that be the case, we believe that NRC has the authority to consider not only the magnitude of the peak, but also the timing and overall trends of dose projections as it evaluates the license application. NRC will examine the full record before it in determining whether there is a reasonable expectation that the standards will be met. As an alternative, we might identify a sliding scale of compliance limits applicable at different times, but, as discussed in Section II.C.2.c, we do not believe there is a clear basis for doing so.

In addition to our proposed level of 350 mrem/yr, we took into account the factors described above in considering various options for the peak dose limit, as discussed in the next section. Clearly, the competing considerations described above are not easily resolved. While the final standard may not be identical to any of these options, we believe that they encompass the range of values we might reasonably select. We request comment upon our proposed annual peak dose limit of 350 mrem applicable beyond 10,000 years through the period of geologic stability, the reasoning outlined above, and other ways in which we might reconcile the various influential factors at very long times.

4. What Other Peak Dose Levels Did EPA Consider?

We considered several other dose options before selecting 350 mrem as the value to propose. We request comment on the dose levels discussed in the following sections.

a. Maintain the 15 Mrem/Yr Standard at Peak Dose

One approach would be simply to apply the same level deemed protective at 10,000 years to peak exposures, whenever they might occur. This approach has been recommended by some stakeholders (Docket No. OAR–2005–0083–0022). Stakeholders have suggested defining the ''compliance period'' as the time from disposal to peak dose, stating that ''[t]his new compliance period is absolutely required by [NAS], which rejects any 10,000-year limitation on the compliance period.'' However, for the reasons discussed earlier, while we are proposing to extend the compliance period throughout the period of geologic stability, we have concerns that an approach that applies the same dose level throughout that period would not adequately recognize the complexities inherent in projections that could extend for several hundred thousand years. As a result, we believe a 15 mrem/yr standard at very long times would not be a meaningful indicator of disposal system performance, and may in fact be misleading.

We disagree with the view that the Court's decision requires us to amend our standards by extending both the compliance period and the dose limit applicable at 10,000 years to the time of peak dose up to 1 million years, and forbids us to establish standards applicable at intermediate times. The Court's decision reflected its judgment that our 2001 standards were not consistent with the recommendations of NAS as they related to the compliance period. Our goal in today's proposal is to amend our standards so that they are clearly consistent with the NAS recommendations, but also address the policy and other concerns we raised in our 2001 rulemaking. Extending the compliance period directly addresses NAS's primary recommendation. Regarding the dose limit applicable at the time of peak dose, NAS stated ''we do not directly recommend a level of acceptable risk'' (NAS Report p. 49). Similarly, NAS offered no opinion on approaches involving multiple dose standards, stating only that it viewed a 10,000-year standard by itself as insufficient (NAS Report pp. 54–56). As the Court made clear in its consideration of the ground-water protection standards, where ''NAS made no 'finding' or 'recommendation' that EPA's regulation could fail to be 'based upon and consistent with' * * * [the EnPA] left [EPA] free'' to promulgate standards to address its policy concerns. (*NEI*, 373 F.3d at 47, Docket No. OAR–2005–0083–0080.) In our view, the standard applicable for the first 10,000 years and the derivation of a different dose limit applicable beyond 10,000 years are both permissible under our EnPA authority.

From a regulatory perspective, a compliance standard on the order of 15 mrem/yr implies far more precision in projections for very long times than can be supported and, as such, is inconsistent with the ''reasonable expectation'' approach. We have also discussed at length the general agreement among international bodies and programs that longer-term standards should recognize the uncertainties involved and projections must be considered in a more qualitative manner, as one element in the overall safety case. As such, we believe it is inappropriate to portray that projections of incremental doses at such low levels can be precisely controlled at far future times and to give them excessive influence when they are not critical to improvements in health and safety. Here again, we believe our statement from the 2001 rulemaking bears repeating: ''[s]etting a strict numerical standard at a level of risk acceptable today would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard'' (66 FR 32098). From that perspective, holding the Yucca Mountain disposal system to a 15 mrem/yr standard would not merely be an issue of ''fairness'' to very far future generations. Instead, by not recognizing the factors that fundamentally affect dose projections at such times, it would place those generations' interests in a much higher regard, and by doing so would unreasonably constrain the current and succeeding generations' abilities to pursue achievable solutions they deem best suited to meet the interests of all generations. It would, in other words, undermine the Chain of Obligation Principle by giving ''long-term hypothetical hazards'' precedence over ''near-term concrete hazards'' (''Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly Across Generations,'' 1997, Docket No. OAR–2005–0083–0087). It is not simply a question of whether a 15 mrem/yr standard could be met in actuality; rather, the question is whether holding probabilistic assessments to such a level over hundreds of thousands of years, when rising uncertainties exist in performance projections and various high-consequence (but necessarily somewhat speculative) scenarios must be considered in the analyses, represents a reasonable test of the disposal system. We believe it does not.

b. 100 Mrem/Yr Standard at Peak Dose

In evaluating dose limits that might be responsive to the concerns outlined above, we also considered 100 mrem/yr as a value that may be appropriate for peak dose calculations. The value of 100 mrem/yr has potential benefits in terms of precedent. The ICRP has since 1985 (Publication 45, ''Quantitative Bases for Developing a Unified Index of Harm,'' Statement from the 1985 Paris Meeting of the ICRP, Docket No. OAR–2005–0083–0087) recommended 100 mrem/yr as the principal overall dose limit for public exposures from all sources excluding natural background, medical, occupational, and accidental (these three man-made sources can involve higher exposures, can involve greater understanding of the reasons for exposure, and may require informed consent from the exposed person). NRC requires that its licensees conduct operations so that individual members of the public are not exposed above this level (10 CFR 20.1301). We view this figure as representing a national and international precedent as a generally-accepted benchmark for annual public exposures from various sources.

The use of 100 mrem/yr can also be interpreted as protective of future generations' interests, yet not so restrictive as to represent an unreasonable standard for the very far future. We recognize that in practice today, doses from any particular source of radiation are generally kept to a fraction of the 100 mrem overall limit, in recognition that a person may be exposed to more than one practice or source. Given our current responsibility to propose a peak dose standard, however, we would argue that allocation to a single source at the time of peak dose could be reasonable, as other contributors currently in the Yucca Mountain area are negligible by comparison (FEIS, DOE/EIS–0250, Section 8.3.2, Docket No. OAR–2005–0083–0086). Moreover, to assume (or even to estimate the chance) whether, how, or where other radiation facilities could develop in the far future would require immense speculation about the long-term evolution of government programs, population demographics, and technology. Relying on current conditions rather than speculating on future sources of exposure to the local population, as recommended by NAS, would justify allocating the entire 100 mrem to Yucca Mountain.[4]

Nevertheless, we have decided not to propose a peak dose standard of 100 mrem/yr because over the very long-term, we believe that natural background levels to which individuals are or could be currently exposed provides a more reasonable context in which to judge the performance of the Yucca Mountain disposal system, and because our proposed approach appropriately reflects international guidance and consensus on this issue. *See* Section II.C.3 (''What Dose Level Is EPA Proposing for Peak Dose?'').

c. Peak Dose Standard Based on Regional Background Radiation Levels

We also considered an alternative approach also based on an examination of natural background radiation levels across the country. In this approach, rather than examining total background radiation at a specific location (or State), as we did to derive the 350 mrem/yr level we are proposing today, we have looked at average levels across many States (''Assessment of Variation in Radiation Exposure in the United States,'' 2005, Docket No. OAR–2005–0083–0077). One reason for taking this approach is that it compares statewide averages calculated on a common basis. Even so, the cautions we expressed in Section II.C.3 regarding the uncertainties and variation in background radiation values remain relevant.

Using this approach, we arrived at a dose limit of 200 mrem/yr. As with our proposed approach, our overall policy goal is to establish a standard that would keep total exposures to the RMEI within the range of exposures incurred by residents of other locations today from natural background sources alone. We would not view 200 mrem/yr as excessive in the context of exposures routinely encountered today, particularly when considering the uncertainties in projecting potential doses over the very long times involved (*i.e.*, 10,000 to 1 million years).

We started by considering States with higher average background levels than Nevada. As with our proposed approach, we believe this is reasonable because the limit we establish must represent some positive incremental exposure to the RMEI. The data compiled in ''Assessment of Variation in Radiation Exposure in the United States'' (Docket No. OAR–2005–0083–0077) show that 32 States have higher average background levels than Nevada's 222 mrem/yr. Rather than identify any particular State as the reference point, as we did in the direct comparison with Amargosa Valley, we averaged the values for those 32 States and obtained an average background radiation level of 429 mrem/yr. We compared this value to the statewide average for Nevada as an indicator of more regional, rather than localized, differences. Thus, on average, residents of those 32 States today receive roughly 200 mrem/yr more from natural background radiation sources than a resident of Nevada. Considering all of the factors involved in very long-term projections, such a limit would represent a level of exposure consistent with that routinely and normally incurred in other locations. However, we have decided not to propose this approach today because our preference is to use Amargosa Valley (and the RMEI as the person our standards are designed to protect) as a point of reference, but we welcome comment on both the approach and the dose level of 200 mrem/yr derived from it.

5. How Will NRC Judge Compliance?

We require that DOE use probabilistic performance assessment to demonstrate compliance with the individual-protection standard in § 197.20 (DOE may, but is not required to, use the same technique to show compliance with the human-intrusion and ground-water protection standards). With this method, DOE will obtain a distribution of calculated dose results. This distribution will be influenced by variations in parameter values as well as fundamental uncertainties and the assumptions underlying the conceptual model(s) of disposal system evolution. In making a compliance demonstration, DOE must satisfy NRC that a specified portion of that distribution satisfies the dose criterion. In our 2001 rulemaking, we specified in § 197.13 that the mean of the distribution of results be used to demonstrate compliance with § 197.20. In doing so, we intended that the arithmetic mean (commonly known as the average) of the distribution be used, but did not feel the need to be so specific. The arithmetic mean is a well-understood measure that is used in many compliance applications, including at WIPP. As discussed later, we intend to retain the arithmetic mean for the compliance measure for the first 10,000 years after disposal.

However, for the period beyond 10,000 years, for which we must consider assessing performance for as long as 1 million years (the NAS's estimated period of ''geologic stability''), we realize that some additional specification is necessary. Although we do not believe that the basic approach to performance assessment should be affected, we discuss in Section II.D certain aspects of that approach that may need to be modified or given special attention to effectively address these much longer times in a meaningful way. Similarly, we must consider whether the arithmetic mean used for compliance at 10,000 years remains the appropriate measure of compliance, particularly at very long times, or whether another measure is more appropriate.

We believe that for these very long-term projections, a measure that represents a ''central tendency'' in the distribution of calculated doses is most appropriate to adequately consider the range of uncertainty in making dose projections over such very long time spans. Such a measure should not be strongly influenced by high or low-end projections that represent low probability situations. Today we are proposing to specify that compliance with the standard that will apply beyond 10,000 years should be measured against the median of the distribution of projected doses. The remainder of this section discusses our rationale for this approach.

In general, the compliance measure we select must be meaningful and representative of the entire distribution of calculated doses, but, as we have stated, not easily influenced by results either at the very high or very low end of the distribution. In conducting

[4] This approach would also be consistent with the recent ICRP draft for consultation on optimization of radiological protection, which states ''the choice of the relevant dose constraint for protection against exposures from the licensed facility under consideration will depend largely on whether or not this facility is the dominant source to the exposed public under consideration. If the facility is the dominant source, a dose constraint of 1 mSv/a [100 mrem/yr] would be the appropriate starting point for optimisation of protection'' (''The Optimisation of Radiological Protection,'' p. 45, April 2005, Docket No. OAR–2005–0083–0052).

performance assessments many assumptions and uncertainties must be incorporated into the complex calculations. In constructing scenarios for repository performance, there are uncertainties in describing how the disposal system will perform and evolve over time, under the influence of natural conditions and the effects of the repository itself on the surrounding host rock. There are significant uncertainties in predicting when discrete events, such as seismic activity, will occur at and around the immediate repository location and the possible effects of these events. Some scenarios incorporating these uncertainties would be of low probability, and the results could vary from relatively poor performance to exceptionally good performance of the disposal system. The results of such low-probability situations with dramatically different results than the majority of the projections would show up in the ''tails'' of the dose results distribution. While we believe such low-probability situations should not be ignored in compliance decisions, neither do we believe they should be given undue influence in judging compliance. Therefore, we believe that the appropriate compliance measure should represent a central measure for the dose projections, and should not be defined in a way that it can be strongly affected by extreme results (''outliers'') in the dose projections (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments, Sections 12.1 and 12.2, July 2005, Docket No. OAR–2005–0083–0085).

Today we are retaining, and more clearly specifying, the arithmetic mean of the dose projections for compliance within the initial 10,000-year period. We believe the arithmetic mean is a familiar and well-understood statistical concept, and that its application in probabilistic risk assessment is sufficiently established to support our decision. In addition, while uncertainties are present in performance assessments during this time frame, we believe that the uncertainties increase in importance as the assessments stretch into the extremely long time frames beyond 10,000 years but within the period of geologic stability. In this sense, we believe that the arithmetic mean (average value) of the dose projections can still be a reasonably reliable measure of the total dose distribution during the 10,000-year period. More importantly, however, we believe it is valuable to maintain consistency between the compliance measure used for the first 10,000 years of disposal system performance for the Yucca Mountain repository and the measure applied for any other geologic disposal application under the authority of our generic regulation for geologic disposal, 40 CFR part 191. We believe that the Yucca Mountain disposal system should be required to meet the same level of protection, and be evaluated under the same regulatory compliance framework, as any other geologic disposal application for the 10,000-year period considered in part 191, which has been applied to the WIPP facility specifically and would apply to any other disposal system in the future. In the unlikely event that performance assessments show that the peak dose would occur within the 10,000-year period, we believe that the same compliance measure and evaluation should be applied for the Yucca Mountain disposal system as for any other geologic disposal system.

However, we have noted repeatedly that extending the compliance period to time frames well in excess of 10,000 years introduces additional uncertainty in making disposal system performance projections, since the natural system will continue to change through time (see ''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Section 12.5, July 2005, Docket No. OAR–2005–0083–0085, and the 2001 BID, section 7.3.11, Docket No. OAR–2005–0083–0050). We believe probabilistic calculations are the most appropriate approach to assess the range of potential doses over very long time frames, both for the period up to 10,000 years and after. The probabilistic approach examines a spectrum of possible site conditions, and allows the construction of conceptual models that address reasonable alternative models of performance within that range of possible physical and chemical conditions at the site. A distribution of projected peak doses will result from these analyses, each representing a possible ''future'' and a dose associated with the specific parameter values chosen for each calculation. Only by examining the relative effects of variations in the parameter values on the calculated dose can the important Adriver'' parameters be identified. Without these types of analyses, an understanding of the disposal system's behavior in the long term would not be possible, and a compliance case supporting a decision about the protectiveness of the disposal system might not be a reasonable representation of potential risks. We are proposing to require that DOE apply this general approach for assessments regardless of time frame, although, as we have discussed earlier, there is much agreement that the level of confidence or meaning that can be placed in such analyses decreases over very long periods. The challenge lies in defining a performance measure that balances the uncertainties inherent in very long term projections and provides a reasonable level of protectiveness.

Similarly, some discussion is warranted on the role of conservatism in performance assessment. Excess conservatism in constructing scenarios, i.e., making assumptions to include or exclude specific FEPs and defining parameter value ranges, can easily lead to very high dose estimates due to a compounding effect of very conservative assumptions. Such excessive conservatism is misleading if incorporated in assessments described as the Anominal'' or Abase case'' performance projections. A simple arithmetic mean calculated for an excessively conservative analysis would suggest that the ''most likely'' dose is higher than if a more reasonable and realistic approach were taken to framing the assessments. Recognizing that conservatism in long-term performance projections may be unavoidable in practice, as discussed below, we believe that a regulatory performance measure should not give undue emphasis to high-end projections. It is always possible to propose scenarios where releases are high, even though the probability of these particular scenarios may be extremely small or very difficult to estimate. The same reasoning also applies to scenarios that result in very low releases in the very long term. The ''bounding'' approach to assessments plays an important role in the light of the increasing uncertainties. Once the time frame for performance projections is extended into the very long term, the confidence that can be placed on either the high- or low-end release scenarios becomes progressively more difficult to estimate even though a ''bounding'' approach may simplify calculations. Consequently, we believe that a performance measure for these very long term assessments should not over emphasize high-end release scenarios or ignore low-end release scenarios under the motivation for conservatism in the assessments.

In addition, uncertainty and conservatism can influence one another. Characterization of the site today yields a range of values for important parameters that would have a dominant effect on projecting doses from contamination plumes eventually released from the repository, and these data form the base of the parameter value distributions input to the dose calculations. Attempting to project the evolution of these parameter values over the 1 million year geologic stability period adds additional uncertainty in their variations. To address these uncertainties in parameter value estimation and scenario construction, analyses of disposal system performance may be done Aconservatively,'' *i.e.*, by selecting parameter values, constructing scenarios, and making assumptions that deliberately overestimate projected doses. This approach provides some confidence that uncertainties and other potential negative influences have been adequately considered and that regulatory decisions will not be based on overly optimistic views of disposal system performance. However, the distribution of doses, as well as peak doses, from such an approach will be biased toward high-end values. As a result of making conservative assumptions and parameter distributions, there is a very real possibility that high-end projections could represent highly improbable situations in a physical sense (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Sections 1 through 12, July 2005, Docket No. OAR–2005–0083–0085). For such cases, arriving at a compliance decision becomes complex and speculative. Thus, we believe the appropriate measure of compliance for peak dose estimates is a ''central tendency'' measure which is not strongly influenced by low-probability realizations giving either very high-end or low-end dose estimates (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments,'' Sections 12.1 and 12.2, July 2005, Docket No. OAR–2005–0083–0085).

The NAS also found this approach to have merit. NAS recommended that regulatory decision making should consider the period when risks are at their highest, whenever that occurs, *i.e.*, the time of peak dose (NAS Report pp. 2, 6). In defining ''risk,'' the NAS used the term Aexpected value'' in referring to a probabilistic distribution of projected doses (NAS Report p.65). NAS did not further define this term in a statistical context, but elsewhere provided qualitative language describing the overall goal: ''define the standard in such a way that it is a useful measure of the degree to which the public is to be protected from releases from a repository'' and ''does not rule out an adequately sited and well-designed repository because of highly improbable events'' (NAS Report pp. 27–28). NAS in its recommendations did not speak explicitly to any particular performance measure to be used in determining compliance with regulatory standards. This decision was to be left to EPA in the course of rulemaking.

Disposal programs abroad also have to consider the role of uncertainty in developing performance assessments. The U.S. is ahead of most other geologic repository programs abroad in terms of having a specific site that has been extensively characterized and for which detailed performance assessments have been done. While other programs have not reached the stage of developing specific regulatory criteria for judging the acceptability of a particular repository site and design, there is a general consensus that multiple lines of evidence and analysis are desirable in establishing a safety case, and that judgment plays a critical role in assessments of disposal system performance as well as establishing and applying regulatory criteria (IAEA–TECDOC–975, Docket No. OAR–2005–0083–0045). The joint NEA-IAEA International Peer Review for DOE's TSPA-SR modeling highlighted the difficulty of specifying the statistical measure of compliance, noting that ''the TSPA nominal case is treated probabilistically yet it involves a mixture of embedded conservatism and statistical analyses to determine the mean, median and the various percentiles of the dose distribution. The reported ''mean'' is therefore not the true mean in a statistical sense. Moreover, that value is reported in the Executive Summary of the TSPA–SR and elsewhere as the expected value of effective dose, without any qualification. This stretches credibility especially as the discrete numerical values are given for times in the far future. The USDOE needs to indicate that, for compliance purposes, a performance indicator has been chosen that is meant to illustrate the safety of the system and argue the compliance with regulation.'' The Peer Review Team further recommended that ''when a best estimate/best knowledge probabilistic analysis is performed, the best estimate or the most probable range of the calculated 'dose' should also be given.'' (pp. 54–55, Docket No. OAR–2005–0083–0062)

In determining the ''expected value'' of performance, some international efforts have considered the possibility of viewing the performance assessment as separate representations of scenarios driven by their relative likelihood, and which might be compared to different regulatory standards. For example, regulatory agencies of France and Belgium have developed a joint document that suggests preparation of ''reference evolution'' and ''altered evolution'' scenarios (''Geological Disposal of Radioactive Waste: Elements of a Safety Approach,'' p. 24, 2004, Docket No. OAR–2005–0083–0066). The reference evolution scenarios would consider ''the most likely effects of certain or very probable events or phenomena,'' while the altered evolution scenarios ''take into account the least likely effects of these events or phenomena'' as well as considering ''the consequences of events or phenomena that are not integrated into the reference scenario, as the likelihood of occurrence is lower.'' Under this approach, the reference evolution scenarios might be directly compared to the dose constraint, while the altered evolution scenarios ''must be appraised on a case by case basis depending on'' various factors, and may then be ''compared to different references * * * without this comparison constituting an absolute acceptance criterion.'' This approach appears to go further than that recommended by the TSPA–SR Peer Review Team (and discussed in relation to our reasonable expectation principle in Section II.B). DOE similarly identifies ''nominal'' and ''disruptive'' scenarios, but aggregates the results for comparison with the relevant criteria.

As stated earlier, we required in our 2001 rulemaking that DOE use the arithmetic mean of the distribution of results to demonstrate compliance with the 10,000-year dose limit (and are today proposing to clarify the use of that measure). However, in considering the much longer times, we are concerned that the arithmetic mean is too easily influenced by extremes in the distribution, particularly very high dose projections resulting from scenarios that are unlikely to occur. A conservative approach to constructing and evaluating performance scenarios tends to generate high-end results and a simple averaging of these results would drive the arithmetic mean to higher values that would not be as representative overall of the actual distribution of projected doses. Therefore, we do not believe the arithmetic mean will satisfy the goals laid out earlier in this section for a performance measure for periods well in excess of 10,000 years.

While typically the ''average'' of a series of values (*i.e.*, a distribution) is thought of as near the midpoint between the highest and lowest values, if a somewhat conservative approach is taken or there are significant outliers, it is not unusual for the arithmetic mean to approach significantly higher percentiles. In such cases, the regulatory compliance decision can be influenced by the high-end doses of an overall set of very conservative performance assessment results. In fact, for early occurrences of disruptive events (human intrusion or igneous intrusion), DOE assessments show that at some periods of time the arithmetic mean of the projected doses can exceed the 95th percentile of the distribution of TSPA results (FEIS, DOE/EIS–0250, Appendix I, Section 5.3, Docket No. OAR–2005–0083–0086). While conservatism in assumptions is not the only reason for the arithmetic mean to occur at a relatively high percentile, in general we do not believe this can be reasonably interpreted to be an adequate representation of central tendency for the purpose of judging the performance of the Yucca Mountain disposal system.

Thus, we found it necessary to consider what other statistical measures might better represent the central tendency for performance assessments at very long time frames. The identification of appropriate statistical measures for central tendency of a dose distribution is influenced by the shape of the distribution, when these estimates are plotted for a particular point in time, or more specifically for the peak dose values from each computer modeling simulation in the disposal system performance assessments. We have examined three measures of central tendency: the arithmetic mean, the geometric mean, and the median. The degree to which they reliably represent the central tendency of a particular distribution, and more importantly how well they could serve as compliance measures, is discussed below. Like the arithmetic mean we have discussed above, each measure has advantages and disadvantages, and is dependent on the actual shape of the dose distribution as to how well it would represent the central tendency (''Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessment,'' Sections 12.1 and 12.2, July 2005, Docket No. OAR–2005–0083–0085).

The most familiar shape for a distribution is the bell-shaped ''normal'' distribution. In a normal distribution, the ''peak'' occurs in the center of the distribution and the remaining values lie evenly on both sides of the center value. A normal distribution is often seen when values are relatively close together (*i.e.*, the range of values does not cover many orders of magnitude), and are produced from a continuous function composed of additive terms. Because the values of the distribution are evenly spread out around the central peak, the distribution can be seen to be symmetrical; that is, one side is the ''mirror image'' of the other. The arithmetic mean can be easily determined from such a distribution because an equal number of values are found at the same distance from the peak (*e.g.*, if the peak is at 10, there will be equal occurrences at 9 and 11, at 8 and 12, and so on). Thus, the center line in a purely normal distribution represents the arithmetic mean of the distribution. From the discussion earlier in this section, it should be clear that the performance results do not represent a purely normal distribution. In a purely normal distribution, the arithmetic mean cannot be as high as the 60th percentile, much less the 70th, 80th, or 95th percentile. It must always be the 50th percentile. For this reason, we believe it likely that at long times the arithmetic mean will be more strongly influenced by higher-end estimates (estimates lower than zero are not possible) and less representative of the overall distribution.

As an alternative, we considered whether the geometric mean of the distribution would be an appropriate statistical measure. Referring back to the shape of the distribution as an indicator of the measure of central tendency, we noted earlier that the bell-shaped curve is the most familiar shape. However, many measured quantities in nature show a distribution skewed toward higher-end values, *i.e.*, there is no symmetrical distribution around a central value (''The Lognormal Distribution in Environmental Applications,'' EPA/600/S–97/006, December 1997, Docket No. OAR–2005–0083–0057). When data like these are transformed by taking their logarithms and plotted on a logarithmic scale, the data can appear ''normally'' distributed. Such distributions are referred to as log-normal. For such ''transformed'' data, the geometric mean is used as the measure of central tendency (that is, the geometric mean of a log-normal distribution has a comparable significance to the arithmetic mean of a normal distribution).[5] The fact that the arithmetic mean has been significantly higher than the 50th percentile in DOE's published performance assessment results suggests those distributions might be log-normal in nature, which would indicate the geometric mean as the appropriate statistical measure of central tendency. As a point of comparison, the geometric mean of a log-normal distribution is always lower than the arithmetic mean. This makes the geometric mean attractive if we are concerned about the undue influence of high-end estimates, as the geometric mean will always show less influence than the arithmetic mean.

However, there are some difficulties in using the geometric mean that must be considered. One difficulty is related to the nature of the geometric mean itself. Because the calculation involves the taking of the logarithm, the distribution values are expressed in terms of their exponential values, which may then be ''averaged.'' For example, the logarithm of 100 is 2, because 100 = 10^2 (or 10 to the 2nd power). Similarly, the logarithm of numbers less than 1 are expressed as negative numbers (*e.g.*, the logarithm of 0.01 = -2, because 0.01 can also be written as 10^{-2}). Thus, in the same way that the arithmetic mean might be affected by a few very large values in a distribution, the geometric mean can be affected by very small numbers whose logarithms are expressed as very large negative numbers.

In practical applications, this means that a distribution that generally appears log-normal can contain some very small numbers (outliers) that affect the geometric mean as a measure of central tendency. Depending on how many and how small these outliers are, the calculated geometric mean can also be very different from the 50th percentile of the distribution. For Yucca Mountain, this situation could represent a case where the waste packages remain essentially unbreached through the geologic stability period, leading to very small doses (and correspondingly high negative logarithms of those dose values). This scenario might have a very low probability in reality, but could influence the geometric mean, possibly causing it to be lower than the 50th percentile of results calculated from all the performance scenarios taken in total (and possibly very much lower). Alternatively, extremely pessimistic scenarios for waste package releases could give high-end outliers, although

[5] The formula for calculating the geometric mean (GM) for a series of values, $x_1, x_2, x_3 \ldots X_n$, is GM = $^n\sqrt{x_1 * x_2 * x_3 \ldots X_n}$, while the formula for calculating the arithmetic mean (AM) is AM = $(x_1 + x_2 + x_3 \ldots x_n)/n$. For the GM calculation no zeros are permissible, and the GM is always less than the AM. For parameter values in a skewed distribution (skewed to high-end values) that is transformed into a log-normal distribution, the formula for the GM is expressed as ln GM = $(1/n)(1n\ x_1 + 1n\ x_2 + 1n\ x_3 \ldots + 1n\ x_n)$. It can be seen that the GM of the log-transformed values in a log-normal distribution is calculated in the same fashion as the AM for a normal distribution. Both the AM and the GM are measures of central tendency for their respective distributions and equivalent to the median of the distributions as long as the distributions are truly normal or log-normal.

the high-end projections may not affect the geometric mean as much because the site's characteristics will not easily allow orders of magnitude increase in releases to reach the RMEI. In terms of the logarithmic values, the difference between 0.001 mrem and 0.1 mrem is exactly the same as the difference between 1 mrem and 100 mrem (two orders of magnitude), yet the difference in actual site performance is clearly more significant between 1 mrem and 100 mrem. Thus, while it is possible to have very low-dose estimates, micro-rem/yr and below, which have large negative logarithms, there will not be correspondingly high dose estimates in the tens to hundreds of thousands of rem/yr (with equally high positive logarithms) to counterbalance the very low numbers, and therefore these very low numbers could exert a stronger effect on the geometric mean as an indicator of central tendency. In such cases, the values of the geometric mean as a central tendency performance measure could be compromised.

An additional complication exists for the regulator using the geometric mean to judge compliance. Because the logarithm of the value must be taken, dose projections of zero must be removed from consideration altogether (the logarithm cannot be calculated). However, extremely low (and highly influential) non-zero values may be retained in the analyses, simply because computers are able to track them. That is, projected doses that are in reality essentially indistinguishable from zero can be calculated and carried through the analysis. If care is not taken, projections could include doses such as 10^{-20} mrem/yr, which is meaningless in actuality (and clearly the logarithmic value of -20 cannot be offset by any single high-end estimate). The regulatory analyst is then faced with the prospect of ignoring simulations that yield no dose, eliminating values below a certain level (for very low dose estimates), or assigning some arbitrary value to them simply to calculate a geometric mean. Eliminating small values from consideration would not be consistent with our cautions (see discussions on reasonable expectation) that low-end projections should not be discounted in favor of higher estimates.

It is also not proven that the distribution of performance assessment results is truly log-normal. As noted above, DOE's previously published TSPA results indicate that the distribution of the peak dose values is skewed to one side, so that values are not evenly distributed around a central point (FEIS, DOE/EIS–0250, Appendix I, Section 5.3, Docket No. OAR–2005–0083–0086). We have mentioned the role of conservatism in framing dose assessments and biasing them to high-end values, so this skewed distribution is not surprising. Such skewed distributions often appear to be log-normal, for which the geometric mean represents the central tendency. However, while we have some confidence that future DOE results will be skewed toward the high end, we cannot predict with certainty that the distributions are truly log-normal, although we can say that they display two prominent characteristics of log-normal distributions. First, the results span several orders of magnitude, making the use of logarithmic conversions effective in putting the values on a convenient scale. Second, its derivation involves multiplicative functions which are imbedded in the performance simulations, while normal distributions arise from simpler functions that are additive in nature. Their actual shape will be affected by DOE's modifications to the TSPA as it works through the licensing process. The geometric mean may not actually represent the best measure of central tendency if the distribution is not log-normal.

For these reasons, we are not proposing to use the geometric mean as the measure of compliance at the time of peak dose. This brings us to the third statistical measure we considered for these very long times, the median of the distribution, for which 50% of the values lie above and 50% lie below. The median is a simpler measure of central value for any distribution of dose estimates. It is independent of the shape of the distribution and therefore avoids concerns about how well the performance assessment results may or may not strictly conform to the normal or log-normal profiles, and attendant uncertainty about how close the respective ''means'' are to the center of the distribution. In this respect, the median is an attractive alternative to the geometric or arithmetic means as a measure of central tendency that will not be strongly influenced by high or low-end outliers in the calculated projections. There is no need to eliminate or truncate results at the low end, as there may be for the geometric mean. Further, if the distribution includes many very low estimates, the median could actually be higher than the geometric mean. As such, it is also consistent with our reasonable expectation principle.

As an additional advantage, if the distribution ultimately falls close to either a normal or log-normal distribution, the median converges with the arithmetic or geometric mean, respectively. It can be clearly seen that the median and arithmetic mean are identical for a normal distribution, as the ''mirror image'' around the arithmetic mean also shows that exactly half of the results fall on either side. For a log-normal distribution, the same result can be seen when the initial values are transformed by taking their logarithms. Since by definition the transformed data takes on the shape of the normal distribution, the geometric mean assumes the role of the arithmetic mean for that transformed distribution and is coincident with the median. From the formulas in footnote 5, it is evident that the geometric mean for log-transformed data (a log-normal distribution) is calculated in the same manner as the arithmetic mean for non-transformed data in a normal distribution. This means that, if the performance assessment results align closely with the defined normal or log-normal distributions, the median will converge with the other statistically defined measures of central tendency for those distributions. If the results are very highly skewed toward a true log-normal distribution, the geometric mean essentially equates to the median, but without the calculational issues described earlier. If less conservatism is incorporated into the analyses and the resulting distribution is less skewed so that it more closely resembles a normal distribution, the arithmetic mean essentially converges with the median and the performance measure approaches that used to show compliance within 10,000 years.

These relationships between the arithmetic and geometric means and the median are strictly correct only as long as the distributions fit the profiles for either the normal or log-normal distributions. If the actual shapes of the distributions differ to some degree from the ideal defined shapes, the means, either arithmetic or geometric, will not be coincident with the median values for the distributions, the degree of departure being dependent on exactly how much the distributions depart from the ideal ''normal'' or log-normal'' shapes. Deviations from the ideal normal and log-normal distribution shapes and the effects on these measures as representative of the central tendency for the calculated dose projections, are of critical importance in selecting the compliance measure. The likelihood of deviations discourages our use of either the arithmetic or geometric mean at the time of peak dose, but has limited effect on the use of the median.

Therefore, we propose to use the median of the dose distribution as the performance measure for compliance in the post-10,000-year period and request comment on that decision. Readers may note that our 1999 proposal, as well as 40 CFR part 191, specified that DOE use the (arithmetic) mean or median, whichever was higher. We determined that the arithmetic mean would always be higher for periods up to 10,000 years. Thus, we specified the more conservative measure to apply up to 10,000 years. However, as noted above, the arithmetic mean may be overly influenced by higher-end estimates. Therefore, we do not consider it the appropriate measure for times in excess of 10,000 years.

In summary, we propose to maintain and clarify the use of the arithmetic mean for compliance with the 10,000-year standard. We believe this is appropriate because the shorter-term projections are not as influenced by the uncertainties or variability in performance scenarios seen at much longer times. Fewer very high-end estimates are expected and, therefore, overall the distribution of doses would be less skewed and more representative of ''expected'' performance. Further, in the unlikely event that the peak dose is found to occur within the first 10,000 years, the arithmetic mean would be consistent with the statistical measure used in all other applications for geologic disposal, *i.e.*, 40 CFR parts 191 and 194 for the 10,000-year time frame. We request comment on the clarification of the arithmetic mean as the 10,000-year compliance measure. For the period extending beyond 10,000 years, we propose to use the median of the distribution of doses calculated from the performance assessments as the compliance measure, and we request comment on this choice.

6. How Will DOE Calculate the Dose?

Our 2001 standards required DOE to calculate doses as an annual committed effective dose equivalent (annual CEDE) to demonstrate compliance with the storage, individual-protection, and human-intrusion standards. Today we are proposing to modify that requirement in a way that would incorporate updated scientific factors necessary for the calculation, but would not change the underlying methodology. Specifically, we are proposing to require DOE to calculate the annual CEDE 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''). This point may seem straightforward to many readers. We wish to incorporate the most recent science into the calculation of dose, so why should we not do so? The complication arises from the terminology employed in the EnPA and ICRP 60 (and the follow-on implementing Publication 72, ''Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 5 Compilation of Ingestion and Inhalation Dose Coefficients,'' 1996, Docket No. OAR–2005–0083–0087). Section 801(a)(1) of the EnPA explicitly requires our standards to ''prescribe the maximum annual effective dose equivalent to individual members of the general public.'' Thus, we are required by law to issue an individual-protection standard presented as an effective dose equivalent. The Court agreed with this reasoning when it stated that the EnPA ''require[s] EPA to establish a set of health and safety standards, at least one of which must include an EDE-based, individual protection standard.'' (*NEI*, 373 F.3d at 45, Docket No. OAR–2005–0083–0080.)

ICRP is an independent body formed to develop consensus recommendations on appropriate radiation protection measures. In doing so, ICRP considers the principles and scientific bases involved in practices that involve the generation of radiation and radioactive materials, as well as the use of those materials. Over the years, ICRP recommendations have been adopted by regulatory authorities and other scientific and advisory bodies, and have helped to provide a consistent basis for national and international regulatory standards.

In 1977 and 1979, ICRP published Report Nos. 26 and 30 (''Limits for Intake of Radionuclides by Workers''), respectively (Docket Nos. OAR–2005–0083–0087). These two reports reflect advances in the state of knowledge of radionuclide dosimetry and biological transport of radionuclides in humans that occurred over the 20 years since ICRP's 1957 dose methodology recommendation (ICRP 2). This methodology, known as the effective dose equivalent (EDE) methodology, is the basis for dose calculations performed to demonstrate compliance with 40 CFR part 191 and envisioned to be applied (although not specified) in the 2001 version of 40 CFR part 197. The EDE methodology was first incorporated into Federal Guidance in 1987, in ''Radiation Protection Guidance to Federal Agencies for Occupational Exposure'' (52 FR 2822, January 27, 1987; Docket No. OAR–2005–0083–0078).

The basis of the EDE methodology is that each organ in the body reacts to radiation differently, *i.e.*, some are more likely than others to react by developing a cancer. This methodology takes these differences into account by assigning a ''weighting factor'' to each organ relative to the whole body. The weighting factor reflects the likelihood, that is, risk, of fatal cancer developing in that organ per unit of dose. When added together, the risk-weighted doses incurred by the individual organs of the body become the ''effective dose equivalent.'' In this manner, the risk of radiation exposure to various parts of the body can be regulated through use of a single numerical standard.

ICRP 26/30 uses the term ''effective dose equivalent.'' ICRP 60/72, which offers some improvements to the biokinetic models used in ICRP 30 and thereupon updates the organ-weighting factors based on more recent scientific studies, uses the term ''effective dose.'' It may appear from this difference in terminology that we cannot both fulfill our statutory mandate and specify the use of the ICRP 60/72 factors.

However, we do not believe this is the case. First, ICRP made it clear in Publication 60 that it was adopting the shorter nomenclature for ease of use, but did not intend to change the underlying approach of ICRP 26/30: ''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*'' (ICRP Publication 60, p. 7, Docket No. OAR–2005–0083–0087).

Second, we have used the different terms interchangeably in various applications over the years. Historically, this concept has been referred to as effective dose equivalent, effective dose, and total effective dose equivalent, depending on when the terms were used and the weighting factors applied. The concept of a ''committed'' dose is inherent in the methodology (and recognized by ICRP, as in the previous citation), but we have applied the term to more explicitly acknowledge the continuing dose contribution over a period of years from radionuclides taken into the body through ingestion, inhalation, or absorption.

For example, our standards in 40 CFR part 191 are written in terms of committed effective dose (CED). These standards were finalized in 1993, after the publication of ICRP 60 and passage of the EnPA. At that time, our most recent Federal Guidance Report No. 11, ''Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion'' (EPA–520/1–88–020, September 1988, Docket No. OAR–2005–0083–0071), which was issued to serve as the basis for regulations setting upper bounds on exposures in the workplace, specified the ICRP 26/30 method to calculate CEDE. Appendix B of 40 CFR part 191 also specified use of the ICRP 26/30 weighting factors, but to calculate CED. Thus, we used two different (albeit similar) terms to represent the use of an identical methodology and associated weighting factors. From this, it should be clear that we have historically considered CED and CEDE to represent essentially the same approach, regardless of the weighting factors used.

In today's proposal, we are specifying in the definition of effective dose equivalent in § 197.2 that DOE will calculate annual CEDE using the radiation- and organ-weighting factors in ICRP 60/72, which we are proposing to be incorporated into a new Appendix A. This represents the most recent science and dose calculation approaches in the area of radiation protection, which we previously endorsed in our Federal Guidance Report No. 13 (''Cancer Risk Coefficients for Environmental Exposure to Radionuclides,'' EPA 402–R–99–001, September 1999, Docket No. OAR–2005–0083–0072). We believe this change is appropriate and reflective of the direction of the international radiation-protection community as well as EPA's own guidance. Furthermore, we believe this approach is consistent with the intent and direction of the EnPA. The EnPA directs us to prescribe our standard for protection of individuals in the form of a general class of standards known as effective dose equivalent standards. We have done that by using a standard in the form of committed effective dose equivalent, which is a member of the class of effective dose equivalent standards. We request comment on this proposed change.

Regardless of the preferences of radiation experts, the public may be unfamiliar with the differences between the two methods and ask whether a given dose level (for example, 15 mrem/yr) is equally protective when expressed under each method. The calculation of dose from individual radionuclides may be affected in different ways, depending on which organs they tend to affect and the pathway through which they enter the body. For example, consider two radionuclides that occur in the expected inventory at Yucca Mountain, such as technecium-99 and neptunium-237. For a given intake, the dose from technecium-99 is higher using the ICRP 60/72 system than it is using the ICRP 26/30 system. On the other hand, the dose from a given intake of neptunium-237 is lower using the latter system compared to that calculated using the former. However, in the majority of cases, the effect of changing from one system to the other is small (''Dosimetric Significance of the ICRP's Updated Guidance and Models, 1989–2003, and Implications for Federal Guidance,'' ORNL/TM–2003/207, August 2003, Docket No. OAR–2005–0083–0070). Further, the overall factors used to convert dose to risk remain unchanged by today's proposal. Therefore, the estimated risk from a given radiation dose remains the same. Therefore, the 15 mrem/yr standard incorporated into today's proposal represents the same level of protection as the originally promulgated standards.

We have also considered whether to allow for the use of future updates to the organ weighting or other factors. We believe this may be appropriate because DOE will continue to perform projections for many years, and the final demonstration before repository closure and license termination may be decades or even more than one hundred years into the future. A provision allowing such updates ensures that the most current science can be applied at all times. Therefore, we are including a provision in our proposed Appendix A allowing DOE to use, with NRC approval, updated dose calculation factors. We have tried in today's proposal to make clear the basis for our acceptance of the ICRP 60/72 factors as sufficiently validated to be incorporated into rulemaking. To ensure that such factors that might be considered in the future have been appropriately reviewed and accepted by the scientific community, we propose that NRC may only approve factors that have been issued by independent scientific bodies (such as ICRP and its successor bodies) and incorporated by EPA into Federal Guidance. To ensure compliance with the EnPA, we would also require that the new approach be compatible with the effective dose equivalent methodology incorporated into today's proposal. We request comment on this approach.

Commenters may be aware that the NAS released in June 2005 the latest in a series of studies on the Biological Effects of Ionizing Radiation (BEIR VII, Docket No. OAR–2005–0083–0087). EPA is a major sponsor of these studies, which we consider in developing our regulations and Federal Guidance. The BEIR VII report reaffirmed that evidence exists that even the smallest radiation dose may convey some risk of incurring a cancer, and that risk increases proportionally to the dose (*i.e.*, if the dose doubles, the risk also doubles). This approach, known as the ''linear non-threshold'' hypothesis, has served for many years as the basis for all radiation protection regulation and guidance, including those issued by EPA. Further, the linear non-threshold approach is the source of the assumptions regarding the dose-risk relationship underlying both our 2001 rulemaking and today's proposal. Thus, the primary conclusion of the BEIR VII study does not affect the revision of our Yucca Mountain standards.

For a detailed discussion of potential health effects related to exposure to radiation, as well as further explanation of the underlying relationship between radiation dose and cancer risk, see the preamble to the 1999 proposed rule (64 FR 46978–46979, August 27, 1999, Docket No. OAR–2005–0083–0041) and Chapter 6 of the 2001 BID (Docket No. OAR–2005–0083–0050).

D. How Will Today's Proposal Affect the Way DOE Conducts Performance Assessments?

We find it important to emphasize certain key aspects of the performance assessment that will apply regardless of the time frame involved. First, the overall purpose of our standards is to provide a reasonable test of disposal system performance. The overall purpose of the performance assessment is to provide a reasonable test for compliance with those standards. A major part of providing that reasonable test is determining which features, events, and processes (FEPs) are to be included in the performance assessment performed by DOE. Regardless of time frame, we find it reasonable to limit the consideration of FEPs and scenarios (sequences or combinations of FEPs) to those reasonably likely to occur and to affect the disposal system during the compliance period. Finally, in addressing those scenarios, it is also reasonable to further prescribe certain aspects of the way they are considered (''stylizing''), particularly when their characteristics are difficult to establish with confidence. This section provides an overview of the performance assessment process and addresses in more detail the key aspects just mentioned.

The long-term performance of the disposal system is assessed through complex probabilistic computer simulations aimed at quantifying the behavior of the disposal system over time. The change in the compliance period does not affect fundamentally how the disposal system performance assessment simulations are constructed and executed. The performance assessment takes into consideration the physical and chemical characteristics of the disposal system, and imposes on that characterization the events and processes expected to occur during the compliance period. The DOE has already conducted and published many of its performance assessment results focusing on periods up to 10,000 years to support its Viability Assessment, FEIS, and site recommendation. While many of those projections did cover times up to 1 million years, DOE did not focus as much attention on the assumptions and characterization of those longer-term processes and events, or necessarily conduct those projections in a way suitable for demonstrating compliance with a regulatory standard because there was no quantitative standard past 10,000 years. Today we are proposing certain provisions that will affect DOE's treatment of longer-term projections for compliance purposes, but will not alter the requirements issued in 2001 for compliance within 10,000 years.

The performance assessment is developed by first compiling listings of features (characteristics of the disposal system, such as the description of the disposal system geologic setting), events (discrete events that can occur at the site, such as seismic events, *i.e.*, earthquakes), and processes anticipated to be active during the performance period of the disposal system (such as corrosion processes operating on the metallic waste package). These items are collectively referred to as ''FEPs'' (features, events and processes). These FEPs are then used in combination to construct scenarios, which are essentially potential ''futures'' for the disposal system. A scenario describes one possible path along which the disposal system could evolve from the time of closure through the time of peak dose. Individual FEPs are components of scenarios and can be combined in various ways; while some FEPs, such as infiltration of water through the repository, will be included in nearly all scenarios, low-probability FEPs may appear in only a few. Thus, a scenario can be visualized as a time history for the disposal system, beginning, for example, with precipitation over Yucca Mountain and water infiltration into the subsurface above the repository, and ending with a dose assessment for the down-gradient RMEI making use of the ground water moving from beneath the site. Natural parameter variations (such as differing ground-water movement rates through the repository and in the aquifers below the repository) give rise to many potential ''futures'' for a particular scenario, depending on the exact parameter values chosen from the distribution of possible values, for each computer simulation of repository performance. For ease of calculations, scenarios with similar characteristics may be grouped into scenario classes. More extensive descriptions of the scenarios used to assess disposal system performance for Yucca Mountain are detailed in DOE documents supporting such analyses for various purposes (see the Viability Assessment, DOE/RW–0508/V.3, Vol. 3, Chapter 1.3, December 1998, Docket No. OAR–2005–0083–0086, and the Science and Engineering Report, DOE/RW–0539, Chapters 4.3 and 4.4, May 2001, Docket Nos. OAR–2005–0083–0069).

Scenarios have differing probabilities, depending on the likelihood of particular FEPs included in them. The dose results calculated for individual scenarios are weighted as a function of their probability to develop an overall distribution of doses with time that is the final product of the analyses. From this distribution of doses, compliance with the regulatory standard is determined in the licensing process.

In considering how to approach assessments potentially out to 1 million years, we have considered international consensus on the qualitative nature of such calculations. Although also true at the 10,000-year time frame, for peak dose it is even more evident that the performance assessment cannot be viewed as a predictor of future events and resultant releases. Instead the goal is to design an assessment that is a reasonable test of the disposal system under a range of conditions that represent the expected case, as well as relatively less likely (but not wholly speculative) scenarios with potentially significant consequences. The challenge is to define the parameters of the assessment so that they demonstrate whether or not the disposal system is resilient and safe in response to meaningful disruptions, while avoiding extremely speculative (and in some cases, fantastical) events. As NAS notes, ''The results of compliance analysis should not be interpreted as accurate predictions of the expected behavior of a geologic repository'' (NAS Report p. 71).

We recognize that many uncertainties can be bounded, and methods exist to take these uncertainties into account in evaluating compliance of the disposal system. Examples include the use of cautious, but reasonable, parameter values and assumptions that ensure the models err on the side of conservatism, and the use of probabilistic models in order to explore the range of possibilities of total system evolution. We further recognize that it can be difficult to determine when conservatism is appropriate and when it is excessive. However, as discussed earlier in this preamble, we are concerned that systematic conservatism in the face of uncertainties is inconsistent with the concept of reasonable expectation embodied in our standards. This view is also shared at the international level. A joint report by the IAEA and the NEA concludes that ''[w]hen uncertainty exists there is a tendency to skew the model or values of parameters towards conservatism,'' which ''results in embedded conservatism'' (''An International Peer Review of the Yucca Mountain Project TSPA–SR,'' p. 52, 2002, Docket No. OAR–2005–0083–0062). However, those aspects of the disposal system and waste behavior that depend upon physical and geological properties can be estimated within reasonable limits of uncertainty.

Still, ''[e]ven in the initial phase of the repository lifetime, a compliance decision must be based on a reasonable level of confidence in the predicted behavior rather than any absolute proof'' (NAS Report p. 72). For performance projections made past 10,000 years, the confidence that can be placed in those projections decreases as time increases. While NAS indicated that analyses of the performance of the Yucca Mountain system dealing with the far future can be bounded, ''the uncertainties in some of the calculations that might be required could render further calculation scientifically meaningless'' (NAS Report p. 29). What is more, a different panel convened by NAS has recently stated that uncertainties often become so large that the results of a risk assessment must be deemed indeterminate (''Risk and Decisions About Disposition of Transuranic and High-Level Radioactive Waste,'' NAS, p. 91, 2005, Docket No. OAR–2005–0083–0060). Regarding natural processes and/or events that can occur during a large period of time, it becomes necessary to restrict the scenarios available to include in a performance assessment by not including events or processes that have a nearly negligible probability of occurrence over the period of geologic stability, or that introduce additional uncertainty without providing significantly new or different information about the performance of the disposal system.

It is neither useful nor necessary for EPA to require DOE to predict or model every conceivable scenario that could occur at Yucca Mountain. Rather, we believe that it is our responsibility to design a reasonable test of the disposal system's performance over a very long time period. This implies that some possible performance scenarios should not be included in the performance assessment because their probability of occurrence is extremely low. As a means of restricting scenarios, in setting the standards in 40 CFR part 197, the Agency outlined how to identify FEPs. For purposes of the performance assessment, the value of considering a particular FEP (or series of FEPs) diminishes if either its likelihood of occurrence or its potential consequence is insignificant. Therefore, a time frame and probability cut-off measure are needed to limit the range of FEPs that could be included as candidates for the performance assessment. Without such measures, the list of FEPs would be limitless, bounded only by the imagination. The Agency determined that FEPs that could occur with a probability equal to or greater than 1 in 10,000 over a period of 10,000 years would be sufficiently likely to occur, so that they should be included among the FEPs available for selection in any particular scenario. FEPs with lower probabilities could be excluded from the analyses. This probability limit represents an annual probability of occurrence of 10^{-8} (1 in 100 million). This means, for example, an event with this minimum probability has only a one-hundredth of one percent chance of happening in any given 10,000-year period. This is an extremely conservative screening criterion. Extending the regulatory compliance period to as much as 1 million years and maintaining the annual probability cut-off of 10^{-8} would still mean that FEPs with only a one percent chance of occurring over this time period must be considered. This probability cut-off for screening FEPs for inclusion in the disposal system performance assessment provides a robust test of compliance, in that even FEPs with very low probabilities are not a priori excluded from the assessments.

Given the conservative nature of this low probability cut-off for initial FEPs screening efforts, the application of the screening criteria still produce a large number of scenarios that could be postulated, presenting perhaps an unmanageable task for the analyses and ultimately the regulatory compliance decision. In the generic rule for geologic disposal, 40 CFR part 191, and the 2001 rule for Yucca Mountain, we provided a means to manage the situation, by allowing individual FEPs or scenarios to be deleted from the licensing performance assessment if they contribute little to the dose received by the RMEI, i.e., their consequences are low—either due to the low probability of the FEPs or the low doses calculated for the scenario. In extending the regulatory performance period in the regulation to the time of peak dose, a similar provision aimed at managing the scope of the analyses is called for.

The need to maintain the assessment within a reasonable scope as a way to manage uncertainties leads us to conclude that a strict extension of the approach for 10,000-year assessments would not accomplish this overall goal. If, for example, we required consideration of events with a probability of occurrence of 10^{-4} over 1 million years ''an approach that has been suggested by some stakeholders '' it would equate to an annual probability of 10^{-10} (one in 10 billion), which encompasses events nearly as remote as the ''big bang'' that created our universe. No disposal system, and perhaps not even our planet itself, would be expected to survive the effects of such an event, and we therefore do not find it a useful indicator to distinguish between safe or unsafe performance of the disposal system. There are an unlimited number of possible futures, some of which would involve risks from a repository and others that would not. We must balance these factors 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).

In addition, NAS recommended ''against an approach under which a large number of future scenarios are specified for compliance assessment, since such an approach could be seen as putting both the regulator and the applicant in the indefensible position of claiming to have considered a sufficient number of scenarios and that all reasonable future situations are represented in the analysis'' (NAS Report p. 98). NAS explicitly recognized that ''[i]t is important that the 'rules' for the compliance assessment be established in advance of the licensing process; that is, that the scenarios that might be excluded from the integrated risk analysis be identified'' (NAS Report p. 73). We emphasize that the purpose of making exposure scenario assumptions is not to identify exhaustively every possible future, but to construct a reasonable (or, as NAS put, a ''fair'') test of disposal system performance for the protection of public health. This is the case regardless of the time frame involved, and from that perspective today's proposal will not alter the way in which DOE will approach its performance assessments.

In addition to placing limits on the probability of FEPs that should be considered, an additional tool to construct the test (or set ''the 'rules' for the compliance assessment,'' as NAS stated) is to specify how certain scenarios should be assessed. This ''stylizing'' of scenarios is similar to the approach we took (and NAS recommended) to defining the human-intrusion scenario. In a more general sense, NAS acknowledged that establishing the ''rules'' ''requires using the rulemaking process to arrive at a regulatory decision about certain assumptions as part of the standard'' (NAS Report p. 34). The NEA has also recommended exploring the possibility of using a similar stylized approach to address uncertainties in the evolution of the surface environment and the nature of future human actions (''The Handling of Timescales in Assessing Post-Closure Safety,'' pp. 22–23, 2004, Docket No. OAR–2005–0083–0046). This approach would avoid speculation regarding the evolution of the geologic environment at times when the hazards associated with the waste are reduced compared to when the waste is emplaced.

Stylized approaches can be utilized to address associated uncertainties in order to allow consideration of events that are deemed potentially important to performance but whose characteristics are difficult to establish with certainty. There is international consensus that this approach may be used to define assumptions that are too difficult to bound (NEA, p. 22, Docket No. OAR–2005–0083–0046). This approach could therefore be used for the determination of the evolution of the geological environment over long periods. As noted above, this approach is similar to that recommended by NAS, and utilized by EPA in examining human intrusion (NAS Report p. 108). The NAS determined that it was technically infeasible to assess the probability of human intrusion into a repository over the long term. It concluded that it was not scientifically justified to incorporate a myriad of alternative scenarios of human intrusion into a fully risk-based compliance assessment that requires knowledge of the character and frequency of various intrusion scenarios. Accordingly, NAS recommended that we specify in our standards a typical intrusion scenario to be analyzed for its consequences on the performance of the repository. The intent of this ''stylized scenario'' is to avoid non-productive speculation on the forms and frequencies of intrusion that can never be predicted, while allowing the ''robustness'' of the containment properties of the repository to be evaluated by a scenario that is plausible, and potentially causes some levels of exposure. The same factors must be balanced in considering how to assess key geologic and other features over very long time frames when it is exceedingly difficult to establish exact parameters—or even distributions of parameter values—with any certainty.

The modifications proposed in Section II.C (''How is EPA Proposing to Revise the Individual-Protection Standard to Address Peak Dose?'') would require DOE to project exposures to the RMEI until the time of peak dose and subject them to a compliance determination. The key aspects emphasized at the beginning of this section guide our requirements for the scope of performance assessments both at 10,000 years and over times extending through the entire period of geologic stability. However, their implementation carries different implications for those different time periods, given the nature of uncertainties and the types of events that can be envisioned to occur. To address these implications, we are proposing four provisions that will affect the judgment of compliance when that judgment is extended to periods up to 1 million years. Specifically, we are proposing:

- A separate compliance standard for the peak dose beyond 10,000 years;
- That compliance beyond 10,000 years be demonstrated using the median of the distribution of results;
- That FEPs and scenarios not included in the 10,000-year analysis because of their limited consequence during that period need not be considered in the peak dose calculations;
- That scenarios involving climate change, seismic activity, igneous activity, and general corrosion be explicitly considered in the peak dose calculations.

We have already discussed the peak dose standard and the use of the median to demonstrate compliance (see Sections II.C.3 and II.C.5). The selection of FEPs (including general corrosion) is discussed in detail in Section II.D.2.a (''Consideration of Likely, Unlikely, and Very Unlikely FEPs''). Discussion of climate, seismic, and igneous scenarios is included in Sections II.D.2.b, c, and d, respectively.

1. Performance Assessments Up To 10,000 Years After Disposal

Our 2001 rulemaking established a framework within which DOE would conduct its performance assessments to show compliance with the 10,000-year standard. The previous section touched on various aspects of this framework. Essentially, the performance assessment involves three basic steps: (1) Identify the FEPs and scenarios that might affect the Yucca Mountain disposal system, along with their probabilities of occurrence; (2) examine the effects of those FEPs and scenarios on disposal system performance; and (3) estimate the dose consequences from those FEPs and scenarios, weighted by their probabilities of occurrence. Today's proposal will not affect this framework in any way.

We supplemented this basic framework with two additional provisions. The first, the underlying principle of reasonable expectation, we have discussed in detail in Sections II.A.4 and II.B. The other important provision, touched on in the previous section, establishes the approach to identifying FEPs and scenarios and their probability of occurrence. We specified that FEPs or scenarios with a probability of occurrence lower than 1 in 10,000 over 10,000 years need not be considered in the performance assessment. FEPs or scenarios with a higher probability of occurrence also need not be considered if they would not significantly change the results of the performance assessment. We are not proposing to alter this provision as it applies to the 10,000-year standard. The standards in 40 CFR part 191 (the EPA regulation that addresses geologic disposal generically) also used this formulation as the means of determining FEPs for any prospective disposal system. In developing 40 CFR part 197 in 2001, the Agency determined that there was no reason, on a site-specific basis, to depart from this conservative screening criterion. We also note that NAS endorsed this same probability level in its specific discussion of volcanism, and suggested that such a level ''might be sufficiently low to constitute a negligible risk [of occurrence]'' (NAS Report p. 95). Probabilities below this level are associated with events such as the appearance of new volcanoes outside of known areas of volcanic activity or a cataclysmic meteor impact in the area of the repository. We believe there is little or no benefit to public health or the environment from trying to regulate the effects of such very unlikely events.

2. Performance Assessments for Periods Longer Than 10,000 Years After Disposal

As discussed in the previous sections, we do not believe that DOE's performance assessments need be changed fundamentally to accommodate an extended compliance period. The general framework described in the previous section applies equally well to periods beyond 10,000 years, although we are proposing specific provisions to apply to this longer period. We recognize, however, that there may be some confusion regarding the conduct of assessments to demonstrate compliance at two different times. DOE will not necessarily conduct one set of assessments to show compliance with the 10,000-year standard, and a separate set of assessments to show compliance with the peak dose standard applicable at times beyond 10,000 years. Rather, DOE's overall approach could be to run its dose assessments from the time of facility closure to the end of the period of geologic stability (1 million years after closure). The FEPs and scenarios selected for each individual run would continue to operate, and the disposal system to evolve, over that entire time period. DOE would extract the results necessary for comparison with our regulatory standards.

As it is with the 10,000-year standards, the main purpose of the post-10,000-year standards is to provide a reasonable test of the performance of the disposal system. The NAS stated it another way: ''The challenge is to define a standard that specifies a high level of protection but that does not rule out an adequately sited and well-designed repository because of highly improbable events'' (NAS Report p. 28).

In formulating our approach to an extended compliance period, we began by reviewing the NAS report. NAS concluded that several gradual and episodic natural processes or events have the potential to modify the properties of the repository and the processes by which radionuclides are transported. NAS concluded that the probabilities and consequences of modifications generated by volcanic eruptions (volcanism), seismic activity, and climate change are sufficiently boundable so that these ''modifiers,'' as it termed them, can be included (along with an undisturbed scenario) in performance assessments that extend over the expected period of geologic stability (on the order of 1 million years) in the Yucca Mountain region (NAS Report p. 91). NAS considered the ''long-term stability of the geologic environment at Yucca Mountain'' to describe the situation where geologic processes such as earthquakes (and similar physical and geological processes that could affect the performance assessment at the Yucca Mountain site) are sufficiently quantifiable and the related uncertainties boundable that the performance can be assessed (NAS Report p. 67). Furthermore, NAS acknowledged that, conceptually, there is a need for screening criteria to distinguish significant FEPs from those that can be considered to have negligible effects (NAS Report, for example, pp. 59, 61, 72, 95, 98). NAS suggested that certain levels (including a probability cut-off of 10^{-8} per year) might be appropriate, but made no recommendation on this issue.

We believe the three categories of FEPs identified by NAS deserve special attention. We will require that DOE consider these FEPs in its long-term projections. However, we are proposing to apply the same overall probability threshold and handle such events in a stylized manner to address only their most significant effects. In essence, DOE must include such FEPs in the peak dose assessment, but need not assess in detail every conceivable variation on those events. Thus, our approach would require that DOE develop reasonable igneous, seismic and climate change scenarios and assess the most likely and significant impacts, with appropriate variability in its assumptions, on dose projections. The NAS did not identify any other ''modifiers'' that it expected could be addressed in a quantitative risk assessment covering the period of geologic stability. In addition, NAS specifically mentioned potential effects of these modifiers, but also noted that, while possible, many of these effects would be so unlikely or limited that they would not be expected to significantly affect disposal system performance (NAS Report pp. 91–95). These igneous, seismic, and climatological FEPs are discussed in more detail in the following sections. We propose to specify certain significant aspects or characteristics of the event or process to which DOE may limit its analyses, and DOE will assess reasonable variations within those bounds, considering such basic assumptions as severity and time of occurrence. DOE must then evaluate the consequences on the disposal system and resulting impacts to the RMEI. By varying the time of occurrence within the probability framework, DOE can also address the effects of these FEPs on the peak dose.

Having identified particular natural FEPs that should be considered throughout the period of geologic stability, we then considered whether there are FEPs affecting the engineered barrier system that should also be identified. In reviewing DOE's published TSPAs and other relevant information, we conclude that general corrosion of the waste packages has been shown to be a potentially significant failure mechanism at times in the hundreds of thousands of years (Yucca Mountain Science and Engineering Report, DOE/RW–0539, Section 4.2.4, May 2001, Docket No. OAR–2005–0083–0069). Unlike certain other corrosion processes, as discussed in the next section, which may be more likely or faster-acting at earlier times, general corrosion may not be a significant factor within 10,000 years and could potentially be removed from consideration at those times because of its limited consequence. Were we simply to state that FEPs not included in the 10,000-year analyses should not be included in the post-10,000-year analyses, there might be some question as to whether DOE would need to consider general corrosion at all. We believe it has been shown potentially to be of sufficient importance that it should be included in those projections. Therefore, we are proposing to remove any ambiguity by specifying that DOE must consider general corrosion in its projections throughout the period of geologic stability.

In general, we continue to believe that it is reasonable to require DOE to exclude from performance assessments those FEPs whose likelihood of occurrence is so small that they are very unlikely, or whose consequence is minimal, as described above. We propose that this probability threshold as expressed in our 2001 rule for the 10,000-year compliance period be extended throughout the entire period to peak dose (*i.e.*, FEPs included in the 10,000-year assessments are included in the assessments beyond 10,000 years), but with the inclusion of the long-term impacts of seismicity, volcanism, and long-term climate change, as consistent with the probability screening criteria described herein (NAS Report p. 94). These are the natural events and processes that NAS determined were reasonably boundable when compliance time frames at Yucca Mountain are extended out to the period of geologic stability. We also propose that DOE must consider the long-term effects of general corrosion on the engineered barriers, particularly on waste package integrity. This is an extremely inclusive standard. It captures significant events in the life of the repository, and yet is not so restrictive that no repository could ever pass, given that there would be no limit to the speculation of scenarios that could occur during the period of geologic stability.

As discussed further in the following sections, we have examined a variety of events and feel confident that the screening analysis for 10,000 years—with the assurance that seismic, igneous, climate change, and general corrosion scenarios are included—includes the appropriate range and severity of FEPs to also serve as a reasonable test of disposal system performance throughout the period of geologic stability. We have not (and have not claimed to) conducted an exhaustive or detailed analysis of variations or permutations of scenarios out to the time of peak dose. In fact, this is precisely the sort of unrestrained and speculative exercise we wish to avoid. We recognize that some commenters may believe it is appropriate to consider whether further analysis or new data could reveal that an event excluded from the 10,000-year screening is important to performance of the disposal system over the geologic stability period. As discussed later, we do not believe such scenarios are either very likely or very important to performance. Nor do we believe that this approach inappropriately constrains NRC, as the licensing authority. Rather, we consider this approach to be consistent with the NAS position that conducting compliance assessments ''requires using the rulemaking process to arrive at a regulatory decision about certain assumptions as part of the standard'' (NAS Report p. 34).

a. Consideration of Likely, Unlikely, and Very Unlikely FEPs

Our individual-protection standards (§ 197.20) as promulgated in 2001 required DOE to consider in the performance assessment FEPs with a one in 10,000 or greater chance of occurring during 10,000 years. FEPs below this probability threshold are considered ''very unlikely'' and can be discounted based on probability alone. We also allowed NRC and DOE to remove from consideration FEPs with a higher probability if their effects on performance assessment results were determined to be insignificant. In addition, performance assessments conducted to show compliance with the human-intrusion and ground-water protection standards may exclude FEPs considered ''unlikely.'' We specified that NRC was to determine the probability below which FEPs would be considered unlikely. NRC set that figure at a probability of occurrence of 1 in 10 over 10,000 years (equivalent to an annual probability of 10^{-5}) (67 FR 62634, October 8, 2002, Docket No. OAR–2005–0083–0059).

In extending the period of compliance, we must consider whether our threshold for probability screening of ''very unlikely'' FEPs remains appropriate. We believe it does, and are proposing to retain it for the extended compliance period. While we are retaining the compliance standard of 150 µSv/yr (15 mrem/yr) applicable to 10,000 years, we are also proposing to introduce a second compliance standard of 3.5 mSv/yr (350 mrem/yr) for the peak dose beyond 10,000 years, which could potentially apply up to 1 million years. This may lead some commenters to suggest that the formulation for FEPs screening should simply be extended by two orders of magnitude, *i.e.*, that very unlikely FEPs would have less than a one in 10,000 chance of occurring over 1 million years. This would recognize that very low-probability FEPs would become more likely to be seen simply with the passage of time (essentially by looking at many 10,000-year periods, the cumulative probability, rather than annual probability, would be increased). However, in our view, such a formulation would be unjustified and unreasonable.

It is important to consider the real meaning of these probability thresholds. A FEP screened in at the existing lower probability threshold would have only a 0.01% chance of occurring through 10,000 years, yet still must be included in the FEPs considered for the performance assessment. We question, then, whether the effort involved in incorporating even less likely events into the ''FEP pool,'' with the level of speculation likely to be attached to them, would be rewarded with even minimal contribution to safety.

The threshold for very unlikely events suggested by NAS was an annual probability of 10^{-8} (1 in 100 million per year), which NAS equated to 1 in 10,000 over 10,000 years, stating that this level ''might be sufficiently low to constitute a negligible risk'' (NAS Report p. 95). We consider these two expressions to be functionally equivalent (and have explicitly included both in our proposal today), but adopted the latter as more clearly tied to the 10,000-year compliance period. Even though the NAS statement above was referring to volcanism, we believe that this probability threshold is a generic consideration that is applicable to any risk at Yucca Mountain, not just volcanism. If one extends the time period of the assessment to 1 million years, a FEP at this level would still have only a 1 in 100, or 1%, chance of occurring within that time, but would still be considered in the performance assessment process. We believe this is a ''cautious, but reasonable'' level, especially when considering the confounding effects of uncertainties at such long time periods. In fact, we are unaware of any international precedents for scrutinizing FEPs of this low probability. Thus, we are proposing to retain the 10^{-8} annual probability threshold for very unlikely FEPs for both the 10,000-year and post-10,000-year assessments.

Application of this screening criterion deserves some additional discussion. For FEPs involving the natural barrier, an annual probability of 10^{-8} theoretically indicates that to compile a definitive list of all FEPs involving the natural barrier, the geologic record at the site would have to be examined back to a time frame of 100 million years to identify FEPs that would be projected to occur at least once in that time period. For the Yucca Mountain site, the volcanic rocks containing the repository are only on the order of 10 million years in age, indicating that essentially any FEP that could be identified in the geologic record during the 10 million year time frame would have an annual probability higher than 10^{-8}, and would be included in the list of FEPs for scenario construction. We believe that the Quaternary period, extending back approximately 2 million years, is a sufficiently long period of the geologic record to allow DOE to make reasonable estimates of natural FEPs (*see* 66 FR 32100). Observed FEPs from that period, as well as other that can be inferred, would be included in a 10^{-8} cut-off.

For FEPs involving the engineered barrier, a similar logic applies. However, the ''record'' to be examined to identify FEPs for the performance of man-made materials and systems is much shorter than the geologic record. Application of the 10^{-8} annual limit ensures all relevant FEPs are considered for inclusion. For example, corrosion processes for which there is accelerated testing and analog information at longer time frames, could still be included in scenario development. Even when such processes would have a low probability, the conservative probability cut-off threshold would still assure they are considered in scenario development. For such processes, however, when probabilities of occurrence over long times may be difficult to assign, the decision to consider them may be based solely on consequence.

By contrast, were we to stretch the probability threshold by two orders of magnitude, to an annual probability of 10^{-10} (one in 10 billion per year), we would be introducing an unprecedented level of conservatism into the performance assessments. At such a level, the performance assessment would be required to consider geologic events likely to have never happened, since the age of the Earth itself is estimated at about 4.5 billion years (*http://pubs.usgs.gov/gip/geotime/age.html*). Further, an event of this annual probability will not reach even a 50% cumulative probability for another 500 million years (a total of 5 billion years), or 500 times the period of geologic stability at Yucca Mountain (defined by NAS as on the order of 1 million years). A probability threshold at that level would sweep in cataclysmic volcanic and seismic events, as well as meteor impacts of the type that extinguished the dinosaurs 65 million years ago. We simply find it inconceivable that such events could be considered a reasonable test of the repository, or that requiring them to be analyzed would provide any benefit to public health and safety. To look at it another way, an event at our current probability threshold of one chance in 100 million per year would still be likely to occur only a few times over an incremental 500 million year period, and roughly 50 times over the entire history of the earth, of which humans have been present only 0.0001% of the time. Examining the geologic record at the Yucca Mountain site for such a time period to identify FEPs would not be meaningful. Even looking at the geologic record with the 10^{-8} probability is challenging. In fact, the volcanic rocks that contain the repository were formed by very extensive volcanism over an area of thousands of square kilometers. Using the annual probability figure alone, it can be argued that such extensive volcanism should be included in the list of FEPs for the performance assessment. We strongly disagree. As emphasized by NAS, we reasonably must confine ourselves to assessing performance of the existing geologic setting. To remove such extreme assumptions, we addressed this particular difficulty by recommending the geologic record through the Quaternary (a period of approximately 2 million years) as the basis for identifying FEPs for the performance assessment (66 FR 32100). Based on this period as compared to the probability threshold we have established, DOE must consider for its performance assessments events that can be shown or reasonably inferred to have occurred during the Quaternary, based on the physical conditions of the site and disposal system.

If the same probability threshold applies at all times, as we are proposing, then the FEP screening performed by DOE for its 10,000-year projections would be expected to adequately represent those longer time periods. We believe it will, and do not believe it should be necessary for DOE to re-examine its results to ''screen in'' FEPs it has previously analyzed and rejected, or FEPs that might be expected to be more probable at longer times, if such exist. Further, our view is that it would be an endless task for DOE to analyze every FEP postulated to occur several hundred thousand years into the future, simply because a scenario can be invented to support it. Even if DOE were to exhaustively pursue each nominated FEP, their effects are likely to be minimal at best, especially when considering what are likely to be the much larger effects of increasing uncertainties and large-scale scenarios such as climate change. It should be clear, however, that FEPs selected for the analysis will continue to unfold as the assessment continues, up to 1 million years. That is, for all FEPs included in the 10,000-year analysis, DOE must project the effects of these FEPs continuing to evolve over the course of the period of geologic stability, and account for their contributions to the peak dose.

If we are starting from the basic screening for 10,000 years, it is reasonable to examine the reasons why FEPs might have been excluded from that screening when considering whether any warrant further evaluation in the post-10,000-year performance analysis. We see three general categories of FEPs (as opposed to the more specific seismic, igneous, and climatic FEPs, which are addressed separately in the following sections of this document) that may have been eliminated from the full analysis:

FEPs Screened Out by Probability

The first category consists of FEPs determined to be ''very unlikely'' to occur. As described above, these are FEPs that would have a chance of occurrence of less than one in 10,000 over 10,000 years, or an annual probability less than 1 in 100 million (10^{-8}). We see no reason to re-consider FEPs removed from the assessment based on this criterion. Such a FEP would have to be more likely to occur at some time in the future than it is now. This does not simply mean that the cumulative expectation of an event or process having already occurred is higher as time extends from 10,000 to 1 million years, which would be the case for any low-probability FEP; rather, it means that the probability itself would have to be higher at some later time (for example, 10^{-9} annual probability until year 50,000, then a 10^{-8} probability thereafter). We have not identified natural FEPs that would be very unlikely for the first 10,000 years, but would rise above that threshold within the period of geologic stability (FEPs whose probability of occurrence is related to the condition of the engineered barrier system are discussed later in this section). It may be argued that a FEP may become more likely if certain other FEPs have altered the site's characteristics in a particular way. As a basis for requiring additional FEP screening, we would find such a claim to be unreasonable and highly speculative. FEP probabilities are derived in large part from examinations of the historic geologic and climatic record going back millions of years. We suggested that the Quaternary period might be an appropriate benchmark for such an examination (66 FR 32100). Probabilities derived from such evaluations are not amenable to that level of fine-tuning. Furthermore, DOE has currently included FEPs which are at the boundary of the 10^{-8} threshold, such as volcanic events (estimated at 1.6×10^{-8}). We would not view such an exercise as useful or of value in the licensing process. We do not believe it is necessary or appropriate for NRC to re-consider the probability criterion.

FEPs Screened Out by Consequence Within 10,000 Years

Our 2001 standards allow NRC to eliminate FEPs whose effects would not significantly change the performance assessment results within 10,000 years. We are proposing today to take the same approach to the peak dose projections, giving special attention to changes to the magnitude of the peak dose. There is no reason for DOE to re-consider FEPs for their effects on the 10,000-year projections, and we are aware that some FEPs have been included whose effects are manifest at times slightly beyond 10,000 years to give perspective on the shorter-term evolution of the disposal system, such as slower-acting corrosion mechanisms.

At issue, then, would be FEPs whose effects might not be evident or as prominent until several tens or hundreds of thousands of years have passed. Such FEPs might be considered to be either gradual, continuing processes or episodic, disruptive events and processes. In general, we believe that the 10,000-year assessments should adequately address the more gradual processes and that the more significant of those processes have been included in those assessments (for example, infiltration of water through the repository and the processes leading to early failure of waste packages heavily influence the 10,000-year assessments and would do the same for peak dose projections). By the time those more gradual processes would take effect, it is likely that the effects of other processes would already be felt at a much higher level. One fundamental purpose of probabilistic performance assessment is to give proportionate emphasis to highly improbable events and processes. With one exception (discussed below), we find it unlikely that any gradual, continuing processes not already included through the screening for the 10,000-year assessments under our proposed rule could significantly affect the projections over such long time periods. It is more likely that their effects would be overwhelmed by other, higher-probability (or faster-acting) processes operating over the same period.

The single such slow-acting process we have decided to include in today's proposal is general corrosion of the engineered barriers, particularly its effects on the waste packages. We recognize that DOE has included general corrosion in its previous analyses for both the 10,000-year period and over the longer term. However, even though general corrosion is significant to performance at longer times, it might reasonably be considered insignificant within the first 10,000 years and could, thus, be screened out of the analysis to demonstrate compliance with the 10,000-year standard. Under our overall approach, were DOE to exclude general corrosion on the basis of consequence within the first 10,000 years, longer-term projections could also exclude this factor. We think such an exclusion over the period of geologic stability would ignore a crucial factor in long-term performance at Yucca Mountain. As we have noted, DOE's own analyses point to general corrosion as the dominant waste package failure mechanism, either alone or in combination with disruptive events (igneous events are assumed to be less dependent on prior degradation of waste packages). Without general corrosion assumed to act, a large proportion of the waste packages could be assumed to remain intact even up to or beyond 1 million years. Other corrosion mechanisms, such as localized corrosion, are highly correlated with temperature and would be expected to operate early in the assessment period, when temperatures inside the repository are likely to be very much higher. Stress-corrosion cracking is another mechanism that is somewhat correlated with temperature, but is of more importance in situations involving mechanical failure, such as rockfall resulting from seismic events. Their longer-term impact is likely to be greatly reduced after the repository cools. The same is not true for general corrosion. The rate of general corrosion is somewhat influenced by temperature, but this process is expected to continue even when the temperature is lower. Our proposed approach would eliminate any questions regarding whether general corrosion should be considered for the longer-term assessments.

Although general corrosion was not called out by NAS, as were the three natural FEPs, we believe this approach to general corrosion is consistent with NAS's overall expectations for the evolution of the disposal system. We have already discussed in the context of uncertainty NAS's expectation that a significant proportion of the waste packages would fail over the period of geologic stability and that, while peak doses might occur much later, significant releases could be anticipated within the first 10,000 years (see Section II.A.5, ''Effects of Uncertainty''). For example, NAS suggested that some uncertainties will be lower ''when enough time has passed that all of the packages will have failed'' (NAS Report p. 29–30); that ''uncertainties in waste canister lifetimes might have a more significant effect on assessing performance in the initial 10,000 years than in performance in the range of 100,000 years'' (NAS Report p. 72); that ''[d]etailed estimates of time for canister failure are less important for much longer-term estimates of individual dose or risk'' (NAS Report p. 85); and that ''[i]nflow of air through failed canisters and oxidation of waste prior to infiltration of water * * * would probably affect estimates of 10,000-year cumulative releases more than estimates of longer-term doses and risks'' (NAS Report p. 86). Further, NAS clearly identified corrosion as the dominant process leading to waste package failure and recognized its importance in projecting peak dose: ''Radionuclide releases from an undisturbed repository * * * can occur through * * * degradation and failure of the waste canister through corrosion'' * * *'' (NAS Report p. 26—see also pp. 68, 82, 85). We also believe our proposed approach to general corrosion is consistent with both NAS's advice to use ''cautious, but reasonable'' assumptions and our principle of reasonable expectation, as general corrosion represents a potentially significant failure mechanism leading to radionuclide releases.

Regarding natural FEPs, we are proposing that DOE explicitly evaluate the effects of seismic, volcanic, and climatological FEPs in its assessments beyond 10,000 years, as discussed in the following sections. It should be understood, however, that these FEPs may also be considered within the 10,000-year period if warranted by probability or consequence. The probabilities of seismic and igneous events beyond 10,000 years will be the same as those probabilities within 10,000 years. Events that DOE judges fall below the 10^{-8} probability threshold need not be included in either the 10,000-year or post-10,000-year assessments. Such events might include seismic episodes above a certain magnitude. There is more certainty that the climate will experience significant changes over the period of geologic stability, and therefore we require it to be considered at all times. The effects of climate change on Yucca Mountain's performance, however, are likely to be minimal within 10,000 years, and potentially more significant at longer times when most of the waste packages are breached.

FEPs Screened Out by Condition of the Engineered Barrier System Within 10,000 Years

We are aware that DOE has identified certain FEPs that were eliminated from consideration within 10,000 years because it was deemed impossible for them to occur while the engineered barrier system remains intact. We believe such FEPs should be considered as a special case, as they depend on the condition of the engineered barrier system rather than a strict probability of occurrence.

The prime example of the FEPs in this category is in-package nuclear criticality. The possibility of this occurring at Yucca Mountain was discounted within 10,000 years on the basis that the waste packages would remain largely intact during that time (although a certain level of premature failures was assumed). DOE stated that ''One of the required conditions is the presence of a moderator, such as water, in the waste package. The waste packages will be designed to make the probability of a criticality occurring inside the waste package extremely small'' (FEIS, DOE/EIS–0250, section I.2.12, p. I–21, Docket No. OAR–2005–0083–0086). At some point beyond 10,000 years, however, packages are anticipated to degrade sufficiently to allow water inside, so the reason for screening out this FEP is no longer credible. We understand that NRC has evaluated this possibility and initial results suggest that the effects would not be significant (''System-Level Performance Assessment of the Proposed Repository at Yucca Mountain Using the TPA Version 4.1 Code,'' CNWRA 2002–005, September 2002, Revised March 2004, Appendix G, Docket No. OAR–2005–0083–0067). More recently, NRC staff analyses regarding the potential effects of a criticality event within the waste package indicated that the effects would be more significant within the first 10,000 years after disposal than at longer times (''Estimating In-Package Criticality Impact on Yucca Mountain Repository Performance,'' International High Level Radioactive Waste Management Conference, Las Vegas, Nevada, March 30–April 2, 2003, Docket No. OAR–2005–0083–0082). Therefore, we do not require that DOE consider in-package criticality beyond 10,000 years if it has not been considered for the first 10,000 years. To the extent DOE's waste package assumptions make such a scenario credible within the initial 10,000 years, however, it would be appropriate to include it in the post-10,000-year projections.

There may be other FEPs that fall within this category. However, this illustrates the very possibility we wish to avoid. It is possible to generate complex and vaguely-defined circumstances and insist that DOE analyze them thoroughly. We see such an exercise as being of no value. Rather, we believe it would be detrimental to the licensing process, as well as contrary to our ''reasonable expectation'' concept and the idea that performance assessments should represent credible projections of disposal system safety.

Having considered the various types of FEPs that may have been excluded from the 10,000-year analysis, our goal is to require an appropriate consideration of FEPs in the analyses beyond 10,000 years. We considered an approach that would provide NRC with broader flexibility to consider previously excluded FEPs that it believes should be included in the peak dose analyses, perhaps based on the effect of the FEP on the magnitude of the peak dose. However, we believe that any potential FEPs to be included are likely to be overwhelmed by increasing uncertainties or larger-scale FEPs such as climate change. For this reason, we do not believe the inclusion of such FEPs will add materially to the understanding of the disposal system's performance or will lead to a safer disposal system. Furthermore, as stated earlier, we are guided by our reasonable expectation principle in not requiring an exhaustive and completely accurate prediction of repository conditions over a million-year period. See Sections II.A, II.B, and II.C for discussions of the relative confidence in calculations at very long times, and the need to view those calculations in a more qualitative way. We aim to construct a reasonable test of the disposal system that accounts for the possible occurrence of significant FEPs at Yucca Mountain, and the system's response to those stresses. We believe that proposing the continued exclusion from peak dose calculations of events that are inconsequential for 10,000 years, with the exception of general corrosion and those identified by NAS, is consistent with this approach.

To summarize our proposal for § 197.36, we propose that DOE continue to use the FEPs selected for compliance with the 10,000-year projections in its projections for peak dose. This does not require that DOE continue to define the characteristics of those FEPs in exactly the same way it has previously (for example, in the FEIS). Rather, DOE may continue to refine its representation of FEPs in the analyses as its understanding of the factors involved improves. The contribution to dose estimates of FEPs selected for the analyses must be assessed throughout the period of geologic stability. We do require that DOE explicitly consider the effects of seismic, igneous, and climate change scenarios, within the overall probability constraints, as described in more detail in the following sections. We also require that DOE consider the effects of general corrosion throughout the period of geologic stability. We have considered two approaches for doing so. Under the first approach, consistent with our approach to climate change outlined in Section II.D.2. DOE may apply a constant representative corrosion rate throughout the period of geologic stability. Under the second approach, consistent with our approach to seismic and igneous FEPs outlined in Sections II.D.2.b and c, DOE may apply corrosion rates as derived for the 10,000-year period, which may be dependent on other factors, such as temperature within the repository.

We have stated our concerns that the screening process should not be used to put forward highly speculative and implausible situations for DOE to analyze. It is our belief that the relevant FEPs are already captured within the 10,000-year screening process, and that any others would be overshadowed by other aspects of the longer-term modeling. We believe our proposal to explicitly include certain FEPs important to the longer-term projections appropriately balances these considerations. We request comment on this approach.

b. Consideration of Seismic FEPs

The NAS stated, and we agree, that the effects of seismicity in the area on (1) the repository and (2) the hydrologic regime are key aspects to be considered during the period of geologic stability (NAS Report p. 93). The effects of seismicity may result in (most significantly) early waste package failure, an increase or decrease in conductivity (movement of water) in the saturated or vadose zones, or a shift in direction of fluid movement in the area (NAS Report pp. 92–93). In addition, we believe the potential effects of seismic activity on the structural stability of the repository itself (*i.e.*, drift collapse) may be important in projecting the failure of waste packages.

In order to reasonably assess the effects of seismicity at the site, and yet also address the increasing uncertainty associated with magnitudes of seismic events over the greatly increased time period, we expect that DOE will take the rate of occurrence of seismic events originally derived for the 10,000-year time period and extend the calculations throughout the period of geologic stability. We are proposing that DOE may limit its assessment of seismicity to the effects on the disposal system of drift collapse and waste package failure, *i.e.*, effects on the engineered barriers that comprise an essential component of the disposal system. At times sufficiently far into the future, a wide range of possibilities could be proposed, and some (for example, an earthquake of such an extreme magnitude that it collapses all the drifts of the repository, allowing for complete destruction of the facility), no matter how remote the probability, could have far-reaching implications for the disposal system. By using this approach, we can adhere to the basic premise that the risk calculations reasonably predict the geologic environment at the repository out to peak dose. We can also capture the potential effects of seismicity and faulting at Yucca Mountain. By extending the performance period to 1 million years, it is expected that more events will occur, consistent with the established seismic hazard curve for the site. No new types or classes of seismic or fault displacement disruptive events can reasonably be anticipated. In the case of seismicity, earthquakes are most likely to occur on the existing network of active seismogenic fault sources under current tectonic conditions. In the case of the fault displacement hazard, it is more likely that fault slip will occur on existing faults that on newly created ones.

DOE has developed a seismic hazard curve that describes the seismicity to be expected at the site (''Seismic Consequence Abstraction,'' MDL–WIS–PA–00003–Rev 00, 2003, Docket No. OAR–2005–0083–0073). A seismic hazard curve determines what the probability is of any particular strength of ground shaking. The goal of probabilistic seismic hazard analysis is to quantify the rate (or probability) of exceeding various ground-motion levels at a site (or a map of sites), given all possible earthquakes. It is reasonable to assume that seismic events will continue with activity rates and magnitudes predicted by the seismic and fault displacement hazards for the site over the period of geologic stability because the geologic record indicates relative tectonic stability of the region over the past 10 million years. This implies that there is continuity in the behavior of major geologic events (such as earthquakes) over that entire time frame. Further, the geologic record extending back millions of years has been used to establish the hazard curves. There is not further data that appropriately can be incorporated into the analysis, or used to justify an adjustment of the estimates simply because they are to be projected further into the future. It is expected that more events, such as earthquakes and fault displacements, will occur with the extended performance period, but that these events are much more likely to occur on existing faults and seismic sources than on newly created ones. Therefore, the rates and magnitudes considered in the probabilistic calculations for 10,000 years can also be used to generate estimates of seismicity out to the period of peak dose. These events should be defined on an annual probability of occurrence. The magnitudes and frequencies of potential seismic events should remain the same as in the 10,000-year analysis; however, the analysis would be expected to show greater consequences as potentially more major seismic events are incorporated into the assessment as a result of extending the analysis throughout the period of geologic stability as events occur at times when packages are expected to be largely degraded and thus more easily damaged.

The NAS stated that seismologic effects on the hydrology at Yucca Mountain can also be bounded over the period of stability due to the fact that the hydrology has been influenced by many similar seismic events in the past (NAS Report p. 93). Seismic activity can account for a number of changes in the hydrology of the area, from the opening or closing of fractures and large-scale changes in water levels to a shift in the direction of ground-water flow in the region. It could also increase the potential for enhanced movement of the radionuclides in the waste, because the potential for increased rate of water movement could contribute to a greater velocity of the ground water in the aquifer, which could reduce the travel time of radionuclides out to the boundary of the controlled area. However, we are proposing today that DOE's analysis for seismic events may exclude the effects of seismicity on the hydrology of the Yucca Mountain disposal system. In making this decision, we considered the NAS's guidance as well as the relative effects of climate change on the hydrology of the disposal system.

In its report, NAS observed that seismicity potentially can affect the hydrologic regime by causing displacements and increasing conductivity along existing fractures. NAS noted that such displacements are likely to occur along existing fractures (as opposed to creating new ones) and, further, that hydrology near Yucca Mountain ''has been conditioned by many similar seismic events over geologic time'' (NAS Report p. 93). Since no major new flow paths would be created, these statements imply that the most likely hydrologic effects are changes in conductivity or a localized shift in the ground-water flow. Nevertheless, NAS concluded that ''such displacements have an equal probability of favorably changing the hydrologic regime'' (NAS Report p. 93). We agree, and also conclude that predicting the magnitude of changes in hydraulic conductivity—whether favorable or unfavorable—or the details of localized changes in the direction of ground-water flow is highly speculative, especially in view of the highly fractured nature of the geology at Yucca Mountain.

However, we also agree with NAS that ''the effect of seismicity on the hydrologic regime could probably be bounded'' (NAS Report p. 93). The endpoint of most concern resulting from changes in flowpaths or hydraulic conductivity would be the potential for greater movement of water through the disposal system. As previously mentioned, this could enhance movement of radionuclides from the waste. Importantly, this is also the endpoint of concern for climate change scenarios. As discussed in more detail in Section II.D.2.d, we are proposing that DOE must consider climate change scenarios that result in an increased flow of water through the disposal system. Unlike seismic events, such climate change scenarios do not have the potential to favorably affect (*i.e.*, reduce) the ground-water flow through the disposal system (at best, they would have a neutral effect on overall performance). In addition, the effects on water flow from climate change would be expected to exceed any such effects resulting from seismicity. Thus, we believe that our proposed requirements for DOE to consider climate change over the period of geologic stability effectively bound the potential hydrologic effects and no further analysis is required separately as part of the seismic scenarios.

In contrast, the potential effects on waste package failure through physical impact with other elements of the engineered barrier system or drift collapse (rockfall) are not clearly captured in analyses of other scenarios. Waste package failure is generally of importance because it is the immediate step allowing water to contact the waste, leading to release of radionuclides. Waste packages may be more vulnerable to seismic effects if corrosion processes have weakened them. Seismic events may cause the failure of the structures supporting the waste packages, allowing them to be physically damaged through impacts with other objects (*i.e.*, if waste packages are no longer held in place, they could collide with other packages or elements of the engineered barrier system). The collapse of the emplacement drift itself could also be significant at these longer times as pieces of rock fall onto the already-weakened waste packages. Regarding waste package failure caused by seismicity, NAS concluded that the rocks in the Yucca Mountain area are so extensively fractured that future seismic events are likely to occur along existing fractures rather than new ones (NAS Report p. 93). By knowing the location of major fractures, DOE may be able to minimize the adverse effects of seismicity. For example, DOE can place waste packages away from these areas (fault avoidance), thereby decreasing the risk of failure by seismic induced rock falls. As can be seen by examples at the Waste Isolation Pilot Plant (WIPP), engineering practices at repositories can be successful in reducing the probability of adverse effects on isolation capabilities and DOE has criteria for such practices at Yucca Mountain. Because faults are being avoided by design, we do not believe DOE must assume they are not. In the end, DOE might be able to show that seismic effects on waste package failure ''could be reduced sufficiently to result in boundable and probably very low risk,'' as postulated by NAS (NAS Report p. 93). Our proposal would require that DOE specifically address waste package failure resulting from seismic events causing damage to the engineered barrier system, either through physical impacts within the drifts through failure of the supporting structures or drift collapse so that the significant effects identified by NAS will be fully considered.

There are other effects that can be envisioned from seismic events near Yucca Mountain. Beyond the key aspects of seismicity discussed above, however, we do not believe there are others that would be expected to significantly affect performance (for example, from events that are of low magnitude or sufficiently distant from the disposal system), and NAS similarly identified none. The consideration of such effects would unnecessarily complicate the development of the performance assessment and the licensing process without contributing information on the protective capabilities of the Yucca Mountain disposal system. We believe they can reasonably be excluded from analysis over the period of geologic stability.

Therefore, in conclusion, we propose that DOE evaluate the effects of seismic activity throughout the period of geologic stability, but limit those effects to those resulting in damage to the engineered barrier system and ultimately the waste packages. The probability of seismic events of different magnitude and duration for the period of geologic stability will be the same as determined for the period within 10,000 years. We request comment on this approach.

c. Consideration of Igneous (Volcanic) FEPs

EPA recognizes that a volcanic intrusion into the repository, although an unlikely event, could release a portion of the radioactive inventory. We agree with the NAS that this possibility exists over the period of geologic stability (NAS Report p. 94). While acknowledging the complexity of the release of radionuclides from the repository, given the known effects of the various types of past volcanic events and the study of the cinder cones in the area, we believe it is possible to develop reasonable estimates of the probability of radionuclide release via volcanic episodes through the repository through the period of geologic stability.

We agree with NAS that the probability of igneous events may be great enough, and the potential consequences significant enough, that they must be considered over the period of geologic stability. An analysis of the probability is based on extrapolations into the future of volcanic activity from the geologic record, and on assumptions about the spatial distribution of future volcanic eruptions in the Yucca Mountain region. Volcanism by nature is an episodic event. In the Yucca Mountain region it has been characterized as involving intermittent concentrated activity followed by long periods of quiescence (NAS Report p. 94). For example, the repository block tuffs are in the age range of approximately 11–12 million years old and were generated by large-scale volcanism involving a large area around the site (''Site Environmental Report for the Yucca Mountain Project Calendar Year 2003,'' PGM–MGR–EC–000005–REV 00, Section 1.1, October 2004, Docket No. OAR–2005–0083–0086). This material is made of layers of ashfalls from volcanic eruptions that consolidated into the rock (of a type known as ''tuff''). Tuff has varying degrees of compaction and fracturing depending on the degree of ''welding'' caused by temperature and pressure when the ash was deposited. An event of this nature is not likely to be repeated during the geologic stability period. It has been suggested by NAS, and fits within our FEPs screening, that a probability of 10^{-8}/yr, which is a 1 in 10,000 possibility of a disruption (affecting the repository, not simply a volcanic event in the region) over 10,000 years ''might be sufficiently low to constitute a negligible risk'' (NAS Report p. 95). Based on available information generated by DOE in its TSPA (Yucca Mountain Science and Engineering Report, DOE/RW–0539, Section 4.4.3, May 2001, Docket No. OAR–2005–0083–0069), the mean annual probability of an igneous event within the Yucca Mountain repository footprint is estimated at 1.6×10^{-8} per year (which is slightly higher than a one in 10,000 possibility of a disruption over 10,000 years). This probability, though extremely low, is just within the regulatory threshold for inclusion of events with very low probability of occurrence, but it can be assumed that this probability will hold throughout the period of geologic stability (NAS Report p. 94). For this reason, we are proposing to require that DOE include consideration of igneous FEPs extending over the period of geologic stability.

We also agree with NAS that reasonable estimates of the effects can be developed (NAS Report p. 95). As with the seismic FEPs, we believe this is best accomplished by limiting the analysis to those effects most significant for performance. As we stated in our 2001 rule, the geologic record is the best source of evidence for the frequency and magnitude of natural features, events, and processes that could affect repository performance, and the geologic record is best preserved in the relatively recent past (66 FR 32100). Studies of the volcanic history of the area in the recent past indicate a different type of volcanic activity other than the intermittent layering volcanic activity that produced Yucca Mountain has occurred (FEIS, DOE/EIS–0250, Appendix I, Section 2.10, Docket No. OAR–2005–0083–0086). Basalt volcanism, exemplified by the Lathrop Wells volcano, and other features near the repository, appears to be the type of igneous activity, though unlikely, that has some probability of occurring within the period of geologic stability. By narrowing the type of events most plausible during the period of stability, we can attempt to constrain the uncertainty involved in using probabilistic analyses. The NAS noted that the most significant effects are related to future events that could intersect the repository (NAS Report p. 94).

Existing DOE calculations provide an example of analysis of such disruptive igneous events. DOE states that, if igneous activity occurred at Yucca Mountain, possible effects on the repository could be grouped into three areas (FEIS, DOE/EIS–0250, Appendix I, Section 2.10, Volcanism, Docket No. OAR–2005–0083–0086):

- Igneous activity that would not directly intersect the repository (can be shown to have no effect on dose from the repository);
- Volcanic eruptions in the repository that would result in waste material being entrained in the volcanic magma or pyroclastic material, bringing waste to the surface (resulting in atmospheric transport of volcanic ash contaminated with radionuclides and subsequent human exposure downwind); or
- An igneous intrusion intersecting the repository (no eruption but damage to waste packages from exposure to the igneous material that would enhance release to the ground water and, thus, enhance transport to the biosphere).

Based on studies of past activity in the region, probabilities for different types of igneous activity have been estimated by DOE. Each type of event was described in detail based on observation of effects of past activities as embodied in the geologic record of the region. These descriptions include geometry of intrusions, geometry of eruptions, physical and chemical properties of volcanic materials, eruption properties (velocity, power, duration, volume, and particle characteristics). Most of the parameters describing the igneous activity were entered in the modeling as probability distributions (FEIS, DOE/EIS–0250, Appendix I, Section 2.10, Volcanism, Docket No. OAR–2005–0083–0086).

DOE's current igneous activity scenario contains two separate possible events: a volcanic eruption that includes exposure as a result of atmospheric transport and deposition on the ground, and an igneous intrusion ground-water transport event. In the volcanic eruption event, a dike (or dikes) would intersect the repository and compromise all waste packages in the conduit. Then, an eruptive conduit of an associated volcano would intersect waste packages in its path. Waste packages in the path of the conduit would be sufficiently damaged that they provide no further protection, and the waste in the packages would be entrained in the eruption and subject to atmospheric transport. In the igneous intrusion ground-water transport event, the analysis calculated releases caused by a dike (or dikes) intersecting emplacement drifts, causing varying degrees of waste-package damage and making the contents of the containers available for transport to the RMEI through ground water. We believe these are the most significant consequences that would result from a volcanic event through the repository. Other results from igneous events—the occurrence of distant events, potential drift instability, or changes in rock fracturing—are secondary to the direct releases of radionuclides. In addition, the response of the disposal system to such effects would likely be captured by consideration of other FEPs (such as seismicity or climate change). Therefore, we are proposing that DOE's consideration of igneous events over the period of geologic stability may be limited to events that intersect the repository, damage the waste packages, and cause releases of radionuclides either directly to the atmosphere and biosphere (*i.e.*, an extrusive event) or to the ground water. We expect that the same probability of occurrence for these events used in the 10,000-year analysis be applied over the period of geologic stability. Using this probability, it is very unlikely that more than one igneous event would be included in a single realization. However, the two types of events are very different in terms of their potential effects and when those effects would be greatest. We believe this approach is appropriate, as described in the next paragraph.

DOE's analysis of releases from waste packages entrained by magma erupted on the surface assume the waste containers are breached by the eruption itself and the wastes are available for dispersal by the eruption. In this scenario, the doses would be highest if the eruption happened early in the geologic stability period (before significant decay of short-lived radionuclides that provide a dose through inhalation as well as through deposition and uptake by plants), and are lower if the event occurs at later times. Assuming waste packages are breached during the event provides that the assessment is a ''worst case'' in terms of potential doses because it does not depend on assumptions regarding other waste package failure mechanisms, such as corrosion. However, other analyses and laboratory experiments have been presented suggesting that intact waste containers can withstand the temperatures of the molten magma without melting or otherwise sustaining significant damage (''Evaluation of the Igneous Extrusive Scenario,'' Presentation to the Nuclear Waste Technical Review Board, September 20, 2004, Docket No. OAR–2005–0083–0074). These analyses suggest that an early eruption might not produce the highest doses since the wastes could not be dispersed as easily. Under these assumptions, an eruption considerably later in the geologic stability period, when the waste containers have degraded considerably from corrosion processes, is more likely to result in widespread dispersal of the wastes. However, at the later times, the radionuclide inventory in the wastes would have decreased from decay, and projected releases would probably not exceed those estimated for the early eruption scenario DOE performed. The existing assessments of the eruptive event based on our previously issued regulations contain a number of assumptions, which we believe has led to conservative assessments. Under DOE's assumptions, the highest dose as a result of volcanic eruptions would occur within the first 10,000 years because that is when the radionuclide inventory is at its highest. We are not assuming this approach will be retained in all details, and have structured our proposed rule accordingly to ensure that igneous events are considered over the period of geologic stability. However, we acknowledge that the current approach, if retained, would meet our requirements and be conservative. We request comment on our proposal.

d. Consideration of Climatological FEPs

The average of weather conditions over a long period of time is the climate (*www.cogsci.princeton.edu/cgi-bin/webwn*), and it has been well documented that climate can vary significantly over geologic time (NAS Report p. 91). Climate controls the range of precipitation and temperature conditions at Yucca Mountain. There are a number of impacts, particularly on the hydrologic regime, that must be taken into account. Run-on, run-off, and evapotranspiration of precipitation influence the rate of infiltration into the subsurface. The greater the amount of infiltration, or recharge, the greater the potential for an increase in ground water to infiltrate into the repository, allowing for an increase in the dissolution of the radionuclides. This could lead to higher release rates from the waste. Consequently, it is important to examine the effects of climate change throughout the period of geologic stability.

At present the Earth is in an interglacial phase (NAS Report p. 91). Climate change historically has been cyclical: ''Over a million-year time scale, however, the global climate regime is virtually certain to pass through several glacial-interglacial cycles * * *'' (NAS Report p. 91). Similarly, the Yucca Mountain FEIS states: ''The record shows continual variation, often with very rapid jumps, between cold glacial climates (* * * pluvial periods) and warm interglacial climates similar to the present. Fluctuations average 100,000 years in length'' (FEIS, DOE/EIS–0250, p. 5–12, Docket No. OAR–2005–0083–0086). NAS stated the following with regard to climate change at Yucca Mountain:

> During the past 150,000 years, the climate has fluctuated between glacial and interglacial status. Although the range of climatic conditions has been wide, paleoclimatic research shows that the bounding conditions, the envelope encompassing the total climatic range have been fairly stable (Jannik *et al.*, 1991; Winograd *et al.*, 1992; Dansgaard *et al.*, 1993). Recent research has indicated that the past 10,000 years are probably the only sustained period of stable climate in the past 80,000 years (Dansgaard *et al.*, 1993). Based on this record, it seems plausible that the climate will fluctuate between glacial and interglacial states during the period suggested for the performance assessment calculations. Thus, the specified upper boundary, or the physical top boundary of the modeled system, would be a conservative approach that captures the most severe, detrimental performance effects of these variations (especially in terms of ground-water recharge).

(NAS Report pp. 77–78.)

We are concerned about the possibility of over-speculation of climatic change over such extremely long time periods, possibly out to the next 1 million years. The NAS recognized this fact in its report, stating ''Although the typical nature of past climate changes is well known, it is obviously impossible to predict in detail either the nature or the timing of future climate change. This fact adds to the uncertainty of the model predictions' (NAS Report p. 77).

EPA agrees with the NAS statement and takes the position that it is not useful to have unconstrained speculation on future climate during the period of geologic stability, because it is possible to assume any number of scenarios of climate over this large amount of time, and there is very little evidence available to accept or refute most of them. Because it is not possible to predict every situation that could occur over such a long time, we feel that the best course, as outlined below, is to construct a climate scenario that assumes reasonable temperature and precipitation values, and allow this scenario to run throughout the period of geologic stability.

Climate change differs from seismic and igneous events in that its effects would not occur instantaneously, and it can affect multiple portions of the disposal system with a very direct effect on performance since the movement of water through the site is the primary means for transporting radionuclides. These effects can persist for very long time periods, even longer than the period of geologic stability. Seismic events and volcanism, in contrast, are episodic events; though the events occur relatively quickly and deliver their consequences over the short term, the consequences themselves can be very long-lasting and fundamentally change the geologic setting.

There are three major effects that climate change can impart on the disposal system (NAS Report p. 91). The first is that increases in erosion might significantly decrease the burial depth of the repository. NAS pointed out that site-specific studies performed by DOE indicate that an increase in erosion to the extent necessary to expose the repository within the period of geologic stability is extremely unlikely (NAS Report p. 91). Therefore, we do not believe it is important or necessary to require DOE to assess the potential for erosion from climate change.

The second change might be a shift in the distribution and activities of human populations (NAS Report p. 92). A cooler, wetter climate may provide a more hospitable environment, increasing the population, and (some have argued) possibly changing the parameters we have outlined for the RMEI. We are not proposing to change the definition or characteristics of the RMEI. We have discussed our reasoning for taking this approach in greater detail in Section II.A.1 of this document. We do not believe that fixing the climate to present-day characteristics is the appropriate way to circumvent the difficulties in defining a biosphere applicable for 1 million years. Our view is that evaluation of reasonable climate change is critical to the integrity and meaning of peak dose projections. Further, as NAS noted, ''there is no simple relation between future climatic conditions and future population'' (NAS Report p. 92).

Finally, for extremely long time periods, major changes in the global climate, for example a transition to a glacial climate, could affect ground-water movement. NAS states ''Change to a cooler, wetter climate at Yucca Mountain would likely result in greater fluxes of water through the unsaturated zone'' (NAS Report pp. 91–92). NAS observed that a doubling of the effective wetness (the ratio of precipitation to effective evapotranspiration) could cause a significant increase in recharge (NAS Report p. 91). This could affect the rates of radionuclide release from the waste and transport to the water table, although the location of the repository in the subsurface would provide a time lag for climate change effects. NAS states, ''The time required for unsaturated zone flux changes to propagate down to the repository and then to the water table is probably in the range of hundreds to thousands of years. The time required for saturated flow-system responses is probably even longer. For this reason, climate changes on the time scale of hundreds of years would probably have little if any effect on repository performance, and the effects of climate changes on the deep hydrogeology can be assessed over much longer time scales'' (NAS Report p. 92).

In its current analysis of future climate states (''Future Climate Analysis,'' ANL–NBS–GS–000008–Rev 00, 2000, Section 6.2, Docket No. OAR–2005–0083–0068), DOE assumed that all future climates were similar to current conditions or wetter than current conditions. The climate model provides a forecast of future climates based on information about past patterns of climates. The model represents future climate shifts as a series of instant changes. During the first 10,000 years, there are three changes, in order of increasing wetness, from present-day to a monsoon and then to a glacial-transition climate. Between 10,000 years and 1 million years there are 45 changes between six climate states incorporated in the TSPA model:

- Interglacial Climate (same as present day)
- Intermediate Climate (same as the Glacial-transition)
- Intermediate/Monsoon Climate
- Three stages of Glacial Climate of varying infiltration rates

Precipitation that is not returned to the atmosphere by evaporation or transpiration enters the unsaturated zone flow system. Water infiltration is affected by a number of factors related to climate, such as an increase or decrease in vegetation on the ground surface, total precipitation, air temperature, and runoff. The infiltration model uses data collected from studies of surface infiltration in the Yucca Mountain region. It treats infiltration as variable in the region, with more occurring along the crest of Yucca Mountain than along its base. The results of the climate model affect assumed infiltration rates. For each climate, there is a set of three infiltration rates (high, medium, low) and associated probabilities. This forms a discrete distribution that is sampled in the probabilistic modeling. Whenever a particular climate state is in effect, the associated infiltration rate distribution is sampled for each realization of the simulation.

One of the issues associated with DOE's existing modeling efforts on climate at very long times is that the analysis assumed instantaneous changes between climate states. In other words, the entire flow field was assumed to immediately switch from one climate state to another. This approach is unrealistic because, as noted above, it would likely take hundreds or thousands of years for increased infiltration from a wetter climate to reach the underlying aquifer and affect transport and flow patterns. DOE also assumed that the climate change occurred at the same time for all realizations, which magnified the effect of the instantaneous change of climate when looked at as a probabilistic analysis. The result is that the doses calculated were the product of the conservatism of the assumptions noted above (*e.g.*, instantaneous climate shift, which was assumed to occur at the same time for all realizations). Such assumptions are unlikely to produce meaningful or realistic results.

We believe that an approach should be developed to answer several basic questions about how climatological effects realistically will impact the proposed repository until the time to peak dose. The questions that concern us are:

1. How much total water will infiltrate into the repository over this large amount of time?

2. Will more water infiltrate the repository over time when modeled as a wave function (current DOE modeling) or as total average?

The answers to these questions assist in identifying conservative, yet reasonable, conditions the repository may encounter over the period of geologic stability. The amount of net infiltration into Yucca Mountain has an effect on the disposal system performance because higher net infiltration leads to the possibility that a greater proportion of the repository will experience ground-water seepage. For solubility-limited radionuclides in the waste, an increase in net infiltration could lead to a higher release rate of radionuclides from the disposal system, thereby affecting the potential dose to the RMEI in the accessible environment. We do not believe that it is important to know or predict with certainty precisely when the climate states with peak precipitation occur during the modeling. There are too many uncertainties and permutations available in trying to project a future set of climate conditions, and it is difficult to place specific times on when discrete pulses of precipitation should be injected into the modeling (NAS Report p. 77). Instead, we believe that it is reasonable to assume an average increase in precipitation over the entire time from 10,000 years through the period of geologic stability, and to model those consequences. An increase in average precipitation throughout the period of geologic stability is a more reasonable approach because it assumes a constant source of precipitation, creating more downward flow that will eventually reach the repository. This scenario need not be dominated by highs or lows in precipitation over the time period and does not require speculation about the exact timing or transient effects of shifts in climate. Rather, setting a constant value somewhat higher than today's average annual rainfall and extending it out to the time of peak dose would account for the greater potential for available fluids at the time of the failure of the waste packages. We believe that this approach provides a reasonable test of the repository conditions out to the time of peak dose, and will give a more conservative idea of potential fluid flow, as well as potential for migration of radionuclides out of the repository.

We are proposing today that DOE, based on past climate conditions in the Yucca Mountain area, should determine how the disposal system responds to the effects of increased water flow through the repository as a result of climate change. We believe that the nature and extent of climate change can be reasonably represented by constant conditions taking effect after 10,000 years out to the time of geologic stability. We are proposing to explicitly require that DOE assume water flow will increase as a result of climate change. We leave it to NRC as the licensing authority to specify the values to be used to represent climate change. However, we expect that a doubling of today's average annual precipitation beginning at 10,000 years and continuing through the period of geologic stability would provide a reasonable scenario, given NAS's statements regarding potential effects on recharge (NAS Report p. 92). NRC could also use the range of projected precipitation values for different climate states and specify a reasonable long-term average precipitation based on the duration of each climate state over the period of geologic stability. We believe that either approach will allow for a reasonable estimate of how water will impact the site without subjecting the assessments to speculative assumptions that may well be unresolvable, while providing a reasonable indicator of disposal system compliance. NRC might choose to express the ground-water flow effects directly as infiltration rates or other representative parameters, avoiding the necessity of translating precipitation and other climate-related parameters (*e.g.*, temperature or evapotranspiration rates) into infiltration.

Finally, we note that there are other potential effects of climate change such as the formation of surficial ponds or changes in fauna and flora (which could affect infiltration through changes in evapotranspiration rates). NAS did not identify these as significant, and also reiterated that speculation on the evolution of the biosphere (aside from climate) is unwarranted and unproductive. We agree fully. Therefore, in summary, we are proposing that DOE must include consideration of climate change in its performance assessment for compliance with the dose standard for the period of geologic stability. The assessment may be limited to the effects of increased water flow through the repository as a result of climate change. Climate change may be represented by constant conditions, which NRC would specify in regulation. We request comment on this proposal.

E. How Is EPA Proposing To Revise the Human-Intrusion Standard (§ 197.25) To Address Peak Dose?

As discussed in Section II.A.2, we believe it is logical and defensible to modify the human-intrusion standard in § 197.25 to parallel the revisions we are proposing for the individual-protection standard. We described in some detail in that section the reasons why we believe that course of action to be appropriate, and briefly summarize our proposal here. Like the individual-protection standard, our provisions for human intrusion in the 2001 rule envisioned some consideration of performance beyond 10,000 years. The exposures resulting from the event were subject to the same compliance standard as the individual-protection standard (15 mrem/yr at 10,000 years or earlier coupled with compilation in the EIS if doses were projected to occur after 10,000 years). In deciding to propose revisions to the human-intrusion standard to conform to changes we are proposing to make to the individual-protection provisions, we kept in mind the NAS recommendation that ''the figure-of-merit for [the human-intrusion] calculation should be the same as in the undisturbed case * * * EPA should require that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed-repository case'' (NAS Report pp. 112–113).

The 2001 standard required that DOE determine when an intrusion by drilling would be possible and assess the consequences. We believe it is still appropriate for DOE to determine the time at which the intrusion could occur. However, under our proposal today, consequences at any time within the period of geologic stability would be subject to a compliance demonstration. We are proposing to apply the same dose limits to the human-intrusion scenario as we are proposing for the individual-protection scenario. Thus, exposures incurred by the RMEI within 10,000 years after disposal as a result of the intrusion must comply with a standard of 150 μSv/yr (15 mrem/yr). Exposures after that time within the period of geologic stability must comply with a standard of 3.5 mSv/yr (350 mrem/yr). DOE must still use the same assumptions regarding the RMEI as it used for the individual-protection analysis.

We are not proposing to modify in any way the circumstances of the intrusion described in § 197.26. We believe those circumstances continue to reflect two key points emphasized by NAS. First, ''there is no scientific basis for estimating the probability of intrusion at far-future times'' (NAS Report p. 106). Second, like future society, future exploration technology cannot be predicted (NAS Report p. 107). Therefore, there is no basis for assuming a different set of circumstances to apply to intrusions beyond 10,000 years.

We request comment on our proposed changes to the human-intrusion standard. We are not soliciting, and will not consider, comments on the overall intrusion scenario or other aspects of the human-intrusion standard that are not proposed to be changed.

F. Summary of Today's Proposal by Section

Today's proposal is limited in scope. We are proposing to amend provisions only as necessary to address the Court ruling. Because of the unique nature of the challenge facing us, in which we must craft a regulatory standard to apply to times up to 1 million years, we have chosen to discuss many aspects of our 2001 rule in this document. We have done so because we believe it important that the public clearly understand what actions we are proposing to take and why, as well as reasons for not amending other provisions. In the listing that follows, we identify only those provisions of the rule that we are proposing to change today. We request public comment only on these proposed amendments. We are not proposing to change any other provisions. Therefore, we are not requesting, and will not respond to, public comments related to those provisions, since they have been previously established in rulemaking and are outside the scope of today's proposal.

Subpart A—Public Health and Environmental Standards for Storage

§ 197.2, What definitions apply in subpart A?—Amends the definition of Effective Dose Equivalent to specify that calculations be performed using organ weighting factors in Appendix A.

Subpart B—Public Health and Environmental Standards for Disposal

§ 197.12, What definitions apply in subpart B?—Modifies the definition of Performance Assessment to remove reference to 10,000 years. Modifies the definition of Period of Geologic Stability as ending 1 million years after disposal.

§ 197.13, How is subpart B implemented?—Specifies that the arithmetic mean of the distribution of projected doses is used to determine compliance within 10,000 years. Specifies that the median of the distribution of projected doses is used to determine compliance beyond 10,000 years but within the period of geologic stability (for §§ 197.20 and 197.25 only).

§ 197.15, How must DOE take into account the changes that will occur during the next 10,000 years after disposal?—Replaces references to 10,000 years with ''period of geologic stability.''

§ 197.20, What [individual-protection] standard must DOE meet?—Retains the standard of 15 mrem/yr to apply up to 10,000 years after disposal. Adds a standard of 350 mrem/yr to apply beyond 10,000 years within the period of geologic stability.

§ 197.25, What [human-intrusion] standard must DOE meet?—Retains the standard of 15 mrem/yr to apply up to 10,000 years after disposal. Adds a standard of 350 mrem/yr to apply beyond 10,000 years within the period of geologic stability. Removes references to time of intrusion and to placement of results in EIS.

§ 197.35, What other projections must DOE make?—Section to be deleted.

§ 197.36, Are there limits on what DOE must consider in the performance assessments?—Addresses probability of features, events, and processes in assessments used to comply with proposed § 197.20(b). Adds provisions to address climate change, igneous, seismic, and general corrosion scenarios.

Appendix A, Calculation of Committed Effective Dose Equivalent—describes the method to calculate the dose for comparison with the appropriate standards.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, [58 Federal Register 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule 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. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

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

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

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

C. Regulatory Flexibility Act

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

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

However, the requirement to prepare a regulatory flexibility analysis does not apply if the Administrator certifies that the rule will not, if promulgated, have a significant economic impact upon a substantial number of small entities (5 U.S.C. 605(b)). The rule proposed today would establish requirements that apply only to DOE. Therefore, it does not apply to small entities. Accordingly, I hereby certify that the rule, when promulgated, will not have a significant economic impact upon a substantial number of small entities. We continue to be interested in the potential impacts of our proposed rules on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 proposed rule contains no Federal mandates (under the regulatory provisions of Title II of UMRA) for State, local, or tribal governments or the private sector. The proposed rule implements requirements specifically set forth by the Congress in section 801 of the EnPA and proposes 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.

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 proposed 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. 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 solicits comment on this 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 proposed rule does not have tribal implications, as specified in Executive Order 13175. The rule proposed today would regulate only DOE on land owned by the Federal government. The rule proposed today 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. EPA specifically solicits additional comment on this proposed rule from tribal officials.

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

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

This proposed 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. The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to radiation.

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

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The rule proposed today would 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 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

In our original proposal (64 FR 46976, August 27, 1999), we requested public comment on potentially applicable voluntary consensus standards that would be appropriate for inclusion in the Yucca Mountain rule. We received no comments on this aspect of the rule. The closest analogy to consensus standards for radioactive waste disposal facilities are our regulations at 40 CFR part 191. As discussed above in this preamble, Congress expressly prohibited the application of the 40 CFR part 191 standards to the Yucca Mountain disposal facility, and, therefore, the standards promulgated in 2001 and today's proposed revisions are site-specific and developed solely for application to the Yucca Mountain disposal facility.

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: August 9, 2005.

Stephen L. Johnson,

Administrator.

The Environmental Protection Agency is hereby proposing to amend part 197 of title 40, Code of Federal Regulations, 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?

* * * * *

Effective dose equivalent means the sum of the products of the dose equivalent received by specified tissues following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors. Annual committed effective dose equivalents shall be calculated using weighting factors in accordance with 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?

(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:

(1) For § 197.20 of this subpart; and

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

(b) NRC will determine compliance based upon the median of the projected doses from DOE's performance assessments for the period after 10,000 years of disposal and through the period of geologic stability:

(1) For § 197.20 of this subpart; and

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

5. Section 197.15 is revised to read as follows:

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

The DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at the time of license application submission to NRC. However, DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions of the changes in these factors that could affect the Yucca Mountain disposal system during the period of geologic stability, consistent with the requirements for performance assessments specified at § 197.36.

6. Section 197.20 is revised to read as follows:

§ 197.20 What standard must DOE meet?

(a) The DOE must demonstrate, using performance assessment, that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than the following annual committed effective dose equivalent from releases from the undisturbed Yucca Mountain disposal system:

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

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

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

7. Section 197.25 is revised to read as follows:

§ 197.25 What standard must DOE meet?

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

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

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

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

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

§ 197.35 [Removed and Reserved]

8. Section 197.35 is 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. 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 10,000 of occurring within 10,000 years of disposal (less than one chance in 100,000,000 per year). In addition, unless otherwise specified in these standards or NRC regulations, DOE's performance assessments need not evaluate the impacts resulting from any features, events, and processes or sequences of events and processes with a higher chance of occurrence if the results of the performance assessments would not be changed significantly in the initial 10,000 year period after disposal.

(b) For performance assessments conducted to show compliance with §§ 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 and failure of the waste packages.

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

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

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

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

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

Unless otherwise directed by NRC, DOE shall use the radiation weighting factors and tissue weighting factors in this Appendix to calculate committed effective dose equivalent for compliance with sections 20 and 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 26/30 and continued in ICRP 60/72, and incorporated in this Appendix.

I. Equivalent Dose

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

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

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

TABLE A.1.—RADIATION WEIGHTING FACTORS, W_R [1]

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

[1] All values relate to the radiation incident on the body or, for internal sources, emitted from the source.

[2] See paragraph A14 in ICRP Publication 60 for the choice of values for other radiation types and energies not in the table.

II. Effective Dose Equivalent

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

$E = \Sigma\, w_T \cdot H_T$.

TABLE A.2.—TISSUE WEIGHTING FACTORS, W_T

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

[a] Remainder is composed of the following tissues: adrenals, brain, extrathoracic airways, small intestine, kidneys, muscle, pancreas, spleen, thymus, and uterus.

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

III. Annual Committed Tissue or Organ Equivalent Dose

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

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

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

IV. Annual Committed Effective Dose Equivalent

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

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

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