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Part IV

Environmental Protection Agency

40 CFR Part 197

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 197

[FRL–6995–7]

RIN 2060–AG14

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: We, the Environmental Protection Agency (EPA), are promulgating public health and safety standards for radioactive material stored or disposed of in the potential repository at Yucca Mountain, Nevada. Section 801 of the Energy Policy Act of 1992 (EnPA, Pub. L. 102–486) directs us to develop these standards. Section 801 of the EnPA also requires 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.'' We have taken the NAS Report into consideration as the EnPA directs.

The Nuclear Regulatory Commission (NRC) will incorporate these final standards into its licensing regulations. The Department of Energy (DOE) must demonstrate compliance with these standards. The NRC will use its licensing regulations to determine whether DOE has demonstrated compliance with our standards prior to receiving the necessary licenses to store or dispose of radioactive material in Yucca Mountain.

DATES: *Effective Date:* This rule becomes effective July 13, 2001.

ADDRESSES: *Documents relevant to the rulemaking.* You can find and access materials relevant to this rulemaking in: (1) Docket No. A–95–12, located in Waterside Mall Room M–1500 (first floor, near the Washington Information Center), 401 M Street, SW., Washington, DC 20460; (2) an information file in the Government Publications Section, Lied Library, University of Nevada-Las Vegas, 4505 Maryland Parkway, Las Vegas, Nevada 89154; and (3) an information file in the Public Library in Amargosa Valley, Nevada 89020.

Background documents for this action. We have prepared additional documents that provide more detailed technical background in support of these standards. You may obtain copies of the Background Information Document (BID), the Economic Impact Analysis (EIA), the Response to Comments document, and the Executive Summary of the NAS Report, by writing to the Office of Radiation and Indoor Air (6608J), U.S. Environmental Protection Agency, Washington, DC 20460-0001. We placed these documents into the docket and information files. You also may find them on our Internet site for Yucca Mountain (see the *Additional Docket and Electronic Information* section later in this document).

FOR FURTHER INFORMATION CONTACT: Ray Clark, Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, Washington, DC. 20460–0001; telephone 202–564–9310.

SUPPLEMENTARY INFORMATION:

Whom Will These Standards Regulate?

The DOE is the only entity directly regulated by these standards. Before it may accept waste at the Yucca Mountain site, DOE must obtain a license from NRC. Thus, DOE will be subject to our standards, which NRC will implement through its licensing proceedings. Our standards affect NRC only because, under the Energy Policy Act of 1992 (EnPA, Pub. L. 102–486, 42 U.S.C. 10141 n. (1994)), NRC must modify its licensing requirements, as necessary, to make them consistent with our final standards.

Additional Docket and Electronic Information

When may I examine information in the docket? You may inspect the Washington, DC, docket (phone 202–260–7548) on weekdays (8 a.m.-5:30 p.m.). The docket personnel may charge you a reasonable fee for photocopying docket materials (40 CFR part 2).

You may inspect the information file located in the Lied Library at the University of Nevada-Las Vegas, Research and Information Desk, Government Publications Section (702–895-2200) when classes are in session. 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).

You may inspect the information file in the Public Library in Amargosa Valley, Nevada (phone 775–372–5340). As of this date, the hours are Tuesday through Thursday (10 a.m.–7 p.m.); Friday (10 a.m.–5 p.m.); and Saturday (10 a.m.–2 p.m.). The library is closed daily from 12:30 p.m.–1 p.m. It also is closed Sundays and Mondays.

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. 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 proposed rule, which appeared in the **Federal Register** on August 27, 1999 (64 FR 46976).

What documents are referenced in today's action? 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 (Docket No. A–95–12). Other documents, e.g., statutes, regulations, proposed rules, are readily available from other public sources. The documents below are referenced most frequently in today's action.

Item No.

II–A–1 Technical Bases for Yucca Mountain Standards (The NAS Report), National Research Council, National Academy Press, 1995

V–A–4 Draft Environmental Impact Statement for Yucca Mountain, DOE/EIS–0250D, July 1999

V–A–5 Viability Assessment for Yucca Mountain, DOE/RW–0508, December 1998

V–B–1 Final Background Information Document (BID) for 40 CFR 197, EPA–402–R–01–004

V–C–1 Final Response to Comments Document for 40 CFR 197, EPA–402–R–01–009

V–A–17 Nevada Risk Assessment/Management Program (NRAMP)

Acronyms and Abbreviations

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

ALARA-as low as reasonably achievable
APA-Administrative Procedure Act
BID-background information document
CAA-Clean Air Act
CEDE-committed effective dose equivalent
CG-critical group
DEIS-Draft Environmental Impact Statement
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
GCD-greater confinement disposal
HLW-high-level radioactive waste
IAEA-International Atomic Energy Agency
ICRP-International Commission on Radiological Protection
LLW-low-level radioactive waste
MCL-maximum contaminant level
MCLG-maximum contaminant level goal
MTHM-metric tons of heavy metal
NAS-National Academy of Sciences
NCRP-National Council on Radiation Protection and Measurements
NEPA-National Environmental Policy Act
NESHAPs-National Emission Standards for Hazardous Air Pollutants
NID-negligible incremental dose
NIR-negligible incremental risk
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
OMB-Office of Management and Budget
RCRA-Resource Conservation and Recovery Act
RME-reasonable maximum exposure
RMEI-reasonably maximally exposed individual
SAB-Science Advisory Board
SDWA-Safe Drinking Water Act
SNF-spent nuclear fuel
TDS-total dissolved solids
TRU-transuranic
UIC-underground injection control
UMRA-Unfunded Mandates Reform Act of 1995
UNSCEAR-United Nations Scientific Committee on the Effects of Atomic Radiation
USDW-underground source of drinking water
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?

Spent nuclear fuel (SNF) and high-level radioactive waste (HLW) have been produced since the 1940s, mainly as a result of commercial power production and defense activities. Since then, the proper disposal of these wastes has been the responsibility of the Federal government. The Nuclear Waste Policy Act of 1982 (NWPA, Pub. L. 97–425) 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 NRC to implement our standards by incorporating them into its licensing requirements for SNF and HLW repositories.

This general division of responsibilities continues for the Yucca Mountain disposal system. Thus, today we are establishing public health protection standards (specific to the Yucca Mountain site, rather than generally applicable). The NRC will issue implementing regulations for this rule. The DOE will submit a license application to NRC. The NRC then will determine whether DOE has met the standards and whether to issue a license for Yucca Mountain. The NRC will require DOE to comply with all of the applicable provisions of 40 CFR part 197 before authorizing DOE to receive radioactive material at the Yucca Mountain site.

In 1985, we established generic standards for the management, storage, and disposal of SNF, HLW, and transuranic (TRU) radioactive waste (see 40 CFR part 191, 50 FR 38066, September 19, 1985), which apply to any facilities 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.

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

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 the Yucca Mountain repository. 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 directs 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.'' The EnPA also directed us to contract with NAS to conduct a study to provide us with its findings and recommendations on reasonable standards for protection of public health and safety. 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. A–95–12, Item II–A–1).

A. What Is the Relationship of 40 CFR Part 191 to the Yucca Mountain Standards?

Throughout today's action, we refer to the provisions of 40 CFR part 191 to support the decisions we made regarding the components of the final Yucca Mountain rule. Pursuant to section 8(b)(2) of the WIPP LWA, 40 CFR part 191 is not applicable to the characterization, licensing, construction, operation, or closure of the Yucca Mountain repository. We believe, however, that while 40 CFR part 191 is not directly applicable to Yucca Mountain, because it contains the fundamental components for the protection of public health and the environment that apply to any SNF, HLW, or TRU radioactive waste repository, certain of its basic concepts must be applied to Yucca Mountain as appropriate. Further, because 40 CFR part 191 provides fundamental support for today's rule, we believe it is useful to explain here the process by which 40 CFR part 191 evolved.

1. Evolution of 40 CFR Part 191

We used the rulemaking for 40 CFR part 191 to define the fundamental components of any environmental standard applicable to the disposal of SNF, HLW, and TRU radioactive waste. In our proposal (47 FR 58196, December 29, 1982), we recognized two basic considerations regarding the disposal of SNF, HLW, and TRU radioactive waste:

• The intent of disposal is to isolate the wastes from the environment for a very long time, longer than any time over which active institutional controls might be effective; and

• The disposal systems will be designed to allow only very small releases to the environment, if not disturbed. A principal concern is the possibility of accidental releases due to unintended events or failure of engineered barriers.

These considerations mean that any standard that we establish and that NRC and DOE implement: (1) Can only be implemented during development and operation of the repository, (2) must address unintentional releases, and (3) must accommodate significant uncertainties. (See 47 FR 58198, December 29, 1982)

From these considerations, we proposed standards consisting of Containment Requirements, which limit the total amount of radionuclides that may enter the environment over 10,000 years; Assurance Requirements, which provide several principles enhancing confidence that the containment requirements will be met; and Procedural Requirements, which assure the proper application of the containment requirements. We also invited public comment on alternative approaches for the standards, specifically on the alternative of establishing exposure limits for individuals. Although the containment requirements, as proposed, were designed to protect people and the environment for a long time, we did not propose an individual exposure limit. We believed the compliance point for such a limit would have to be some distance from the repository. Otherwise, it would have to ignore the risks from unplanned events such as human intrusion. It seemed likely that individuals located extremely near the repository or who intrude into the repository would receive doses far exceeding any existing or reasonably acceptable radiation limits.

EPA received substantial public comment on the 40 CFR part 191 proposal. As a direct result of information provided in many of the comments, we issued a final rule (50 FR 38066, September 19, 1985) that differed in many respects from the proposal. In addition to containment and assurance requirements, the final rule included two new components:

• Individual Protection Requirements, which protect members of the public for 1,000 years of undisturbed performance; and

• Ground Water Protection Requirements, which protect ''special sources of ground water'' for 1,000 years of undisturbed performance.

The risk objectives for the containment requirements in the final rule maintained the same limiting level of health impacts as the proposal (1000 fatal cancers over 10,000 years for a repository containing 100,000 metric tons of heavy metal (MTHM)); however, we did modify the radionuclide-specific release limits to reflect updated performance analyses and updated information on the health effects of ionizing radiation. However, members of the public and our Science Advisory Board (SAB) expressed some concerns regarding residual risks and the ability of the licensee of any repository to demonstrate compliance with the standards given the uncertainties about these facilities that arise over the long time periods at issue (see the ''Report on the Review of Proposed Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes,'' January 1984, Docket No. A–95–12, Item V–A–21). To address these concerns, we incorporated the concept that the standards be met with ''reasonable expectation'' (§ 191.13(b)). Improved performance assessments indicated that the containment requirements could, in fact, be achieved by a variety of repository site/design combinations without significant effects on disposal costs. The final rule also defined for the first time a ''controlled area,'' or tract of land inside of which compliance is not evaluated. The concept of a controlled area was carried from the proposal, where it was included in the definition of ''accessible environment''. In addition, we added

''Guidance for Implementation,'' which replaced the previous procedural requirements section. It addresses some of the uncertainties with demonstrating compliance, such as the limitations of passive and active institutional controls and the degree of certainty required to demonstrate compliance with the individual and ground water protection requirements.

On the basis of public comments and our analyses of disposal systems, we incorporated individual protection requirements, applicable to all pathways of exposure effective for 1,000 years after disposal. In addition, our analyses of disposal systems supported setting ground water protection requirements to protect ''special sources of ground water'' to limits very similar to the Maximum Contaminant Levels (MCLs) at 40 CFR part 141. Public comment was very influential towards our incorporation of individual-protection requirements and ground-water protection requirements. To address the concerns expressed in the proposed rule related to protection of individuals who are extremely near the repository or who may intrude into the repository, the individual-protection requirements apply to any member of the public in the accessible environment for the case of undisturbed performance.

Legal challenges required us to reconsider the individual and ground water protection requirements in a subsequent rulemaking to amend 40 CFR part 191 (see 58 FR 66398, December 20, 1993). In 1987, the U.S. Court of Appeals for the First Circuit remanded subpart B of the 1985 standards to EPA for further consideration (*Natural Resources Defense Council, Inc.* v. *United States Environmental Protection Agency*, 824 F.2d 1258 (1st Cir. 1987)). The court questioned the appropriateness of the 1,000 year time frame for the individual protection requirement, the inter-relationship of the individual-protection requirement with the Safe Drinking Water Act (SDWA), and whether the Agency provided proper notice for the ground water protection requirements. For a more detailed discussion of the court's decision, see the preamble to the final amendments to 40 CFR part 191 (58 FR 66399–66411, December 20, 1993). The Waste Isolation Pilot Plant Land Withdrawal Act of 1992 reinstated the 1985 version of 40 CFR part 191 except for those portions of the rule that were the subject of the remand. In the final amendments to 40 CFR part 191, which replaced the remanded portions of 40 CFR part 191, we set the individual-protection requirement at 15 mrem/yr, calculated as an annual committed effective dose, for all pathways of exposure of any member of the public in the accessible environment, effective for 10,000 years after disposal. The ground water protection provisions limit the concentrations of radioactivity in any underground source of drinking water (USDW) in the accessible environment to the MCLs of the SDWA (40 CFR part 141).

2. The Role of 40 CFR Part 191 in the Development of 40 CFR Part 197

The EnPA directs us to develop site-specific public health protection standards for the Yucca Mountain site. To perform this task properly, we must answer two fundamental questions relative to the content of the standards. These two questions are:

(1) What are the relevant components of such standards?

(2) How can they be applied in more detail in a reasonable but conservative manner to the Yucca Mountain site?

There are two primary sources of information, insight, and guidance on repository performance standards in general and the standards applicable to the Yucca Mountain site in particular. These sources are the generic standards for land disposal of SNF, HLW, and TRU radioactive waste (40 CFR part 191) and the NAS report mentioned above. We relied heavily on these sources in developing the Yucca Mountain standards.

As described in the previous section, we developed 40 CFR part 191 as generic standards that apply to the land disposal of SNF, HLW, and TRU radioactive wastes. The components of generic standards like 40 CFR part 191, such as the individual-protection requirement, would all apply to some degree to any candidate site, but may not be equally important at any particular site. The WIPP LWA exempts the Yucca Mountain site from being licensed under the generic standards; however, the basic components of the generic standards clearly are valid components for consideration in developing standards that apply to a specific site. For example, in the EnPA, Congress specifically instructs us to ''prescribe the maximum annual effective dose equivalent to individual members of the public'' (EnPA section 801(a)(1)); such an individual dose standard is an integral part of 40 CFR part 191.

We believe that 40 CFR part 191 is a logical starting point for developing the site-specific Yucca Mountain standards because it contains the fundamental components necessary to evaluate whether a potential geologic repository site will perform satisfactorily relative to the protection of public health and the environment. Where appropriate in the site-specific context of the Yucca Mountain standards, we rely on the precedent of, and the reasoning in, 40 CFR part 191 throughout this preamble as support for including specific components in the Yucca Mountain standards. This statement does not mean that we have applied the 40 CFR part 191 standards to Yucca Mountain. Rather, we evaluated the 40 CFR part 191 standards de novo to determine whether it may be appropriate for us to apply any of them in the Yucca Mountain context. The NAS Report is relevant because it contains recommendations on scientific issues involved with geologic disposal in general, as well as specific recommendations based upon examination of the Yucca Mountain site. We refer to these two sources in the discussions that follow to explain why we structured the standards in a particular way and how we considered the public comments we received in response to the proposed standards.

We evaluated each generic component of 40 CFR part 191 on an individual basis to determine whether it is appropriate to apply it to the Yucca Mountain site as a component of a standard protective of public health. If we found it was appropriate to apply one of 40 CFR part 191's generic components to Yucca Mountain, we included that component in the Yucca Mountain standards. Next, we considered how to incorporate each appropriate component in a reasonable, but conservative, manner to the site-specific conditions at the Yucca Mountain site. The NAS Report was a primary source of guidance and insight in answering that question, supplemented by the available data on the characteristics of the site including information on the distribution, lifestyles, and other demographic characteristics of the population in the vicinity of the site. The BID accompanying the 40 CFR part 197 standards contains much of this information. Other sources of information, such as DOE's Yucca Mountain DEIS, are noted in the following discussions as appropriate.

Before selecting and formulating specific elements of the standards, we must consider that radiological hazards to public health from a deep geologic repository come from the release of radionuclides and the subsequent exposure of the population to these radionuclides. This exposure occurs as a result of two different processes: the expected degradation over time (caused by natural processes and events) of the natural and engineered barriers in the repository; and the breaching of these barriers by human activities. It is necessary to include both of these release modes in a health-based standard if it is to be protective. It also is necessary to develop standards against which it is possible, using reasonable means, to judge repository performance to determine compliance. Based upon basic principles of health physics, we believe that, any releases and consequent exposures to the public from the radionuclides emplaced into the repository could affect public health. Therefore, it is appropriate for us to evaluate the effects of these releases to determine whether we should address them in our standards. The NAS Report (Chapters 2 & 3) describes the potential pathways through which exposures to the public can occur from geologic disposal. Part 191 contains three provisions related to these potential release pathways that we believe are appropriate for application at Yucca Mountain. More specifically, 40 CFR part 191 contains an individual-protection standard (which limits exposure from all pathways by which an individual can be exposed), ground-water protection standards (aimed at the protection of ground water resources for use by individuals who may be exposed from using those resources), and a human-intrusion component of the containment requirements (aimed at protection from the inadvertent breaching of the repository containment barriers and subsequent exposures to the population). We believe these three basic components of the generic 40 CFR part 191 standards apply to the Yucca Mountain site because they represent avenues of exposure and mechanisms of release that are reasonably foreseeable given the conditions at Yucca Mountain.

We did not see the need to include in 40 CFR part 197 the containment requirements in 40 CFR part 191 for several reasons. First, we decided that, unlike the generic analyses supporting the development of release limits in 40 CFR part 191, the potential for large-scale dilution of radionuclides (and consequent wider exposure to large populations), through ground water and into surface water, as modeled in the supporting analyses for 40 CFR part 191, does not exist at Yucca Mountain. As discussed in Chapters 7 and 8 and Appendix IV of the BID and the preamble to proposed 40 CFR part 197 (64 FR 46991, August 27, 1999), the Yucca Mountain repository will be located in an unsaturated rock formation with limited amounts of infiltrating water passing through it and into the underlying tuff aquifer. Any releases into the ground water will be heavily constrained by the geologic features of the surrounding rocks to move in relatively confined pathways, rather than widely dispersed into the surrounding area around the repository. The aquifer is within a ground water system that discharges into arid areas having high evaporation rates and very little surface water, further limiting the potential for widespread population exposures.

As discussed in the preamble to the proposed 40 CFR part 191 (58 FR 46991), we developed the containment requirements in 40 CFR part 191 during the siting process mandated by the NWPA in the 1980s. In that context, population doses are an important consideration. The release limits in 40 CFR part 191 were found to be reasonably achievable for several types of geologic settings (including tuff) and would keep the risks to future populations acceptably small. Because the potential for significant exposures from the Yucca Mountain repository is primarily through a strongly directional ground water pathway (BID, Chapters 7 and 8), a ''cautious, but reasonable'' individual-protection standard will offer the same protection as the containment requirement included in 40 CFR part 191.

Although we included important components of 40 CFR part 191 in our Yucca Mountain standards, we did not simply replicate the provisions of 40 CFR part 191. For example, as discussed above, we do not include containment requirements because we believe that the individual-protection requirements adequately will protect the general population given the specific conditions at Yucca Mountain. Similarly, we do not include assurance requirements because we expect NRC to incorporate equivalent requirements into its implementing regulations. Because the assurance requirements in 40 CFR part 191 do not apply to NRC-licensed facilities [2], NRC will need to include assurance requirements in its implementing regulations for the Yucca Mountain repository. Measures that are effectively equivalent to the 40 CFR part 191 assurance requirements have been included in NRC's proposed 10 CFR part 63. The site-specific nature of the Yucca Mountain standards requires us to evaluate the unique characteristics of the Yucca Mountain site to develop the more detailed aspects of our standards, such as appropriate compliance points. The relative importance of the three regulatory components of 40 CFR part 191 in determining compliance in the regulatory review process is a direct reflection of site-specific conditions. For example, for WIPP, evaluating releases from human intrusion (by drilling to explore for or exploit the oil, gas and mineral resources present at the site) was the primary test for compliance against the standards because under expected undisturbed conditions no releases from the repository are anticipated. Compliance with the individual-protection standard was consequently based upon a scenario related to the migration of radionuclides from the repository to a near surface aquifer via an abandoned deep borehole. Consequently, we defined details for assessing an intrusion scenario at the WIPP site on the basis of current and historical practices regarding exploring for and recovering natural resources in the area. In contrast, the Yucca Mountain site is relatively poor in known attractive natural resources, other than ground water (see Chapter 8 of the BID). Therefore, consistent with NAS's recommendations, we adopted a stylized human-intrusion scenario for analysis. The NAS's recommendations and the data base of information available about the site allowed us to develop the specific details of the human-intrusion scenario, which we proposed in the draft rule. Comments we received during the public comment process also played an important role in framing the contents of the scenario. See the Response to Comments document for a more detailed discussion of these issues.

II. Background Information

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

1. Introduction and the Role of Comments in the Rulemaking Process

Section 801(a)(1) of the EnPA requires us to set public health and safety radiation protection standards for Yucca Mountain by rulemaking.[3] Pursuant to Section 4 of the Administrative Procedure Act (APA), regulatory agencies engaging in informal rulemaking must provide notice of a proposed rulemaking, an opportunity for the public to comment on the proposed rule, and a general statement of the basis and purpose of the final

[2] NRC agreed to include assurance requirements in its regulations for geologic repositories (10 CFR part 60, ''Disposal of High-Level Radioactive Wastes in Geologic Repositories'', 46 FR 13980, February 25, 1981).

[3] EnPA, Public Law No. 102–486, 106 Stat. 2776, 42 U.S.C. 10141 n. (1994).

rule.[4] The notice of proposed rulemaking required by the APA must ''disclose in detail the thinking that has animated the form of the proposed rule and the data upon which the rule is based.'' (*Portland Cement Association* v. *Ruckelshaus*, 486 F. 2d 375, 392–94 (D.C. Cir. 1973)) The public thus is enabled to participate in the process by making informed comments on the proposal. This provides us with the benefit of ''an exchange of views, information, and criticism between interested persons and the agency.'' (*Id.*)

There are two primary mechanisms by which we explain the issues raised in public comments and our reactions to them. First, we discuss broad or major comments in the succeeding sections of this preamble. Second, we are publishing a document, accompanying today's action, entitled ''Response to Comments'' (Docket No. A–95–12, Item V–C–1). The Response to Comments document provides more detailed responses to issues addressed in the preamble. It also addresses all other significant comments on the proposal. We gave all the comments we received, whether written or oral, consideration in developing the final rule.

2. How Did We Respond to General Comments on Our Proposed Rule?

We received many comments that addressed broad issues related to the proposed standards. Several commenters simply expressed their support for, or opposition to, the Yucca Mountain repository. The purpose of our standards is to ensure that any potential releases from the repository do not result in unacceptably high radiation exposures. Our standards make no judgment regarding the suitability of the Yucca Mountain site or whether NRC should issue a license for the site. Such a decision is beyond the scope of our statutory authority.

Some comments suggested our standards should consider radiation exposures from all sources because of the site's proximity to the Nevada Test Site (NTS) and other sources of potential contamination. We are aware of the other such sources of radionuclide contamination in the area. However, our mandate under the EnPA is to set standards that apply only to the storage or disposal of radioactive materials in the Yucca Mountain repository, not to these other sources. Our standards do follow the widely accepted principle that, to allow for the consideration of other exposures in developing a total acceptable dose, any specific source accounts for only a fraction of one's total exposure.

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

We received some comments that suggested we should have provided more or better opportunities for public participation in our decision making process. For example, that we should have rescheduled public hearings, extended the public comment period, and provided alternatives to the public hearing process. We provided numerous opportunities and avenues for public participation in the development of these standards. For example, we held public hearings in four locations: Washington, DC; Las Vegas, NV; Amargosa Valley, NV; and Kansas City, MO. We also opened a 90-day public comment period and met with key stakeholders during that time, including Native American tribal groups. We fully considered all comments that we received through May 1, 2000. We have, in effect, provided more than 240 days of public comment on the proposal. These measures greatly exceed the basic requirements for notice-and-comment rulemaking, and they are in full compliance with the public participation requirements of the APA.

Some comments argued that our standards for Yucca Mountain do not protect Nevadans to the same level as New Mexicans around WIPP. In fact, the individual-protection standards for Yucca Mountain and WIPP are the same: 15 mrem annual committed effective dose equivalent. The differences between the standards for Yucca Mountain and those for WIPP begin with the various statutes and the subsequent regulations promulgated under those authorities. The WIPP LWA required us to apply our generic radioactive waste standards (40 CFR part 191) to WIPP. The standards for Yucca Mountain, which we promulgate under authority granted in the EnPA, are site-specific, and therefore there are some differences compared with the standards applicable to WIPP; however, we are confident that the standards provide essentially the same level of protection from radiation exposure at both sites, as the exposure limits are the same for both.

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

B. What Are the Sources of Radioactive Waste?

Radioactive wastes result from the use of nuclear fuel and other radioactive materials. Today, we are issuing standards pertaining to SNF, 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, please understand that no decision has been made regarding the acceptability of Yucca Mountain for storage or disposal. 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.) These standards apply only to facilities on the Yucca Mountain site.

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). Sources of SNF include:

(1) Commercial nuclear power plants;

(2) Government-sponsored research and development programs in universities and industry;

(3) Experimental reactors, such as liquid metal fast breeder reactors and high-temperature gas-cooled reactors;

(4) Federal government-controlled, nuclear-materials production reactors;

(5) Naval and other Department of Defense reactors; and

(6) U.S.-owned, foreign 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

[4] 5 U.S.C. 553.

reprocessing become part of the acidic liquid wastes that DOE plans to convert into various types of solid materials. High-level wastes (HLW) are the highly radioactive liquid or solid wastes that result from reprocessing SNF. The only commercial reprocessing facility to operate in the United States, the Nuclear Fuel Services Plant in West Valley, New York, closed in 1972. Since then, there has been no reprocessing of commercial SNF in the United States. In 1992, DOE decided to phase out reprocessing of its SNF, which supported the defense nuclear weapons and propulsion programs. The SNF that does not undergo reprocessing prior to disposal becomes the waste form.

Where is the waste stored now? Today, storage of most SNF occurs in water pools or in above-ground dry concrete or steel canisters at more than 70 commercial nuclear-power reactor sites across the nation. Approximately three percent of SNF is produced by DOE, and is in storage at several DOE sites (see Appendix A, Figure A–2, of DOE's Draft Environmental Impact Statement (DEIS) for Yucca Mountain (DOE/EIS–0250D, Docket No. A–95–12, Item V–A–4)). The storage of HLW occurs at Federal facilities in Idaho, Washington, South Carolina, and New York.

What types of waste will be placed into Yucca Mountain? We anticipate that most of the waste emplaced in Yucca Mountain will be SNF and solidified HLW (in the rest of this document, HLW will refer to solidified HLW, unless otherwise noted). Under current NRC regulations (10 CFR 60.135), liquid HLW must be solidified, through processes such as vitrification (mixing the waste into glass), because non-solid waste forms are not to be stored or disposed of in Yucca Mountain. The DOE estimates that, by the year 2010, about 66,000 metric tons of SNF and 284,000 cubic meters (containing 450 million curies of radioactivity) of HLW in predisposal form and 2,900 cubic meters (containing 235 million curies) of the disposable form of HLW will be in storage at various locations around the country (DOE/RW–0006, Rev. 13, December 1997). For more information, see the waste descriptions in Appendix A of DOE's DEIS for Yucca Mountain (DOE/EIS–0250D, Docket No. A–95–12, Item V–A–4).

In the future, other types of radioactive materials could be identified for storage or disposal in the Yucca Mountain repository. These materials include highly radioactive low-level waste (LLW), known as ''greater-than-Class-C waste,'' and excess plutonium or other fissile materials resulting from the dismantlement of nuclear weapons. Because the plans for the disposal of these materials have not been finalized, neither NRC nor DOE has analyzed their impact upon the design and performance of the disposal system. However, regardless of the types of radioactive materials that finally are disposed of in Yucca Mountain, the disposal system must comply with 40 CFR part 197.

C. What Types of Health Effects Can Radiation Cause?

Ionizing radiation can cause a variety of health effects, which can be either ''non-stochastic'' or ''stochastic.'' Non-stochastic effects are those for which the damage increases with increasing exposure, such as destruction of cells or reddening of the skin. These effects appear in cases of exposure to large amounts of radiation. Stochastic effects are associated with long-term exposure to low levels of radiation. The types or severity of stochastic effects does not depend on the amount of exposure. Instead, the chance that a stochastic effect, such as cancer, will occur is assumed to increase with increasing exposure. For a detailed discussion of potential health effects related to exposure to radiation, see the preamble to the proposed rule (64 FR 46978–46979) and Chapter 6 of the BID.

Teratogenic effects can occur following fetal exposure. We believe that fetuses are more sensitive than are adults to the induction of cancer by radiation (see Chapter 6.5 of the BID). The fetus also is subject to radiation-induced physical malformations, such as small brain size (microencephaly), small head size (microcephaly), eye malformations, and slow growth prior to birth. Recent studies have focused on the apparently increased risk of severe mental retardation (as measured by the intelligence quotient). These studies indicate that the sensitivity of the fetus is greatest during 8 to 15 weeks following conception and continues, at a lower level, between 16 and 25 weeks.[5] We do not know exactly the relationship between mental retardation and dose; however, we believe it prudent to assume that there is a linear, non-threshold, dose-response relationship between these effects and the dose delivered to the fetus during the 8-to 15-week period (see Chapter 6.5 of the BID).

The NAS published its reviews of human health risks from exposure to low levels of ionizing radiation in a series of reports issued between 1972 and 1990. However, scientists still do not agree on how best to estimate the probability of cancer occurring as a result of the doses encountered by members of the public[6] because it is necessary to base estimates of these effects on the effects observed at higher doses (such as effects seen in the survivors of the Hiroshima and Nagasaki atomic bombs). Many organizations, including the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the National Radiological Protection Board of the United Kingdom, have recommended the use of the linear non-threshold model for estimating cancer risks.

Over the last decade, the scientific community has performed an extensive reevaluation of the doses and effects in the Hiroshima and Nagasaki survivors (see Chapter 6.3 of the BID). These studies have resulted in increased estimates (roughly threefold between 1972 and 1990) of the extrapolated risk of cancer occurring because of exposure to environmental (background) levels of radiation. Nonetheless, the estimated number of health effects induced by small incremental doses of radiation above natural background levels remains small compared with the total number of fatal cancers that occur from other causes. In addition, because cancers that result from exposure to radiation are the same as those that result from other causes, it may never be possible to identify them in human epidemiological studies (see Chapter 6 of the BID and the example discussed later in this section). This difficulty in identifying stochastic radiation effects does not mean that such effects do not occur. It also is possible, however, that effects do not occur as a result of these small doses. That is, there might be an exposure level below which there is no additional risk above the risk posed by natural background radiation. Sufficient data to prove either possibility scientifically is lacking. Thus, we believe that the best approach is to assume that the risk of cancer increases linearly starting at zero dose. In other

[5] Health Effects of Exposure to Low Levels of Ionizing Radiation, National Academy Press, Washington, DC, 1990.

[6] The risk of interest is not at or near zero dose, but that due to small increments of dose above the pre-existing background level. Background in the U.S. is typically about 3 millisieverts (mSv), that is, 300 millirem (mrem), effective dose equivalent per year, or 0.2 Sv (20 rem) in a lifetime. Approximately two-thirds of this dose is due to radon, and the balance comes from cosmic, terrestrial, and internal sources of exposure.

words, any increase in exposure to ionizing radiation results in a constant and proportionate increase in the potential for developing cancer.

The NAS Report stated that radiation causes about five cancers for every severe hereditary disorder caused by radiation exposure. Also, NAS concluded that nonfatal cancers are more common than fatal cancers. Despite this conclusion, NAS cited an ICRP study that judged that non-fatal cancers contribute less to overall health impact than fatal cancers ''because of their lesser severity in the affected individuals.'' (NAS Report pp. 37–39). We based our risk estimates for exposure of the population to low-dose-rate radiation on fatal cancers rather than on all cancers for the same reasons enumerated by NAS.

For radiation-protection purposes, we estimate (using a linear, non-threshold, dose-response model) an average risk for a member of the U.S. population of 5.75 in 100 (5.75×10^{-2}) fatal cancers per sievert (Sv)[7] (5.75×10^{-4} fatal cancers per rem) delivered at low dose rates.[8] For this calculation, as long as the exposure rate is low, the number of incremental cancers depends on the amount of radiation received, not the time period over which the dose is delivered, because the linear non-threshold model assumes that any incremental dose carries a risk (see Chapter 6.3 of the BID). For example, if 100,000 people randomly chosen from the U.S. population each received a uniform dose of 1 millisievert (mSv) (0.1 rem) to the entire body at a rate equivalent to that observed from natural background sources, the assumption is that approximately five to six people will die of cancer during their remaining lifetimes because of that exposure. These five to six deaths are in addition to the roughly 20,000 fatal cancers that would occur in the same population from other causes. The risk of fatal childhood cancer that results from exposure while in the fetal stage is about 3 in 100 (3×10^{-2}) per Sv (that is, 3×10^{-4} effects per rem). The risk of severe hereditary effects in offspring is estimated to be about 1×10^{-2} per Sv (1×10^{-4} effects per rem).[9] The risk of severe mental retardation from doses to a fetus is estimated to be greater per unit dose than the risk of cancer in the general population.[10] However, the period of increased sensitivity is much shorter. Hence, at a constant exposure rate, fatal cancer risk in the general population remains the dominant factor. Please see the BID for more details on this subject.

Of course, our risk estimates do contain some uncertainty. A recent uncertainty analysis published by NCRP (NCRP Report 126, Docket A–95–12, Item II–A–13) estimated that the actual risk of cancer from whole-body exposure to low doses of radiation could be between 1.5 times higher and 4.8 times lower (at the 90-percent confidence level) than our basic estimate of 5.75×10^{-2} per Sv (5.75×10^{-4} per rem). The risks of genetic abnormalities and mental retardation are less well known than those for cancer. Thus, they may include a greater degree of uncertainty. Further, existing epidemiological data does not rule out the existence of a threshold. If there is a threshold, exposures below that level would pose no additional risk above the risk posed by natural background radiation. However, in spite of uncertainties in the data and its analysis, estimates of the risks from exposure to low levels of ionizing radiation are known more clearly than are those for virtually any other environmental carcinogen. See Chapter 6 of the BID.

D. What Are the Major Features of the Geology of Yucca Mountain and the Disposal System?

The geology. Yucca Mountain is in southwestern Nevada approximately 100 miles northwest of Las Vegas. The eastern part of the site is on 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. For more detailed descriptions of Yucca Mountain's geologic and hydrologic characteristics, and the disposal system, please see chapter 7 of the BID and the preamble to the proposed rule (64 FR 46979–46980). These documents are in the docket for this rulemaking (Docket No. A–95–12, Items III–B–2, V–B–1).

Yucca Mountain is made of layers of ashfalls from volcanic eruptions that happened more than 10 million years ago. The ash consolidated into a rock type called ''tuff,'' which has varying degrees of compaction and fracturing depending upon the degree of ''welding'' caused by temperature and pressure when the ash was deposited. Regional geologic forces have tilted the tuff layers and formed Yucca Mountain's crest (Yucca Mountain's shape is a ridge rather than a peak). Below the tuff is carbonate rock formed from sediments laid down at the bottom of ancient seas that existed in the area.

There are two general hydrologic zones within and below Yucca Mountain. The upper zone is called the ''unsaturated zone'' because the pore spaces and fractures within the rock are not filled entirely with water. Below the unsaturated zone, beginning at the water table, is the ''saturated zone,'' in which water completely fills the pores and fractures. Fractures in both zones could act as pathways that allow for faster contaminant transport than would the pores. The DOE plans to build the repository in the unsaturated zone about 300 meters below the surface and about 300 to 500 meters above the water table (DOE Viability Assessment (DOE/VA), Docket No. A–95–12, Item V–A–5).

There are two major aquifers in the saturated zone under Yucca Mountain. The upper one is in tuff. The lower one is in carbonate rock. Regional ground water in the vicinity of Yucca Mountain is believed to flow generally in a south-southeasterly direction. See Chapters 7 and 8 of the BID for a fuller discussion of the aquifers and the other geologic attributes of the Yucca Mountain region.

The disposal system. The NAS Report described the current concept of the potential disposal system as a system of engineered barriers for the disposal of radioactive waste located in the geologic setting of Yucca Mountain (NAS Report pp. 23–27). Based on DOE's current design, entry into the repository for waste emplacement would be on gradually downward sloping ramps that enter the side of Yucca Mountain. Section 114(d) of the NWPAA limits the capacity of the repository to 70,000 metric tons of SNF and HLW. Current DOE plans project that about 90 percent (by mass) would be commercial SNF; and 10 percent would be defense HLW

[7] The traditional unit for dose equivalent has been the rem. The unit ''sievert'' (Sv), a unit in the International System of Units that was adopted in 1979 by the General Conference on Weights and Measures, is now in general use throughout the world. One sievert equals 100 rem. The prefix ''milli'' (m) means one-thousandth. The individual-protection limit being finalized today may be expressed equivalently in either unit.

[8] ''Low dose rates'' here refers to dose rates on the order of or less than those from background radiation.

[9] The risk of severe hereditary effects in the first two generations, for exposure of the reproductive part of the population (with both parents exposed), is estimated to be 5×10^{-3} per Sv (5×10^{-5} per rem). For all generations, the risk is estimated to be 1.2×10^{-2} per Sv (1.2×10^{-4} per rem). For exposure of the entire population, which includes individuals past the age of normal child-bearing, each estimate is reduced to 40% of the cited value.

[10] Assuming a linear, non-threshold dose response, estimated risk for mental retardation due to exposure during the 8th through 15th week of gestation is 4×10^{-1} per Sv (4×10^{-3} per rem); under the same assumption, the estimated risk from the 16th to 25th week is 1×10^{-1} per Sv (1×10^{-3} per rem).

(NAS Report p. 23). The NAS further stated that within 100 years after initial emplacement of waste, the repository would be sealed by closing the opening to each of the tunnels and sealing the entrance ramps and shafts (NAS Report pp. 23, 26).

We expect the engineered barrier system to consist of at least the waste form (SNF assemblies or borosilicate glass containing the HLW), internal stabilizers for the SNF assemblies, and the waste packages holding the waste. Spent nuclear fuel assemblies consist of uranium oxide, fission products, fuel cladding, and support hardware, all of which will be radioactive (see the *What are the Sources of Radioactive Waste?* section above).

E. Background on and Summary of the NAS Report

Section 801(a)(2) of the EnPA directs us to contract with NAS to conduct a study to provide findings and recommendations on reasonable standards for protection of public health and safety. Section 801(a)(2) specifically calls for NAS to address the following three issues:

(A) Whether a health-based standard based upon doses to individual members of the public from releases to the accessible environment (as that term is defined in the regulations contained in subpart B of part 191 of title 40, Code of Federal Regulations, as in effect on November 18, 1985) will provide a reasonable standard for protection of the health and safety of the general public;

(B) Whether it is reasonable to assume that a system for post-closure oversight of the repository can be developed, based upon active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits; and

(C) Whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.

On August 1, 1995, NAS submitted to us its report, entitled ''Technical Bases for Yucca Mountain Standards.'' The NAS Report is available for review in the docket (Docket No. A–95–12, Item II–A–1) and the information files described earlier. You can order the report from the National Academy Press by calling 800–624–6242 or on the World Wide Web at *http://www.nap.edu/catalog/4943.html.*

1. What Were NAS's Findings (''Conclusions'') and Recommendations?

The NAS Report contained a number of conclusions and recommendations. (The EnPA used the term ''findings;'' however, the NAS Report used the term ''conclusions''). A summary of NAS's conclusions appears below. See pages 1–14 of the NAS Report, or the preamble to our proposed rule (64 FR 46980), for a list of NAS's conclusions and recommendations. For details on public participation in our review of the NAS Report, please see the preamble to the proposed rule (64 FR 46980–46981).

Conclusions. The conclusions in the Executive Summary of the NAS Report (pp. 1–14) were:

(a) ''That an individual-risk standard would protect public health, given the particular characteristics of the site, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk'' (later termed ''negligible incremental risk''). (This conclusion is the response to the issue Congress identified in EnPA Section 801(a)(2)(A));

(b) That the Yucca Mountain-related ''physical and geologic processes are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance can be assessed over time frames during which the geologic system is relatively stable or varies in a boundable manner;''

(c) ''That it is not possible to predict on the basis of scientific analyses the societal factors required for an exposure scenario. Specifying exposure scenarios therefore requires a policy decision that is appropriately made in a rulemaking process conducted by EPA;''

(d) ''That it is not reasonable to assume that a system for post-closure oversight of the repository can be developed, based on active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits.'' (This conclusion is the response to the issue Congress identified in EnPA section 801(a)(2)(B));

(e) ''That it is not possible to make scientifically supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years.'' (This conclusion is the response to the issue Congress identified in EnPA Section 801(a)(2)(C)); and

(f) ''That there is no scientific basis for incorporating the ALARA (as low as reasonably achievable) principle into the EPA standard or USNRC (U.S. Nuclear Regulatory Commission) regulations for the repository.''

Recommendations. The recommendations in the Executive Summary of the NAS Report were:

(a) ''The use of a standard that sets a limit on the risk to individuals of adverse health effects from releases from the repository;''

(b) ''That the critical-group approach be used'';

(c) ''That compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment;'' and

(d) ''That the estimated risk calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case because a repository that is suitable for safe long-term disposal should be able to continue to provide acceptable waste isolation after some type of intrusion.''

Other Conclusions and Recommendations. The NAS made other conclusions and recommendations in addition to those listed above. Most of them were related to or supported those presented in the Executive Summary.

III. What Does Our Final Rule Do?

Our rule establishes public health and safety standards governing the storage and disposal of SNF, HLW, and other radioactive material in the repository at Yucca Mountain, Nevada.

As noted earlier, section 801(a)(1) of the EnPA gives us rulemaking authority to set ''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.'' The statute also directs us to develop standards ''based upon and consistent with the findings and recommendations of the National Academy of Sciences.'' Section 801(a)(2) of the EnPA directs us to contract with NAS to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. Because the EnPA directs us to act ''based upon and consistent with'' NAS's findings, a major issue in this rulemaking is whether we must follow NAS's findings and recommendations without exception or whether we have discretionary decision-making authority.

As we discussed in the preamble to the proposed rule, we believe we have discretionary decision-making authority and, therefore, are not required to adopt, without exception, NAS's findings and recommendations. See 64 FR 46981–46983 for this discussion. As a practical matter, the difficulty of resolving this issue is reduced because NAS expressed some of the findings and recommendations in a non-binding manner. In other words, in many instances NAS either stated its findings and recommendations as starting points for the rulemaking process or recognized those recommendations that involve public policy issues that are addressed more properly in this public rulemaking proceeding. However, the report also contains some findings and recommendations stated in relatively definite terms. These issues present most squarely the question of whether we are to treat all of NAS's findings and recommendations as binding.

Whether the EnPA binds us to following exactly NAS's findings and recommendations is a question that warrants close attention because it affects the scope of our rulemaking. If we must follow every view expressed in the NAS Report, we would have to treat any such issue as having been addressed conclusively by NAS. We would not need to entertain public comment upon the affected issues because the outcome would be predetermined by NAS.

We believe the EnPA does not bind us absolutely to follow the NAS Report. Instead, we used it as the starting point for this rulemaking. As Congress directed, today's rule is based upon and consistent with the NAS findings and recommendations. We were guided by the panel's findings and recommendations because of the special role Congress gave it and because of NAS's scientific expertise. However, the entirety of our standards is the subject of this rulemaking. Therefore, we have not treated the views expressed by NAS as necessarily dictating the outcome of this rulemaking, thereby foreclosing public scrutiny of important issues. For the reasons described below, we believe this interpretation of the EnPA is both consistent with the statute and prudent, because it avoids potential constitutional issues. Further, this interpretation supports an important EPA policy objective and legal obligation: Ensuring an opportunity for public input regarding all aspects of the issues presented in this rulemaking.

Section 801(a)(2) of the EnPA requires NAS to provide ''findings and recommendations on reasonable standards for protection of the public health and safety.'' This section of the EnPA calls for NAS to address three specific issues; however, Congress did not place any restrictions on other issues NAS could address. The report of the Congressional conferees underscored that ''the (NAS) would not be precluded from addressing additional questions or issues related to the appropriate standards for radiation protection at Yucca Mountain beyond those that are specified.'' (H.R. Rep. No. 102–1018, 102nd Cong., 2d Sess. 391 (1992)). Thus, given the potentially unlimited scope of NAS's inquiry under the statute, it could have provided findings and recommendations that would dictate literally all aspects of the public health and safety standards for Yucca Mountain, rendering our function a merely ministerial one.

Section 801(a)(1) of the EnPA plainly gives us the authority to issue, by rulemaking, public health and safety standards for Yucca Mountain. If at the same time that Congress gave NAS the authority to provide findings and recommendations on any issues related to the Yucca Mountain public health and safety standards, Congress also intended that NAS's findings and recommendations would bind us, then Congress effectively would have delegated to NAS a standard-setting authority that overrides our rulemaking authority. Carried to its logical conclusion, under this view of the statute, NAS would have authority to establish the public health and safety standards without a public rulemaking process. Congress' direction to EPA to set standards ''by rule'' would be unnecessary or relatively meaningless. It is both reasonable and appropriate to resolve this tension in the statute by interpreting NAS's findings and recommendations as non-binding, but highly influential, expert guidance to inform our rulemaking.

Thus, we do not believe the statute forces our rulemaking to adopt mechanically NAS's recommendations as standards. If it did, the statutory provisions would allow us to consider only those issues that NAS did not address. Further, the provisions calling for us to use standard rulemaking procedures in issuing the standards would be unnecessary to reach results that NAS already established. We consider the NAS Report's explicit references to decisions that should be made during the rulemaking process to be support for our position.

The EnPA conference report also reveals that Congress did not intend to limit our rulemaking discretion. The conference report clarifies that Congress intended NAS to provide ''expert scientific guidance'' on the issues involved in our rulemaking and that Congress did not intend for NAS to establish the specific standards:

> The Conferees do not intend for the National Academy of Sciences, in making its recommendations, to establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards. Under the provisions of section 801, the authority and responsibility to establish the standards, pursuant to rulemaking, would remain with the Administrator, as is the case under existing law. The provisions of section 801 are not intended to limit the Administrator's discretion in the exercise of his authority related to public health and safety issues. (H.R. Rep. No. 102–1018, p. 391)

Our interpretation of the EnPA as not limiting the issues for consideration in this rulemaking is consistent with the views we expressed to Congress during deliberations over the legislation. The Chair of the Senate Subcommittee on Nuclear Regulation requested our views regarding the bill reported by the conference committee. The Deputy Administrator of EPA indicated the NAS Report would provide helpful input. Moreover, the Deputy Administrator pointed to the language, cited above, stating the intent of the conferees not to limit our rulemaking discretion and assured Congress that any standards for radioactive materials that we ultimately issue would be the subject of public comment and involvement and would fully protect human health and the environment (138 Cong. Rec. 33,955 (1992)).

Our interpretation also is consistent with the role that both NAS and Congress understood NAS would fulfill. During the Congressional deliberations over the legislation, NAS informed Congress that while it would conduct the study, it would not assume a standard-setting role because such a role is properly the responsibility of government officials. (138 Cong. Rec. 33,953 (1992)) Our interpretation of the NAS Report also avoids implicating potentially significant constitutional issues. Construing the EnPA as delegating to NAS the responsibility to determine the health and safety standards at Yucca Mountain may violate the Appointments Clause of the Constitution (Art. II, sec. 2, cl. 2), which imposes restrictions against giving Federal governmental authority to persons not appointed in compliance with that Clause. In addition, the Constitution places restrictions arising under the separation of powers doctrine upon the delegation of governmental authority to persons not part of the Federal government. We are not concluding, at this time, that an alternative interpretation necessarily would run afoul of constitutional limits. We believe, however, that it is reasonable both to assume that Congress intended to avoid these issues when it adopted section 801 of the EnPA and to interpret the EnPA accordingly.

In summary, we do not believe we must, in this rulemaking, adopt all of NAS's findings and recommendations. The statute does, however, give NAS a special role. As noted previously, NAS's findings and recommendations were instrumental in this rulemaking. Our proposal is consistent with those findings and recommendations. We included many of the findings and recommendations in this rule. We tended to give greatest weight to NAS's judgments about issues having a strong scientific component, the area in which NAS has its greatest expertise. In addition, we reached final determinations that are congruent with NAS's analysis whenever we could do so without departing from the Congressional delegation of authority to us to promulgate, by rule, public health and safety standards for protection of the public. We believe our mandate from Congress required the consideration of public comments and the exercise of our own expertise and discretion.

We requested public comments concerning: how we should view and weigh NAS's findings and recommendations in the context of the specific issues presented in this rulemaking; whether we have given proper consideration to NAS's findings and recommendations; and whether we should give them more or less weight, and what the resulting outcome should be.

We received many comments regarding our EnPA authority and our interpretation of the NAS Report. Several comments took issue with our reasons for not simply adopting each of the NAS recommendations verbatim and stated that we are bound to do so. One comment asserted that our reasoning ''exaggerates the impact of the NAS Report'' on our rulemaking authority. However, these comments generally recognized that we can depart from the NAS panel's recommendations if it specifically stated that policy considerations could play a role in the decision, or if the recommendation at issue otherwise was not definitive (e.g., there was disagreement among the panel members). In particular, some comments suggested that we cannot include any provision if NAS did not recommend it. We disagree with this position. In the preamble to the proposed rule, we clearly stated our intentions regarding our use of the NAS Report (see 64 FR 46980–46983). We gave the NAS Report special consideration as ''expert scientific guidance.'' However, as discussed above, we do not believe that Congress intended the NAS Report to bind us absolutely. We note that NAS, in its comments on our proposed rule, did not offer an opinion on this point. Also, NAS acknowledges in several places in its report that, for policy or other reasons, we may elect to take approaches that differ from its recommendations. These statements show NAS did not consider its recommendations to be binding directions to EPA. The NAS did, however, identify aspects of the proposal it believes are inconsistent with its recommendations. A copy of NAS's comments on the proposal is in the docket (Docket No. A–95–12, Item IV–D–31). See the Response to Comments document for additional discussion of comments regarding our incorporation of the NAS recommendations (Docket No. A–95–12, Item V–C–1).

The following sections describe our public health and safety standards for Yucca Mountain and the considerations that underlie these standards. The next section addresses the storage portion of the standards. All of the other sections pertain to the disposal portion of the standards.

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 (to be differentiated from the disposal system, which is made up of the repository, the engineered barriers, and the natural barriers). The EnPA differentiates between ''stored'' and ''disposed'' waste, although it indicates that we must issue standards that apply to both storage and disposal. Congress was not clear regarding its intended use of the word ''stored'' in this context. Also, NAS did not address the issue of storage versus disposal (see § 197.2 for our definition of ''storage'' and § 197.12 for our definition of ''disposal''). The DOE currently conceives of the Yucca Mountain repository as a disposal facility, not a storage facility; however, this situation could change. Therefore, we decided to interpret the statutory language as directing us to develop standards that apply to waste that DOE either stores or disposes of in the Yucca Mountain repository. The storage standard, therefore, applies to waste inside the repository, prior to disposal.

We received several comments regarding our proposed definition of ''disposal'' in § 197.12, arguing that the potential benefits of backfilling are unknown at present. In response to these comments, we changed the definition in the final rule to exclude the requirement that DOE use backfilling in the Yucca Mountain repository. We believe that DOE should have the flexibility to design the repository so that it is as protective of public health and the environment as possible. Therefore, in order not to constrain DOE unnecessarily in its choice of repository designs, we changed the definition of ''disposal'' as the comments suggested. Thus, under the revised definition in our final rule, it is no longer necessary for DOE to use backfilling for waste disposal to occur.

Several comments also suggested that our proposed definitions of ''disposal'' and ''barrier'' run counter to established notions of deep geologic repositories because they allow DOE to rely upon both engineered and natural barriers, instead of natural barriers alone, to contain the radioactive material to be stored in Yucca Mountain. These comments suggested we amend these definitions, as appropriate, to delete references to engineered barriers. According to the comments, the Yucca Mountain repository must meet public health and safety standards with no assistance from manmade structures or barriers. The EnPA mandates that we establish site-specific standards for Yucca Mountain. Under this mandate, we believe it is appropriate, based on the conditions present at Yucca Mountain, to allow DOE the flexibility to develop a combined system, using engineered barriers and natural barriers, to contain radioactive material to be disposed of in Yucca Mountain. For additional discussion of this topic, please see Chapter 7 of the BID.

The DOE also will handle, and might store, radioactive material aboveground (that is, outside the repository). Our existing standards for management and storage, codified at subpart A of 40 CFR part 191, apply to such storage activities. Subpart A of 40 CFR part 191 requires that DOE manage and store SNF, HLW, and transuranic radioactive wastes at a site, such as Yucca Mountain, in a manner that provides a reasonable assurance that the annual dose equivalent to any member of the public in the general environment will not exceed 25 millirem (mrem) to the whole body. (Note that a demonstration of ''reasonable assurance'' is necessary to comply with the standard for storage, while subpart B of both 40 CFR part 191 and today's 40 CFR part 197 specify a demonstration of ''reasonable expectation'' to comply with the disposal standards. ''Reasonable assurance'' is an appropriate measure to apply to storage, as the facility will be in operation, with active monitoring and personnel present, during this time. The level of certainty connected with this period of active operation is significantly higher than can be attached to the much longer regulatory time period applicable to disposal standards. See our discussion of ''reasonable expectation'' in section III.B.2.c., *What Level of Expectation Will Meet Our Standards?*) This standard is the one that DOE must meet for WIPP and the greater confinement disposal (GCD) facility. (The GCD facility is a group of 120-feet deep boreholes, located within NTS, which contain disposed transuranic wastes.)

We take this position regarding the applicability of subpart A of 40 CFR part 191 because section 801 of the EnPA specifically provides that the standards we issue shall be the only ''such standards'' that apply at Yucca Mountain. Thus, the EnPA is the exclusive authority for today's action regarding storage inside the repository. The WIPP LWA does not exclude Yucca Mountain from the management and storage provisions in subpart A of 40 CFR part 191. The 40 CFR part 197 standards supercede our generally applicable standards (40 CFR part 191) only to the extent that the EnPA requires site-specific standards for storage inside the repository at Yucca Mountain. Otherwise, the 40 CFR part 197 standards have no effect on our generic standards. As noted, we interpret the scope of section 801 to include both storage and disposal of waste in the repository. Thus, waste inside the repository is subject to the standards in today's action. Our generic standards (subpart A of 40 CFR part 191) will apply to waste stored at the Yucca Mountain site, but outside of the repository.

The storage standards in 40 CFR 191.03(a) are stated in terms of an older dose-calculation method and are set at an annual whole-body-dose limit of 25 mrem/yr. The storage standard for Yucca Mountain uses a modern dose-calculation method known as ''committed effective dose equivalent'' (CEDE). Even though today's final rule uses the modern method of dose calculation, we believe that the dose level maintains a similar risk level as in 40 CFR 191.03(a) at the time of its promulgation (see the discussion of the different dose-calculation methods in the *What Is the Level of Protection For Individuals?* section later in this document). The difference between these dose calculation procedures presents a problem in combining the doses for regulatory purposes. However, we have begun to develop a rulemaking to amend both 40 CFR parts 190 and 191. That rulemaking would update these limits to the CEDE methodology. However, because we have not yet finalized that change, we need to address the calculation of doses under the two methods in another fashion (see the last paragraph in this section for more detail).

As discussed in the preamble to the proposed rule (64 FR 46983), we considered the differences among the conditions covered by the storage standards in 40 CFR 191.03(a) and the conditions that could affect storage in the Yucca Mountain repository. The most significant difference is that the storage in Yucca Mountain would be underground, whereas most storage covered under 40 CFR part 191 is aboveground. Otherwise, the technical situations we anticipate under both the existing generic standards and the Yucca Mountain standards are essentially the same. Also, our final rule extends a similar level of protection as in the 1985 version of subpart A of 40 CFR part 191. In other words, under the 40 CFR part 197 storage standard, exposures of members of the public from waste storage inside the repository would be combined with exposures occurring as a result of storage outside the repository but within the Yucca Mountain site (as defined in 40 CFR 197.2). The total dose could be no greater than 150 microsieverts (μSv) (15 mrem) CEDE per year (CEDE/yr).

We requested comments regarding our interpretation of section 801 and our approach to coordinating the doses originating from inside and outside the Yucca Mountain repository. We received two comments regarding this issue. One comment urged us to establish a single, new, and separate standard for the Yucca Mountain site that would encompass the pre-closure operations both aboveground and in the repository. The comment further stated that the suggested approach would avoid using two different rules for the same site. This suggested approach also would avoid the need to use the older dose methodology currently in 40 CFR part 191. Another comment stated that the application of subpart A of 40 CFR part 191 would not be inappropriate.

We considered establishing a new standard to cover the entirety of the management and storage operations at Yucca Mountain, as was suggested by one comment. This had the attractive feature of applying one standard, instead of two, to the management and storage activities in and around Yucca Mountain.

However, after considering the comments, the wording in section 801(a)(1) of the EnPA, and the impending rulemaking to amend subpart A of 40 CFR part 191, we have decided to cover the surface management and storage activities within the Yucca Mountain site under 40 CFR part 191 and management and storage activities in the Yucca Mountain repository under 40 CFR part 197. However, the combined doses incurred by any individual in the general environment from these activities must not exceed 150 μSv (15 mrem) CEDE/yr. This will require the conversion of doses from the surface activities from the older dose system (under which the 40 CFR part 191 standards were developed) into the newer system to be able to combine the doses from the two areas of operation. There are established methods to do this, e.g., in the appendix to 40 CFR part 191, but we are leaving the methodology in this case to NRC's implementation process. We are continuing to develop a rulemaking to update the dose system used in subpart A of 40 CFR part 191. When that amendment is finished, the conversion for the activities subject to subpart A of 40 CFR part 191 will be unnecessary.

B. What Are the Standards for Disposal? (§§ 197.11 through 197.36)

Subpart B of this final rule consists of three separate standards (or sets of standards) that apply after final disposal, which are discussed in more detail in the appropriate sections of this document. The disposal standards are:

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

1. What Is the Standard for Protection of Individuals? (§§ 197.20 and 197.25)

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 disposal system.

a. Is the Limit on Dose or Risk? Section 801(a)(1) of the EnPA directed that our standards for Yucca Mountain ''shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository * * *.'' The EnPA also requires us to issue our standards ''based upon and consistent with'' NAS's findings and recommendations.

The NAS recommended that we adopt a risk-based standard to protect individuals, rather than a dose-based standard as Congress prescribed. The NAS offered two reasons for its recommendation. First, a risk-based standard is advantageous relative to a dose-based standard because it ''would not have to be revised in subsequent rulemakings if advances in scientific knowledge reveal that the dose-response relationship is different from that envisaged today'' (NAS Report p. 64). Second, NAS believes a risk-based standard more readily enables the public to comprehend and compare the standard with human-health risks from other sources.

We reviewed and evaluated the merits of a risk-based standard as recommended by NAS (NAS Report, pp. 41–ff.). However, we chose to adopt a dose-based standard for the following reasons. First, EnPA section 801(a)(1) specifically directs us to promulgate a standard prescribing the ''maximum annual dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository.'' Also, the Conference Committee specifically stated that EPA's standards ''shall prescribe the maximum annual dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository. (H. R. Rep. 102–1018, 102nd Cong., 2d Sess. 390 (1992)). In a situation such as this, where both the statutory language and the legislative history are clear, we are obliged to implement the clearly stated plain language of the statute and to carry out the unambiguous intent of the Congress.

Second, both national and international radiation protection guidelines developed by bodies of non-governmental radiation experts, such as ICRP and NCRP, generally have recommended that radiation standards be established in terms of dose. Also, national and international radiation standards, including the individual-protection requirements in 40 CFR part 191, are established almost solely in terms of dose or concentration, not risk. Therefore, a risk standard will not allow a convenient comparison with the numerous existing dose guidelines and standards.

However, we did establish the dose limit using the risk of developing a fatal cancer. The level of risk, about 8.5 fatal cancers per million members of the population per year (see the preamble to the proposed rule at 64 FR 46984), is a level the Agency has judged to be acceptable taking into account many factors, including existing radiation standards (such as subpart B of 40 CFR part 191), Congressional action (the WIPP LWA), and the comments received on the proposed standards. On page 46985 of the preamble to the proposed rule, we cited a risk of approximately seven in a million per year. This value was based upon the NAS risk value of 5×10^{-2} per Sv (5×10^{-4} per rem, NAS Report p. 47). However, for consistency, we should have used the value which was first discussed on page 46979 of the preamble to the proposed rule, 5.75×10^{-2} per Sv (5.75×10^{-2} per rem), and which is from Federal Guidance Report 13 (Docket A–95–12, Item V–A–20). This higher value associates an annual risk of about 8.5 in a million with 150 μSv (15 mrem). Because this underlying risk level is a matter of public policy, it is possible that the level could change if future decisionmakers make a different judgment as to the level of risk acceptable to the general public. Likewise, as NAS noted, it could become necessary to change the dose limit as a result of future scientific findings about the cancer-inducing aspects of radiation (i.e., in correlating dose with risk). Therefore, no matter which form of standard is used, it is subject to change in the future, though the reasons for change may not be identical. However, either way, risk is the underlying basis of the standards. It is for the other reasons cited in this section that we chose to use dose. In addition, dose and risk are closely related. It is possible to convert one to the other by using the appropriate conversion factor. We have discussed the correlations that we used in converting risk to dose, both in this preamble and in Chapter 6 of the BID.

Finally, we did not receive any comments in favor of a risk standard that provided either a compelling technical or policy rationale for promulgating such a standard (see the Response to Comments document).

Therefore, we establish a standard stated as a dose rather than a risk.

We requested comments as to whether the standard should be expressed as risk or dose. Not unexpectedly, the comments were divided between the alternatives. Most of the comments supported the use of dose.

One comment stated that the calculation of a dose limit through a probabilistic performance assessment is a reasonable way to assure that the repository will meet the overall health risk objective. It is NRC's responsibility to determine how DOE must demonstrate compliance with our standards; however, we envision the use of a probabilistic assessment for the compliance demonstration. Another comment stated that a dose limit is a reasonable way for us to incorporate cancer risk into the regulation. As discussed to some extent in section III.B.1.b (*What Factors Can Lead to Radiation Exposure?*), and in more detail in the preamble to the proposed standards (beginning on 64 FR 46984), the risk of fatal cancer, an annual risk of about 8.5 in a million for an exposure of 150 μSv, is the basis of the level of protection that we have established.

A few comments supported stating the standard in terms of risk rather than dose. For example, NAS was concerned that a dose standard would preclude the public from being able to compare risks with other hazardous materials. According to NAS, the use of a dose standard also makes it difficult for the public to compare the risks inherent in the ground-water protection standards with the risks inherent in the individual-protection standard. The NAS also stated that its recommendation to use a risk standard did not preclude us from using a dose standard, as long as the underlying risk basis was clearly understood. We believe that we have been sufficiently clear in describing the risk basis of the standards within this preamble and the Response to Comments document.

b. What Factors Can Lead to Radiation Exposure? Protection of the public from exposure to radioactive pollutants requires knowledge and understanding of three factors: the sources of the radiation, the pathways leading to exposure, and the recipients of the radiation dose. The standards must consider all three factors. This section discusses the sources of radiation and the pathways of exposure. The following two sections discuss the recipients of the dose. Dose assessments are conducted through a type of calculational analysis called ''performance assessment''. The performance assessment is the quantitative analysis of the projected behavior of the disposal system, which considers release scenarios for the repository and carries the analysis through various pathways in the environment that culminate in exposures to members of the public.

Sources. The waste disposed of in Yucca Mountain will contain many radionuclides, including unconsumed uranium, fission products (such as cesium-137 and strontium-90), and transuranic elements (such as plutonium and americium).

The inventory of radionuclides over time will depend upon the type and amount of radionuclides originally disposed of in the repository, the half-lives of the radionuclides, and the amount of any radionuclides formed from the decay of parent radionuclides (see Chapter 5 of the BID). In the time frame of tens to hundreds of thousands of years, the short-lived radionuclides initially present in SNF and HLW will decay. Therefore, the waste eventually will have radiologic hazards similar to a large uranium ore body; such ore bodies naturally occur in a variety of settings throughout the country. A typical uranium ore body contains relatively low concentrations of very long-lived radionuclides similar to those present in the radioactive wastes to be disposed of in Yucca Mountain (see the preamble to the final rule establishing 40 CFR part 191 (50 FR 38083, September 19, 1985)).

Barriers to Radionuclide Movement. To delay and limit the movement of radionuclides into the biosphere, DOE plans to use multiple barriers. These barriers will be both engineered (human-made) and natural based on the design of, and conditions in and around, the disposal system.

Both the natural and engineered barriers must delay and limit releases of radionuclides from the repository. For example, an engineered barrier could be the waste form. The DOE plans to convert liquid HLW, derived from reprocessing SNF, into a solid by entraining the radionuclides into a matrix of borosilicate glass. The molten glass then would be poured into and solidified in a second engineered barrier, a metal container (see Chapter 7 of the BID). In addition, it is possible to have other engineered barriers in the repository to serve as part of the disposal system (see Chapter 7 of the BID).

Natural barriers at Yucca Mountain also could slow the movement of radionuclides into the accessible environment. For instance, DOE plans to construct the repository in a layer of tuff located above the water table. The relative dryness of the tuff around the repository would limit the amount of water coming into contact with the waste, and would retard the future movement of radionuclides from the waste into the underlying aquifer. Any radioactive material that dissolved in infiltrating water, originating as surface precipitation, still would have to move to the saturated zone. In the saturated zone, which lies below the unsaturated zone, water completely fills the pores and fractures in the rock. Minerals, such as zeolites, in the tuff beneath the repository could act as molecular filters and ion-exchange agents for some of the released radionuclides, thereby slowing their movement. These minerals also could limit the amount of water that contacts the waste and could help retard the movement of radionuclides from the waste to the water table. This mechanism would be most effective if flow was predominantly through the matrix (the pores in the rock) (see Chapter 7 of the BID).

Pathways. Once radionuclides have left the waste packages, water or air could carry them to the accessible environment. Ground water will carry most of the radionuclides released from the waste packages away from the repository. However, air moving through the mountain will carry away those radionuclides, such as carbon-14 (^{14}C) in the form of carbon dioxide, that escape from the waste packages in a gaseous form. For more detailed discussions of the ground water and air pathways, see the preamble to the proposed rule (64 FR 46986) and Chapters 8 and 9 of the BID.

Movement via water. Radionuclides will not move instantaneously into the water table. The length of time it will take for radionuclides to reach the water table depends partly on how much the water moves via fractures or through the matrix of the rock. Once radionuclides reach the saturated zone, they would move away from the disposal system in the direction of ground water flow.

There are currently no perennial rivers or lakes adjacent to Yucca Mountain that could transport contaminants. Therefore, based on current knowledge and conditions, ground water and its usage will be the main pathways leading to exposure of humans. Current knowledge suggests that the two major ways that people would use the contaminated ground water are: (1) Drinking and domestic uses; and (2) agricultural uses (see Chapters 8 and 9 of the BID). In other words, radionuclides that reach the public could deliver a dose if an individual: (1) Drinks contaminated ground water or uses it directly for other household uses; (2) drinks other liquids containing contaminated water; (3) eats food products processed using contaminated water; (4) eats vegetables or meat raised using contaminated water; or (5) otherwise is exposed as a result of immersion in contaminated water or air or inhalation of wind-driven particulates left following the evaporation of the water.

Movement via air. Releases of gaseous ^{14}C from the wastes can move through the tuff overlying the repository and exit into the atmosphere following release from the waste package. Once the radioactive gas enters the atmosphere, it would disperse across the globe. This global dispersion would result in significant dilution of the ^{14}C. The major pathway for human exposure to ^{14}C is the uptake of radioactive carbon dioxide by plants that humans subsequently eat (see Chapter 9 of the BID).

c. What Is the Level of Protection for Individuals? Our individual-protection standard sets a limit of 150 μSv (15 mrem) CEDE/yr. This limit corresponds approximately to an annual risk of fatal cancer of about 8.5 chances in 1,000,000 (8.5×10^{-6}). It is within NAS's recommended starting range of 1 in 100,000 to 1 in 1,000,000 annual risk of fatal cancer (see the NAS Report p. 5, Docket No. A–95–12, Item II–A–1). The NAS's recommended risk range corresponds to approximately 20 to 200 μSv (2 to 20 mrem) CEDE/yr.

We considered NAS's findings and recommendations in our determination of the CEDE level that would be adequately protective of human health. We also reviewed established EPA standards and guidance, other Federal agencies' standards for both radiation and non-radiation-related actions, and other countries' regulations. In addition, we evaluated guidance on dose limits provided by national and international non-governmental advisory groups of radiation experts.

Section 801(a)(1) of the EnPA calls for our Yucca Mountain standards to ''prescribe the maximum annual effective dose equivalent to individual members of the public from releases of radioactive materials.'' Development of the individual-protection standard required us to evaluate and specify several factors, which include the level of protection, whom the standards should protect, and how long the standards should provide protection. Determining the appropriate dose level is ultimately a question of both science and public policy. As NAS stated: ''The level of protection established by a standard is a statement of the level of the risk that is acceptable to society. Whether posed as 'How safe is safe enough?' or as 'What is an acceptable level?', the question is not solvable by science'' (NAS Report p. 49).

We requested comment regarding the reasonableness of our proposed 15 mrem CEDE/yr individual-protection standard. We received many comments, some of which supported the proposal, while others stated that we should make the level higher or lower. This final rule establishes a limit of 15 mrem CEDE/yr for the reasons discussed in the preamble to the proposed rule (see 64

FR 46984 and following). Principally, the reasons were: This level is within the NAS-recommended range (which NAS based upon its review of other Federal actions, guidelines developed by national and international advisory bodies, and the regulations in other countries); the fact that many existing standards are at this level, particularly the EPA standards (40 CFR part 191) applicable to WIPP (in the case of some older standards, the equivalence is based upon more recent understanding of the damage that radiation can cause); and, after consideration of the comments and the site-specific conditions, we believe that this level is a sufficiently stringent level of protection for this situation.

Many comments argued that the proposed level was too low. For example, a few comments preferred a dose level of 25 mrem/yr to maintain consistency with current NRC regulations. Another comment advocated a dose level of 70 mrem/yr, given the long time frames, the national importance of the repository, and other factors. Other comments thought that the standard should be lower. Several of these comments supported a limit of 5 mrem/yr. Other comments supported a zero dose limit.

Some comments stated that, though they preferred a zero-release standard, they realized that our level was implementable. We agree that the disposal program should ideally have a goal of no releases. However, we believe it is incumbent upon us to set a stringent, yet reasonable, standard. We are establishing a standard that provides comparable protections to those of other activities related to radioactive and non-radioactive wastes. Given the current state of technology, it may not be possible to provide absolute certainty that there will be no releases over a 10,000 year or longer time frame. Therefore, we have attempted to establish a standard that is protective that can be implemented to show compliance.

Our final consideration in selecting a level of protection was guidance from national and international non-governmental bodies, such as ICRP and NCRP, which have recommended a total annual dose limit for an individual of 1 mSv (100 mrem) effective dose from exposure to all radiation sources except background and medical procedures. The dose level of 1 mSv (100 mrem) corresponds to an annual risk of fatal cancer of about 6 in 100,000 (6×10^{-5}). In its Publication No. 46, ''Radiation Protection Principles for the Disposal of Solid Radioactive Waste,'' the ICRP recommends apportionment of the total allowable radiation dose among specific practices. (Docket No. A–95–12, Item V–A–12). The apportionment of the total dose limit among different sources of radiation is used to ensure that the total of all included exposures is less than 1 mSv (100 mrem) CED/yr. Thus, ICRP recommends that national authorities apportion or allocate a fraction of the 1 mSv (100 mrem)-CED/yr limit to establish an exposure limit for SNF and HLW disposal facilities. Most other countries have endorsed the apportionment principle.

There are multiple sources of potential radionuclide contamination on and near NTS, one of which is the Yucca Mountain site. Portions of NTS have been subjected to both underground and aboveground nuclear weapon detonations. A substantial quantity of radionuclides was created by these tests. An estimated inventory of 300 million curies remains underground (see Appendix II of the BID; Chapter 8 of DOE's Draft Environmental Impact Statement for Yucca Mountain (DOE/EIS/0250D), Docket No. A–95–12, Item V–A–4; and Nevada Risk Assessment/Management Program (NRAMP), Docket No. A–95–12, Item V–A–17). Elsewhere on the NTS, DOE is burying LLW in near-surface trenches and TRU radioactive waste has been disposed of in the Greater Confinement Disposal facility. Finally, there is a commercial LLW disposal system located west of Yucca Mountain near Beatty, Nevada. Each of these facilities could have releases of radioactivity into the ground water (see Chapter 8 of DOE's Draft Environmental Impact Statement for Yucca Mountain (DOE/EIS/0250D), Docket No. A–95–12, Item V–A–4; and Nevada Risk Assessment/Management Program (NRAMP), Docket No. A–95–12, Item V–A–17). The regional flow of ground water is believed to be generally from the locations where some of these practices have occurred toward the area where radionuclides released from the Yucca Mountain disposal system are presumed to go (see Nevada Risk Assessment/Management Program (NRAMP), Docket No. A–95–12, Item V–A–17). The total of the releases from these sources should be constrained to the total dose limit of 1 mSv (100 mrem) CED/yr, as recommended by ICRP, because the releases from these sources could affect the same group of people. The potential doses from these other sources might contribute to individual doses for the reasonably maximally exposed individual (RMEI) over different time frames. According to Chapter 8 of the DEIS for Yucca Mountain (DOE/EIS/0250D, Docket No. A–95–12, Item V–A–4), potential releases from LLW management and disposal operations may contribute very small individual doses. A quantitative attempt to allocate potential dose from these other sources would be highly speculative; however, it would be reasonable to maintain the allocation approach reflected in the established dose limits in both the United States and internationally.

In summary, based on our review of the guidance, regulations, and standards cited above, and the NAS Report, we are establishing a standard of 150 μSv (15 mrem) CEDE/yr for the Yucca Mountain disposal system (40 CFR 197.13). This level is 15% of the ICRP-recommended total dose limit. It falls within the range of standards used in other countries and the range recommended by NAS, and is also consistent with the individual-protection requirement in 40 CFR part 191. This level will be the CEDE level with which the dose over the compliance period must be compared. The compliance period is the time interval over which projections of the performance of the disposal system must be made for the purpose of assessing the future performance of the disposal system (see the *How Far Into the Future is it Reasonable to Project Disposal System Performance?* section later in this document for more detail).

d. 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. We expect that NRC will define the details, beyond those which we have specified, necessary for the dose calculation.

Our approach for the protection of individuals. We examined two possible approaches: the critical group (CG) approach recommended by NAS (NAS Report, pp. 49–54, Appendix C, and Appendix D) and the reasonably maximally exposed individual (RMEI) approach. The goal in representing the exposed population is to estimate the level of exposure that is protective of the vast majority of individuals in that population, but still within a reasonable range of potential exposures. We chose the RMEI approach because we believe it more appropriately protects individuals and is less speculative to implement than the CG approach given the unique conditions present at Yucca

Mountain. Also, it remains a conservative but reasonable approach that accomplishes the same goal as the CG approach.

The NAS definition of critical group. The NAS Report recommended that we use the risk to a CG as the basis for the individual-protection standard. The CG would be the group of people that, based upon cautious, but reasonable, assumptions, has the highest risk of incurring health effects due to releases from the disposal system. In its report, NAS discussed two specific examples of critical groups. The NAS considered the probabilistic critical group based upon a present-day farming community to be more appropriate and less reliant on speculative assumptions than the other critical group it discussed, which was based upon subsistence farming. However, following due consideration, we decided that the subsistence-farmer approach discussed by NAS would be inappropriate, since we could not find nor did any other party demonstrate that there is the subsistence-farmer lifestyle at, or downgradient from, Yucca Mountain. For detailed discussions of NAS's CG approaches, please see the preamble to the proposed rule, 64 FR 46986–46988, and the NAS Report at pp. 49–54 and 145–159.

The Reasonably Maximally Exposed Individual (RMEI). As just mentioned, NAS recommended that the standard incorporate a CG approach for estimating individual exposures from repository release projections (NAS Report p. 52). As NAS pointed out, the CG approach has been examined internationally and recommendations for its application have been proposed (NAS Report, Chapter 2). In addition to recommending the use of the CG approach, NAS posited the use of a ''probabilistic'' CG, which is a CG evaluated using probabilistic techniques for assessing exposures, not only for the parameters that affect repository releases but also for the probability that an individual will use contaminated ground water away from the site. As NAS points out, ''the components of a probabilistic computational approach have considerable precedent in repository performance, we are not aware that they have previously been combined to analyze risks to critical groups'' (NAS Report, Appendix C). In that sense, NAS ''probabilistic'' CG is a departure from the more widely understood application of the CG concept. The approach we have chosen 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. We chose to use an approach involving limiting exposure to a defined ''reasonably maximally exposed individual'', the RMEI. There are similarities between the probabilistic CG and RMEI approaches, and also some significant differences arising from the Yucca Mountain site, that caused us to select the RMEI alternative (see also ''Characterization and Comparison of Alternative Dose Receptors for Individual Radiation Protection for a Repository at Yucca Mountain'', Docket No. A–95–12, Item V–B–3).

In both approaches, the attempt is made to consider a range of conditions for the exposed individuals that affect exposures, including geographic population distributions, lifestyles, and food consumption patterns for populations at risk. 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 in question. Such characterizations typically are done by surveying existing populations, and a ''composite'' RMEI is defined with one or more parameters that significantly affect exposure estimates set at high values so that the individual is ''reasonably maximally exposed.'' The CG approach typically is used under the assumption of a larger population within which a smaller group (the critical group) incurs a more homogeneous risk from exposures, in contrast to the larger population group where exposures will vary widely. Characteristics of the CG also are derived from information or assumptions about the potentially exposed population; however, a small group within the larger population, rather than a composite individual, is defined. Both the CG and the RMEI are then located above the path of the contamination plume and the exposure variations are calculated as a function of the parameters that control radionuclide transport from the contamination source (here, the repository). The ''probabilistic'' CG defined in the NAS Report (Appendix C) adds an additional layer of analytical detail by introducing the idea that the path of the radionuclide contamination is subject to considerable uncertainty and the exposure of the CG is further qualified by the probability that the contamination plume is tapped by the CG at any point in time. This approach assumes the location of the probabilistic CG is fixed independently of the projected path(s) for radionuclide migration from the repository, and the potential exposures then are a direct function of the probability that the contamination plume reaches the location of the group. The more common approach to locating the CG, for the purpose of estimating exposures, is to determine where the group can receive exposures from the contamination plume and then locating the CG at that place, regardless of whether a population is currently at that location or not. Both of these approaches appear to give essentially the same maximum dose levels to at least some individuals, because at some point in time the CG would tap into the contamination plume and receive the exposures. However, if assumed to be widely distributed geographically, many members of the CG could receive considerably smaller doses, or no dose, resulting in an average dose which does not reflect the intent of the CG concept. Overall, as explained further, below, the difference in the distribution of doses using the CG approach depends upon the implementation details describing how the total spectrum of dose assessments would be calculated.

We relied upon many factors in making the decision to use the RMEI concept. First, this approach is consistent with widespread practice, current and historical, of estimating dose and risk incurred by individuals even when it is impossible to specify or calculate accurately the exposure habits of future members of the population, as in this case where it is necessary to project doses for very long periods. Second, we believe that the RMEI approach is sufficiently conservative and that it is fully protective of the general population (including women and children, the very young, the elderly, and the infirm). The risk factor upon which the dose level was established is very small, 5.75 chances in 10,000,000 per mrem for fatal cancer. The lifetime risk then is this factor multiplied by the total dose received in each year of the individual's lifetime. We believe that the risk prior to birth is very similar to this risk level; however, relative to the rest of that individual's lifetime, the difference is small. Third, we believe that it provides protection similar to the CG recommended by NAS. The RMEI model uses a series of assumptions about the lifestyle of a hypothetical individual. This belief was supported by NAS in its comments on the proposed 40 CFR part 197. The NAS agreed that EPA's RMEI approach is ''broadly consistent with the TYMS report's recommendation'' (Docket No. A–95–12, IV–D–31). Fourth, it is possible to build the desired degree of conservatism into the model through choices of assumed values of RME parameters. However, these values would be within certain limits because we require the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR part 197, we establish a framework of assumptions for NRC to incorporate into its implementing regulations. Fifth, we believe that the RMEI approach is more straightforward in its application than the CG approach (particularly the probabilistic CG approach). The RMEI can reasonably be assumed to incur doses from the plume of contamination. By locating the RMEI for dose assessment purposes above the plume's direct path, high-end dose estimates will result. A probabilistic CG implies some, or even many, locations of the members across a broader geographic area than the plume covers. This dispersal inescapably involves additional decisions for the method to be used for combining dose estimates for the group members and comparison against regulatory limits and could average some, or many, doses with a zero magnitude. In addition, specifying certain assumptions regarding consumption habits, e.g., requiring the assumption that the RMEI drinks a high-end estimate of 2 liters/day of ground water and that dietary intake is determined using surveys of today's population in the Town of Amargosa Valley, assure that the RMEI is ''reasonably maximally'' exposed (§ 197.21). We believe this approach is consistent with the NAS recommendation of ''cautious, but reasonable'' assumptions for repository dose assessments (NAS Report p. 6). With these assumptions about the location to be used for dose assessments and food and water consumption, we believe that the RMEI approach would result in dose estimates comparable to a small CG. For a CG, food and water consumption patterns would also be determined from surveys of the local population and, possibly, by some assumptions to push the dose assessments toward higher-end dose estimates. The important difference between the composite RMEI and probabilistic CG approaches is in the assumed distribution of the group members relative to the projected path of radionuclide contamination from the repository. And, finally, sixth, we previously have used the RMEI approach in our regulations (see FR 22888, 22922, May 29, 1992). We have not used the CG approach. For example, the WIPP certification criteria (40 CFR part 194) use an approach involving estimating doses to individuals rather than to a defined CG.

We believe the RMEI approach is more direct and easily understood than the probabilistic CG approach because the uncertainties of estimating doses for a randomly located population is avoided, but the approach is still ''cautious, but reasonable.'' We believe that the ''probabilistic'' CG described by NAS would give essentially the same high-end dose results for situations where the group is small, located in a relatively small area, and is above the path of the contamination plume. However, this was not the concept recommended by NAS. Therefore, we believe our RMEI approach captures the essential ''cautious, but reasonable'' approach recommended by NAS while minimizing speculative aspects of the probabilistic CG approach. We do not mean to imply that a CG approach would never be appropriate, or that we would never use a CG approach in a regulatory action or other decision. However, in this particular site-specific situation, had we used a CG, we would have considered it necessary to define it in detail (in terms of size and location) using cautious, but reasonable, assumptions, but as discussed elsewhere in this document, we believe that the RMEI approach is preferable for Yucca Mountain.

Our RMEI is a theoretical individual representative of a future population group or community termed ''rural-residential'' (see Chapter 8 of the BID for a description of this concept). The DOE will calculate the CEDE the RMEI receives using cautious, but reasonable, exposure parameters and parameter-value ranges as described below. The NRC would use the projected CEDE in determining whether DOE complies with the standard. The DOE will perform the dose calculation to estimate exposure resulting from releases from the waste into the accessible environment based upon the assumption of present-day conditions in the vicinity of Yucca Mountain. Under our standard, the RMEI will have food and water intake rates, diet, and physiology similar to those of individuals in communities currently living in the downgradient direction of flow of the ground water passing under Yucca Mountain.

We did, however, receive comments from tribal representatives expressing concern regarding an alternative approach. The Paiute and Shoshone Tribes stated that they use the Yucca Mountain area for traditional and customary purposes, including traditional gathering, and it is their belief that these uses should be incorporated into the formula upon which the final standards are based. We considered the Tribes' comments, but, for several reasons explained below, we conclude, after considering their description of tribal uses of the area, that the rural-residential RMEI is fully protective of tribal resources.

First, the tribal use of natural springs is apparently occurring in the vicinity of Ash Meadows, since we are not aware of another area downgradient from Yucca Mountain where water discharges in natural springs, with the possible exception of springs in the more distant Death Valley. These natural springs are likely fed by the ''carbonate'' aquifer, which is beneath the ''alluvial'' aquifer being used Town of Amargosa Valley (including at Lathrop Wells) now, and which we assume will be used in the future. The available data indicate that although it is likely that the alluvial aquifer would be contaminated by releases from the potential Yucca Mountain repository, flow is generally upward from the carbonate aquifer into the overlying aquifers, suggesting that there is no potential for radionuclides to move downward into the carbonate system. If downward movement were to occur, however, radionuclide concentrations would be significantly diluted in the larger carbonate flow system. As a result, springs fed from the carbonate aquifer would have lower contamination levels than would wells at the Lathrop Wells location, which tap aquifers closer to, and more directly affected by, the source of potential contamination. A more extensive discussion of the aquifer systems and geology in the Yucca Mountain area may be found in sections II.D and III.B.4.e of this preamble, and Chapters 7 and 8 of the BID.

Second, the tribal use of wildlife and non-irrigated vegetation should not contribute significantly to total individual dose estimates. Gaseous releases from the repository are not a significant contributor to individual doses (NAS report, pg. 59) through inhalation or rainfall, and should contribute less to contamination of wildlife and non-irrigated vegetation than the use of contaminated well water for raising crops and animals for food consumption. We believe our requirement that DOE and NRC base food ingestion patterns on current patterns for the agricultural area directly down gradient from the repository is a more conservative requirement.

Third, the dose incurred by the RMEI is calculated at a location closer to the disposal system than the Ash Meadows area (approximately 18 km versus 30 km). The RMEI would receive a higher dose from ground water consumption than would an individual at Ash Meadows, even if the carbonate aquifer could be contaminated by repository releases, for the reasons mentioned above.

Fourth, the RMEI is assumed to be a full-time resident continually exposed to radiation coming from the disposal system. It appears that the tribal uses are intermittent and involve resources which are less likely to be contaminated, resulting in lower doses than those to the RMEI.

Presently, we expect the ground water pathway to be the most significant pathway for exposure from radionuclides transported from the repository (NAS Report p. 48; Chapter 8 of the BID). Our initial evaluation of potential exposure pathways from the disposal system to the RMEI suggests that the dominant fraction of the dose incurred by the RMEI likely will be from ingestion of food irrigated with contaminated water (see Chapter 8 of the BID). It is possible, however, that DOE and NRC will determine that another exposure pathway is more significant. Consequently, DOE and NRC must consider and evaluate all potentially significant exposure pathways in the dose assessments. As a result of the dose assessments using different combinations of parameter values, there will be a distribution of potential doses incurred by the RMEI. The NRC will use the mean value of that distribution of RMEI doses to determine DOE's compliance with the individual-protection standard. We requested comments regarding both the use of the RMEI approach and the use of the higher of the mean or median value to determine compliance with the individual-protection standard. We also requested comments regarding the desirability of adopting the CG approach rather than the RMEI approach. We further requested that comments supporting the CG approach address the level of detail our rule should include for the parameters used to describe the CG. Comments on various aspects of the RMEI approach appear later in this section. Comments on the mean/median compliance level are in the answer to Question #13 in section IV.

We received comments supporting both the RMEI and the CG approaches. For example, one commenter felt that NRC's proposed licensing regulation for Yucca Mountain (64 FR 8640, February 22, 1999) was more consistent with the NAS recommendation because it included a farming community CG (see NRC's proposed 10 CFR 63.115). This commenter also stated that the proposed 10 CFR part 63 contains the appropriate level of detail to define the CG. Other commenters recommended the use of a subsistence farmer CG approach on the grounds that such an approach is more protective than the rural-residential RMEI. These groups stated that the RMEI is ''purely speculative.''

As noted earlier, NAS recommended using the CG concept. This approach can account for differences in age, size, metabolism, habits, and environment to avoid heavily skewing the results based upon personal traits that make certain people more or less vulnerable to radiation releases than the average within the group. In comparison, under the RMEI approach, the dose that the RMEI incurs is calculated using some maximum values and some average values for the factors that are important to estimating dose. Physical differences such as age, size, and metabolism are also incorporated into the risk value for development of cancer, in effect making the RMEI a ''composite'' individual. This procedure also projects doses that are within a reasonably expected range rather than projecting the most extreme cases.

Regarding the comments stating that the RMEI is ''purely speculative,'' we agree that the RMEI approach is speculative; however, it is less speculative than the scenario suggested in the comments supporting the use of a subsistence farmer. We are not aware of any subsistence farmers (as defined by the comments) in Amargosa Valley. If we used the comments' approach we would, therefore, be engaging in even more speculation than we are by using a current lifestyle. Any future projection involves speculation. Our basis for using the RMEI is that we are following NAS's recommendation to use current technology and living patterns because speculation upon future society and lifestyle variations can be endless and not scientifically supportable (NAS Report p. 122). As stated earlier, the danger in defining a probabilistic CG is that it may be skewed by including randomly located people who will have minimal exposures, resulting in less conservative estimates for the group. Given the conditions at Yucca Mountain, we considered this to be a very real possibility. We consider using a composite individual to be a much simpler means of accomplishing the same purpose while maintaining more control over who is represented in the exposure assessments. Had we opted to use a probabilistic CG, we would have identified certain characteristics of the group in order for it to meet our intent, as we have done with the RMEI.

Overall, we believe that the RMEI approach both meets the intent of NAS and the EnPA and continues a regulatory methodology that we previously have used successfully. Further, though it recommended that we use a CG approach, NAS seemed to recognize that a non-CG approach could accomplish the same purpose. In its report, NAS stated ''[i]t is essential that the scenario that is ultimately selected *be consistent* with the critical-group concept that we have advanced'' (NAS Report p. 10, emphasis added). In its comments on the proposed 40 CFR part 197, NAS stated that our RMEI approach is ''broadly consistent with the TYMS report's recommendations'' (Docket No. A–95–12, Item IV–D–31). Given this acknowledgment by NAS, and that our evaluation of public comments identified no significant deficiencies in our proposed approach, we see no compelling reason to change our position that the RMEI is the appropriate method to use at Yucca Mountain.

Exposure scenario for the RMEI. A major part of the exposure scenario is the RMEI's location. To make this decision, we collected and evaluated information about the Yucca Mountain area's natural geologic and hydrologic features that may preclude drilling for water at a specific location, such as topography, geologic structure, aquifer depth and quality, and water accessibility. Based upon this information and the current understanding of ground water flow in the Yucca Mountain area, it appears that individuals theoretically could reside anywhere along the projected ground water flow path extending from Forty-Mile Wash, starting approximately five kilometers (km) from the repository location, to the southwestern part of the Town of Amargosa Valley, Nevada, where the ground water is close to the land surface and where most of the farming in the area occurs. However, in practice an individual's ability to reside at any particular point depends upon the available resources. To explore these variations, we developed four scenarios (described in the preamble to the proposed rule). See Chapter 8 of the BID for a fuller version of our evaluation of the factors associated with these scenarios. In developing scenarios, we assumed that the level of technology and economic considerations affecting population distributions and life styles in the future are the same as today (for more detail on this assumption, see the *What Do Our Standards Assume About the Future Biosphere?* section below). See below for a fuller discussion of our choice for the RMEI's location. We requested comments regarding the appropriateness of these scenarios and our preferred choice.

We selected a rural-residential RMEI as the basis of our individual exposure scenario. 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, this RMEI, as part of a community typical of Amargosa Valley, might do personal gardening and earn income from other sources of work in the area. We assume further that the RMEI drinks two liters per day of water contaminated with radionuclides, and some of the food (based upon surveys) consumed by the RMEI is from the Town of Amargosa Valley. We consider the consumption of two liters per day of drinking water to be a high-exposure value because people consume water and other liquids from outside sources, such as commercial products. We intended that it would push the dose estimates towards a ''reasonably maximal exposure.'' Similarly, we assume that local food production will use water contaminated with radionuclides released from the disposal system. We believe this lifestyle is similar to that of most people living in Amargosa Valley today.

We received comments stating that: we should be more specific in defining characteristics of the RMEI; we should take future changes in population, land use, climate, and biota into consideration; and that something other than a rural-residential lifestyle would be a more appropriate choice.

One comment suggested that we should be more specific in setting the location, behavior, and lifestyle, or allow NRC to make that choice. There were also a few comments stating that NRC should specify the parameter values. We believe that we have specified the characteristics of the rural-residential RMEI in the detail necessary, given our current understanding, for the concept to be implemented as we intend. We also believe that our specification of the parameter values such as location for the RMEI and drinking water intake rate is appropriate and necessary for our standard to be implemented in the context in which we developed it. We further believe we have the authority to specify other parameter values; however, we believe that NRC, in its role as the licensing authority, can and should set most of the details for implementing the standard, such as water usage in the community where the RMEI resides. Also, under our standard, NRC has the flexibility to make any assumptions, other than those we specified (assumptions we specified include location, water intake rate, and diet reflective of current residents of the Town of Amargosa Valley), if alternative selections prove to be more appropriate for implementing the standard as we intend. The location we specified is not a fixed point but rather it must be in the accessible environment above the highest concentration of radionuclides in the plume of contamination. To assess water usage in the hypothetical community, DOE and NRC could use an approach similar to the representative volume approach described later in this document (*How Does Our Rule Protect Ground Water?*). In doing so, the NRC may wish to consider the volume we specified as the representative volume for ground water protection (*i.e.*, 3,000 acre-feet). Given the extreme technical difficulty in modeling the small volumes of water used by an individual, it would be reasonable for DOE and NRC to assume that the RMEI is one of a number of people (in the hypothetical ''community'' of which the RMEI is a member) withdrawing water from the plume of contamination. Such an approach would involve assumptions about the number of people withdrawing water and the various uses for which the water is withdrawn, which would define the overall volume of water. The RMEI would then be a representative person using water with ''average'' concentrations of radionuclides. These assumptions should be reflective of current water uses in the projected path of the plume of contamination.

Among the comments regarding our assumptions about future populations, land use, climate, and biota, one stated that it is arrogant, as well as insensitive, to assume that all future people will be like us today, and that it is unrealistic to assume that future population distribution, patterned as it is today, will be static. The comment is correct in that there are many possible futures. However, it is necessary to limit speculation about possible futures so that the performance assessments can provide meaningful input into the decision process and the decision process itself is not confounded with speculative alternatives. Therefore, we agreed with and followed NAS when it recommended, ''[i]n view of the almost unlimited possible future states of society * * * we have recommended that a particular set of assumptions be used about the biosphere * * * we recommend the use of assumptions that reflect current technologies and living patterns'' (NAS Report p. 122).

A similar question arose when we developed the implementing regulations for WIPP. We resolved the question by developing the ''future states'' assumption (see 40 CFR 194.25). The position we have taken for the Yucca Mountain standards is consistent with our previous approach to this question.

There was a spectrum of suggestions recommending alternative RMEIs (from a fetus to the elderly and infirm). For example, one comment suggested pregnant women and the unborn within their wombs, children, the infirm, and the elderly as appropriate RMEIs. Other commenters urged using a subsistence farmer. Regarding the various ages and stages of human development, the risk value used for the development of cancer is an overall average risk value (see Chapter 6 of the BID for more details) that includes all exposure pathways, both genders, all ages, and most radionuclides. However, it does not cover the ''unborn within the womb.'' It is thought that the risk to the unborn is similar to that for those who have been born; however, the exposure period for the unborn is very short compared to the rest of the individual's average lifetime (see Chapter 6 of the BID for a discussion of cancer risk from *in utero* exposure). Therefore, the risk is proportionately lower and thus would not have a significant impact upon the overall risk incurred by an individual over a lifetime. On the other end of the spectrum, radiation exposure of the elderly at the levels of the individual-protection standard would be less than the overall risk value because they have fewer years to live and, therefore, fewer years for a fatal cancer to develop.

Some comments on our RMEI characteristics stated that they need to be more site-specific and should consider the alternative lifestyles of Native Americans. Other comments stated that the characteristics and location of the RMEI are implementation issues that should be left for determination by NRC. We believe that the final rule achieves the proper balance of site-specific characteristics that is fully protective of the public health and safety, and that the attributes of the RMEI specified in this rule are necessary to ensure that the Yucca Mountain disposal system achieves the level of protection that we intend.

Location of the RMEI. The location of the RMEI is a basic part of the exposure scenario. We considered locations within a region occupying an area bordering Forty-Mile Wash, within a few kilometers of the repository site, to the southwestern border of the Town of Amargosa Valley. This region, which we believe is hydrologically downgradient from Yucca Mountain, can be considered as three general subareas. See the preamble to the proposed rule, 64 FR 46989–46990, for a fuller discussion of these subareas.

Based upon these considerations of the subareas, we proposed the intersection of U.S. Route 95 and Nevada State Route 373, known as Lathrop Wells, as the point where the RMEI would reside. We consider it improbable that the rural-residential RMEI would occupy locations significantly north of U.S. Route 95, because the rough terrain and increasing depth to ground water nearer Yucca Mountain would likely discourage settlement by individuals because access to water is more difficult than it would be a few kilometers farther south. Also, there are currently several residents and businesses near this location whose source of water is the underlying aquifer (which we understand flows beneath Yucca Mountain). Therefore, we believe it is reasonable to assume that a rural community could be located near this intersection in the future, and that population increases in the short term would cluster preferentially around the main roads through the area.

We are requiring 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 BID), we have chosen the latitude of the southern edge of the Nevada Test Site (corresponding to the line of latitude 36° 40′ 13.6661″ North (described in Docket A–95–12, Item V–A–29)), as the southernmost extent of the controlled area, *i.e.*, DOE and NRC could establish the southern boundary of the controlled area farther north (and presumably the location of the RMEI), but no farther south (see *Where Will Compliance With the Ground Water Standards be Assessed?*). (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 noted above, we proposed the intersection of U.S. Route 95 and Nevada State Route 373 (*i.e.*, Lathrop Wells) as the location of the RMEI. After further review, we determined that the southern edge of NTS would be a more appropriate maximum distance from the repository footprint than the location we proposed because of Nye County's plans to develop the area between the intersection at Lathrop Wells and NTS and the potential for members of the public to reside in that same area (Docket No. A–95–12, Items V–14, 15, 16). This location is also slightly more protective than the Lathrop Wells location since it is approximately 2 km closer to the repository footprint, but still falls within the conditions which led us to propose the Lathrop Wells intersection, *e.g.*, the ground water is not significantly deeper than at the intersection and the soil conditions are the same.

Commercial farming occurs today farther south, in the southwestern portion of the Town of Amargosa Valley in an area near the California border and west of Nevada State Route 373. However, soil conditions in the vicinity of Lathrop Wells are similar to those in southwestern Amargosa Valley. Therefore, it should be feasible for the RMEI to grow some food, using contaminated water tapped by a well. We believe that it is reasonable to assume that other gardening, farming, and raising of domestic animals could occur using contaminated water (see Appendix IV of the BID). We have specified that selected parameters, such as the percentage of food grown by the RMEI, should reflect the lifestyles of current residents of the Town of Amargosa Valley.

Finally, we believe a rural-residential RMEI slightly north of Lathrop Wells would be among the most highly exposed individuals downgradient from Yucca Mountain, even though the ground water nearer the repository could contain higher concentrations of radionuclides. If individuals lived nearer the repository, they would be unlikely to withdraw water from the significantly greater depth for other than domestic use, and in the much larger quantities needed for gardening or farming activities because of the significant cost of finding and withdrawing the ground water. It is possible, therefore, for an individual located closer to the repository to incur exposures from contaminated drinking water, but not from ingestion of contaminated food. Based upon our analyses of potential pathways of exposure, discussed above, we believe that use of contaminated ground water (*e.g.*, drinking water and irrigation of crops) would be the most likely pathway for most of the dose from the most soluble, more mobile radionuclides (such as technetium–99 and iodine–129). The percentage of the dose that results from irrigation would depend upon assumptions about the fraction of all food consumed by the RMEI from gardening or other crops grown using contaminated water, which should reflect the lifestyle of current residents of the Town of Amargosa Valley. Therefore, the exposure for an RMEI located approximately 18 km south of the repository (where ingestion of locally grown contaminated food is a reasonable assumption) actually would be more conservative than an RMEI located much closer to the repository who is exposed primarily through drinking water. We also are establishing that protection of a rural-residential RMEI would be protective of the general population downgradient from Yucca Mountain (see the *How Do Our Standards Protect the General Population?* section below).

As stated above, the method of calculating the RMEI dose is to select average values for most parameters except one or a few of the most sensitive, which are set at their maximum. We believe that an RMEI location above the highest concentration in the plume of contamination in the accessible environment and a consumption rate of two liters per day of drinking water from the plume of contamination represent high-end values for two of these factors. The NRC may identify additional parameters to assign high-end values in projecting the dose to the RMEI. To the extent possible, NRC should use site-specific information for any remaining factors. For example, NRC should use site-specific projections of the amount of contaminated food that would be ingested in the future. The NRC might base projections upon surveys that indicate the percentage of the total diet of Amargosa Valley residents from food grown in the Amargosa Valley area.

We requested comment regarding the potential approaches and assumptions for the exposure scenario to be used for calculating the dose incurred by the RMEI, particularly whether:

(1) Based upon the above criteria, there is now sufficient information for us to adequately support a choice for the RMEI location in the final rule or should we leave that determination to NRC in its licensing process based upon our criteria;

(2) Another location in one of the three subareas identified previously should be the location of the RMEI; and

(3) Lathrop Wells and an ingestion rate of two liters per day of drinking water are appropriate high-end values for parameters to be used to project doses to the RMEI.

Of the three subjects listed above, the only comments we received suggested different locations for the RMEI. A few commenters thought that the Lathrop Wells location is appropriate. However, a number of others stated that the

RMEI's location should be at the edge of the footprint of the repository. Finally, one commenter suggested that 30 kilometers away from the repository (in the current farming area in southern Amargosa Valley) would be reasonable; however, this commenter also stated that Lathrop Wells would be acceptable using the rural-residential scenario to provide conservatism to protect public health and safety.

As stated earlier, we are designating the location above the point of highest concentration in the plume of contamination in the accessible environment (no farther south than 36° 40′ 13.6661″ North) as the location of the RMEI. This point would be approximately 18 kilometers south of the repository footprint. We do not believe that an RMEI likely would live much farther north of the compliance point (toward Yucca Mountain) because of the increasing depth to ground water and the increasing roughness of the terrain. In addition, we believe that, at approximately 18 km, a rural-resident RMEI will likely have the highest potential doses in the region because of both drinking contaminated water and eating food grown using contaminated water. That is, the rural resident at 18 km will receive a higher dose than would an individual living much closer to Yucca Mountain because the cost of extracting the water likely will allow only drinking the water and not having a garden capable of supplying a portion of an individual's annual food consumption (see Chapters 7 and 8 of the BID). Likewise, we do not believe that hypothesizing that the RMEI lives 30 km away is a cautious, but reasonable, assumption because: (1) At 30 km, the RMEI likely would use water that contains much lower concentrations of (*i.e.*, more diluted) radionuclides; (2) the downgradient residents closest to Yucca Mountain are currently near Lathrop Wells; and (3) Nye County's short-term projections (20 years) show population growth at and near that location (see Docket No. A–95–12, Items V–A–14, V–A–15, and V–A–16). Therefore, a distance of 18 km adds to the conservatism and provides more protection of public health, relative to one commenter's suggested distance of 30 km.

There were a few other comments related to the location of the RMEI. For example, one comment stated that the location should take into account the geology and hydrology of the site rather than be chosen in advance. Another comment believes that we should base the location upon the ability of the RMEI to sustain itself consistent with topography and soil conditions. Further, this commenter believes that depth to ground water should not be a factor because it is impossible to predict either human activities or economic imperatives.

We determined the point of compliance for the individual-protection standard using site-specific factors and NAS's recommendation to use current conditions (NAS Report p. 54). In preparing to propose a compliance point for the RMEI, we collected and evaluated information on the natural geologic and hydrologic features, such as topography, geologic structure, aquifer depth, aquifer quality, and the quantity of ground water, that may preclude drilling for water at a specific location (see Chapter 7 of the BID). For example, as stated above, we do not believe that a rural-residential individual would occupy areas much closer to Yucca Mountain because of the increasingly rough terrain and the increasing depth to ground water. With increasing depth to ground water come higher costs: (1) To drill for water; (2) to explore for water; and (3) to pump the water to the surface. We agree that it is impossible to predict either human activities or economic imperatives. Therefore, we followed NAS's recommendation to use current conditions to avoid highly speculative scenarios. This approach leads us to considering the depth to ground water as a key factor in determining the location and activities of the RMEI. The current location of people living in the vicinity of the repository is a reflection of this key factor.

And, finally, one commenter stated that the proposed RMEI concept forces DOE to assume the RMEI will withdraw water from the highest concentration within the plume without consideration of its likelihood. Forcing such an assumption neglects the low probability that a well will intersect the highest concentration within the plume.

This commenter's approach, which would use a probabilistic method to determine the radionuclide concentration withdrawn by the RMEI, is similar to one of the example CG approaches that NAS provided in its report (NAS Report Appendix C). The NAS approach would use statistical sampling of various parameters, *i.e.*, considering the likelihood (probability) of various conditions existing to arrive at a dose for comparison to the standard. However, we did not use the probabilistic CG approach for the following reasons: (1) There is no relevant experience in applying the probabilistic CG approach, (2) the CG approach is very complex relative to the RMEI approach and is difficult to implement in a manner that assures it would meet the requirements of defining a CG, and (3) we are concerned that this approach does not appear to identify clearly which individual characteristics describe who is being protected. Finally, a significant majority of the public comments we received on the NAS Report opposed the probabilistic CG approach. We further believe that prudent public health policy requires that our approach be followed to provide reasonable conservatism. In this case, this is not a prediction of exactly whom will be exposed as much as it is a reasonable test of the performance of the repository. To allow the probability of any particular location being contaminated is not a prudent approach to the ultimate goal of testing acceptable performance.

e. *How Do our Standards Protect the General Population?* Pursuant to section 801(a)(2)(A) of the EnPA, one of the issues to be addressed by NAS in its study is whether an individual-protection standard will provide a reasonable standard for protection of the health and safety of the general public. NAS concluded that an individual-protection standard could provide such protection in the case of the Yucca Mountain disposal system. The NAS premised this conclusion on the condition that the public and policymakers would accept the idea that extremely small individual radiation doses spread out over large populations pose a negligible risk (NAS Report p. 57). The NAS refers to this concept as ''negligible incremental risk'' (NIR) (NAS Report p. 59). See the preamble to the proposed rule for a detailed discussion of NAS's concept of NIR (64 FR 46990–46991).

We agree with NAS that an individual-protection standard can adequately protect the general population near Yucca Mountain because of the particular characteristics of the Yucca Mountain site. However, we chose not to adopt either a negligible incremental dose (NID) or NIR level because we are concerned that such an approach is not appropriate in all circumstances, and because of reservations regarding NAS's reasoning and analysis. We based our determination that an individual-risk standard is adequate to protect both the local and general population on considerations unique to the Yucca Mountain site. This is not, however, a general policy judgment by us regarding other uses of the NID or NIR concepts.

As noted in the preamble to the proposal (64 FR 46990), NAS referred to the NID level of 10 μSv (1 mrem)/yr per source or practice recommended by the NCRP. The International Atomic Energy Agency (IAEA) has made similar recommendations regarding exemptions in its Safety Series No. 89, ''Principles for the Exemption of Radiation Sources and Practices from Regulatory Control'' (1998) (Docket No. A–95–12, Item II–A–6). The IAEA has recommended that individual doses not exceed 10 μSv (1 mrem)/yr from each exempt practice (IAEA Safety Series No. 89, p. 10). The IAEA's recommendations relate to criteria for exempting whole sources or practices, such as waste disposal or recycling generally, not whether radiation doses from a portion of a given practice, such as the release of gases from a specific geologic repository, may be considered negligible. Finally, the IAEA's recommendations intend the exemption to be for sources and practices ''which are inherently safe'' (IAEA Safety Series No. 89, p. 11). It is not clear that the low individual doses or risks projected from gaseous releases from the Yucca Mountain repository should be considered on their own as a ''source'' or ''practice,'' given the definitions of these terms in IAEA's Safety Series No. 89. Further, given the extraordinarily large inventory of long-lived radionuclides to be disposed of in the Yucca Mountain repository, it is not clear that such a source or practice should be considered inherently safe. Also, we believe it is inappropriate to not calculate a radiation dose merely because the dose rate from a particular source is small.

Further, we do not believe it is appropriate to apply the NIR concept to consideration of population dose. A recent NCRP report questions the application of the NID concept to population doses. According to NCRP Report No. 121: ''(a) Concept such as the NID (Negligible Incremental Dose) provides a legitimate lower limit below which action to further reduce individual dose is unwarranted, but it is not necessarily a legitimate cut-off dose level for the calculation of collective dose. Collective dose addresses societal risk while the NID and related concepts address individual risk.'' (Principles and Application of Collective Dose in Radiation Protection, NCRP Report No. 121, Docket No. A–95–12, Item II–A–8). Based upon this principle, we think it inappropriate to use the NID or NIR concept to evaluate whether an individual-protection standard adequately protects the general population.

In summary, we are establishing an individual-protection standard for Yucca Mountain that will limit the annual radiation dose incurred by the RMEI to 150 μSv (15 mrem) CEDE. At the same time, we chose not to adopt a separate limit on radiation releases for the purpose of protecting the general population. Instead, we recommended in our proposal that DOE estimate and consider collective dose in its analyses. We based this recommendation upon several factors. The first factor is NAS's projection of extremely small doses to individuals resulting from air releases from Yucca Mountain. That dose level is well below the risk corresponding to our individual-protection standard for Yucca Mountain. It is also well below the level that we have regulated in the past through other regulations. Further, while we decline to establish a general Negligible Incremental Risk (NIR) level, we do agree with NAS that estimating the number of health effects resulting from a 0.0003 mrem/yr dose equivalent rate (NAS Report p. 59), in addition to the dose rate from background radiation, in the general population is uncertain and controversial. The second major factor is that, based upon current and site-specific conditions near Yucca Mountain, there is not likely to be great dilution resulting in exposure of a large population. In addition, we are establishing additional ground water protection standards that would set specific limits to protect users of ground water and that protect ground water as a resource. Finally, we require that all of the pathways, including air and ground water, be analyzed by DOE and considered by NRC under the individual-protection standard. We requested comment on this approach. We requested that commenters who disagree with this approach specifically address why it is inappropriate for the Yucca Mountain disposal system and make suggestions about how we might reasonably address this issue.

Most comments supported not establishing a collective-dose limit for Yucca Mountain. Two comments supported our decision not to establish an NIR or NID level. The NAS went further by also opposing our suggestion that DOE estimate collective dose for use in examining design alternatives because it is inconsistent with the NAS Report and with our conclusion that a collective-dose limit is unnecessary for the purpose of protecting the general public. On page 57 of its report, NAS stated:

''Earlier in this chapter, we recommend the form for a Yucca Mountain standard based on individual risk. Congress has asked whether standards intended to protect individuals would also protect the general public in the case of Yucca Mountain. We conclude that the form of the standards we have recommended would do so, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk. This latter requirement exists for all forms of the standards, including that in 40 CFR (part) 191. We recommend addressing this problem by adopting the principle of negligible incremental risk to individuals.

''The question posed by Congress is important because limiting individual dose or risk does not automatically guarantee that adequate protection is provided to the general public for all possible repository sites or for the Yucca Mountain site in particular. As described in the previous section, the individual-risk standard should be constructed explicitly to protect a critical group that is composed of a few persons most at risk from releases from the repository. The standards are then set to limit the risk to the average member of that group. Larger populations outside the critical group might also be exposed to a lower, but still significant, risk. It is possible that a higher level of protection for this population represented by a lower level of risk than the one established by the standards might be considered.''

The NAS also states: ''(O)n a collective basis, the risks to future local populations are unknowable. We conclude that there is no technical basis for establishing a collective population-risk standard that would limit risk to the nearby population of the proposed Yucca Mountain repository'' (NAS Report p. 120)

After consideration of comments received on this question, we have determined that it is not necessary for us to recommend that DOE calculate collective dose, primarily because we believe the individual-protection standard will adequately protect the general population.

f. *What Do Our Standards Assume About the Future Biosphere?* For assessments of potential exposures, there are two important aspects of defining the future biosphere characteristics: the selection of parameter values to define the natural characteristics of the site, and the assumptions necessary to define the characteristics of the potentially exposed population. Examples of the site's natural characteristics include rainfall projections and the hydrologic characteristics of the rocks through which radionuclides may migrate. Examples of the assumptions necessary to define the potentially exposed population's characteristics include assumptions regarding population distributions, lifestyles, and eating habits.

In conducting required analyses of repository performance, including the performance assessment for determining compliance with the standards, the assessment for determining compliance with the ground water standards, and the human-intrusion analysis, DOE and NRC may not assume that future geologic, hydrologic, and climatic conditions will be the same as they are at present. We require that these conditions be varied within reasonably ascertainable bounds over the required compliance period. We are imposing this requirement, which is consistent with the recommendation of the NAS Report, because we believe it is possible to reasonably bound the parameter values in the performance assessment that relate to these conditions.

To avoid unsupportable speculation regarding human activities and conditions, we believe it is appropriate to assume that other parameters describing human activities and interactions with the repository (such as the level of human knowledge and technical capability, human physiology and nutritional needs, general lifestyles and food consumption patterns of the population, and potential pathways through the biosphere leading to radiation exposure of humans) will remain as they are today. Consistent with the NAS Report, we believe there may be an essentially unlimited number of predictions that could be made about future human societies, with an unlimited number of potential impacts on the significance of future risk and dose effects. Regulatory decision making involving many speculative scenarios for future societies and impacts would become extraordinarily difficult without any demonstrable improvement in public health and safety and should be avoided as much as possible. Therefore, DOE and NRC must assume that future states applicable to the repository, except for geologic, hydrologic, and climatic conditions, will remain unchanged from the time of licensing.

Comments we received on this subject strongly favored our approach, particularly with respect to changes in natural conditions. The comments noted that climatic variations should be expected to occur over the time frames for which performance projections are made because the climate has changed in the past. Another reason to consider climatic changes is that these changes could have a significant effect on repository performance in comparison to performance projections made using current day conditions. Comments also pointed out the seismically active nature of the area and implied that DOE should examine the effects of seismic activity on the disposal system's performance. Here again, we require DOE to consider variations in geologic conditions. The approach we proposed on this subject is consistent with the approach we used for the WIPP certification (40 CFR 194.25) and NAS's recommendations. We received no comments opposing this approach.

g. *How Far Into the Future Is It Reasonable To Project Disposal System Performance?* The NAS recommended that the time over which compliance should be assessed (the compliance period) should be ''the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment'' (NAS Report p. 7). The NAS stated that the bases for its recommendation were technical, not policy, considerations (NAS Report pp. 54–56). The NAS acknowledged, however, that this is not solely a technical decision, and that policy considerations could be important to the decision (NAS Report p. 56). We agree that the selection of the compliance period necessarily involves both technical and policy considerations. For example, as NAS pointed out, we could decide that it is appropriate to establish similar policies for managing risks ''from disposal of both long-lived hazardous nonradioactive materials and radioactive materials'' (NAS Report p. 56). Such a decision necessarily would result in a compliance period that is less than the period of geologic stability. As NAS recognized, we had to consider, in this rulemaking, both the technical and policy issues associated with establishing the appropriate compliance period for the performance assessment of the Yucca Mountain disposal system.

We offered for comment two alternatives for the compliance period for the individual-protection standard. One alternative was to adopt a compliance period as the time to peak dose within the period of geologic stability. The second alternative was to adopt a fixed time period during which the repository must meet the disposal standards.

For the reasons discussed below, we selected the second alternative, which establishes a regulatory time period of 10,000 years. Therefore, the peak dose within 10,000 years after disposal must comply with the individual-protection standard. In addition, we require calculation of the peak dose within the period of geologic stability. The intent of examining the disposal system's performance after 10,000 years is to project its longer-term performance. We require 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 does not, however, require that DOE meet a specific dose limit after 10,000 years. We have concerns regarding the uncertainties associated with such projections, and whether very long-term projections can be considered meaningful; however, existing performance assessment results indicate that the peak dose may occur beyond 10,000 years (see Chapter 7, Section 7.3, of the BID). Such results may, therefore, give a more complete description of repository behavior. We acknowledge, however, that these results, because of the inherent uncertainties associated with such long-term projections, are not likely to be of the quality necessary to support regulatory decisions based upon a quantitative analysis and thus need to be considered cautiously. In any case, these very long-term projections will provide more complete information on disposal system performance.

As discussed below in section III.B.2.a (*What Limits Are There on Factors Included in the Performance Assessment?*), the principal tool used to assess compliance with the individual-protection standard is a quantitative performance assessment. This method relies upon sophisticated computer modeling of the potential processes and events leading to releases of radionuclides from the disposal system, subsequent radionuclide transport, and consequent health impacts. To consider compliance for any length of time, several facets of knowledge and technical capability are necessary. First, the scientific understanding of the relevant potential processes and events leading to releases must be sufficient to allow quantitative estimates of projected repository performance. Second, adequate analytical methods and numerical tools must exist to incorporate this understanding into quantitative assessments of compliance. Third, scientific understanding, data, and analytical methods must be adequately developed to allow evaluation of performance with sufficient robustness to judge compliance with reasonable expectation over the regulatory period. Finally, the analyses must be able to produce estimated results in a form capable of comparison with the standards.

The NAS evaluated these requirements for Yucca Mountain. First, it concluded that those aspects of disposal system and waste behavior that depend upon physical and geologic properties can be estimated within reasonable limits of uncertainty. Also, NAS believed that these properties and processes are sufficiently understood and boundable [11] over the long periods

[11] We define ''boundable'' to mean that these properties and processes fall within certain limits. We are defining probabilities of occurrence below

at issue to make such calculations possible and meaningful. The NAS acknowledged that these factors cannot be calculated precisely, but concluded that there is a substantial scientific basis for making such calculations. The NAS concluded that by considering uncertainties and natural variations, it would be possible to estimate, for example, the concentration of radionuclides in ground water at different locations and the times of gaseous releases. Second, NAS concluded that the mathematical and numerical tools necessary to evaluate repository performance are available or could be developed as part of the standard-setting or compliance-determination processes. Third, NAS concluded that: ''[s]o long as the geologic regime remains relatively stable, it should be possible to assess the maximum risks with reasonable assurance'' (NAS Report p. 69). The NAS used the term ''geologic stability'' to describe the situation where geologic processes, such as earthquakes and erosion, that could affect the performance assessment of the Yucca Mountain disposal system are active or are expected to occur (NAS Report pp. 91–95). Based upon the use of the terms ''stable'' and ''boundable'' throughout the NAS Report, one can infer that NAS applied the term ''geologic stability'' or ''stable'' to the situation where the rate of processes and numeric range of individual physical properties could be bounded with reasonable certainty. The subsequent use of the term ''stable'' will not imply static conditions or processes. Rather, it will describe the properties and processes that can be bounded. Finally, NAS found that the established procedures of risk analysis should enable the results of each performance simulation of the disposal system to be combined into a single estimate for comparison with the standard.

We previously considered the question of the appropriate compliance period for land disposal of SNF, HLW, and TRU radioactive waste in the 40 CFR part 191 standards, where we promulgated a generic compliance period of 10,000 years. We set the 40 CFR part 191 compliance period at 10,000 years for three reasons:

(1) After that time, there is concern that the uncertainties in compliance assessment become unacceptably large (50 FR 38066, 38076, September 19, 1985);

(2) There are likely to be no exceptionally large geologic changes during that time (47 FR 58196, 58199, December 29, 1982); and

(3) Using time frames of less than10,000 years does not allow for valid comparisons among potential sites. For example, for 1,000 years, all of the generic sites analyzed appeared to contain the waste approximately equally both because of long ground water travel times at well-selected sites (47 FR 58196, 58199, December 29, 1982) and because of the containment capabilities of the engineered barrier systems (58 FR 66401, December 20, 1993).

The purpose of geologic disposal is to provide long-term barriers to the movement of radionuclides into the biosphere (NAS Report p. 19). As described earlier, DOE plans to locate the Yucca Mountain repository in tuff about 300 meters above the local water table. When the waste packages release nongaseous radionuclides, the released radionuclides most likely will be transported by water that moves through Yucca Mountain from the surface toward the underlying aquifer both horizontally between individual tuff layers and vertically downward, through fractures in the tuff layers. Once the radionuclides reach the aquifer, the ground water will carry them away from the repository in the direction of ground water flow in the aquifer. The most probable route for exposing humans to radiation resulting from releases from the Yucca Mountain disposal system is via withdrawal of contaminated water for local use. In the case of Yucca Mountain, DOE estimates that most radionuclides would not reach currently populated areas within10,000 years, because of the expected performance of the engineered barrier system (see Chapter 7 of the BID).

This finding alone seems to indicate that the compliance period for Yucca Mountain should be longer than 10,000 years to be protective; however, NAS concluded that the need to consider the exposures when they are calculated to occur must be weighed against the uncertainty associated with such calculations (NAS Report p. 72). As discussed below, exposures could occur over tens-of thousands to hundreds-of-thousands of years. As the compliance period is extended to such lengths, however, uncertainty generally increases and the resulting projected doses are increasingly meaningless from a policy perspective. The NAS stated that there are significant uncertainties in a performance assessment and that the overall uncertainty increases with time. Even so, NAS found that, ''* * * there is no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value'' (NAS Report p. 55). The NAS also stated that data and analyses of some of the factors that are uncertain early in the assessment might become more certain as the assessment progresses(NAS Report p. 72), though this would tend to apply more to assessments covering very long periods (*i.e.,* longer than 10,000 years). Also, NAS stated that many of the uncertainties in parameter values describing the geologic system are not due to the length of time but rather to the difficulty in estimating values of site characteristics that vary across the site. Thus, NAS concluded that the probabilities and consequences of the relevant features, events, and processes that could modify the way in which radionuclides are transported in the vicinity of Yucca Mountain, including climate change, seismic activity, and volcanic eruptions, ''are sufficiently boundable so that these factors can be included in performance assessments that extend over periods on the order of about one million years'' (NAS Report p. 91). As discussed below, we believe that such an approach is not practical for regulatory decisionmaking, which involves more than scientific performance projections using computer models.

Today's rule requires that DOE demonstrate compliance for a period of 10,000 years after disposal. As discussed above, NAS concluded ''there is no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value'' (NAS Report p. 55). Despite NAS's recommendation, we conclude that there is still considerable uncertainty as to whether current modeling capability allows development of computer models that will provide sufficiently meaningful and reliable projections over a time frame up to tens-of-thousands to hundreds-of-thousands of years. Simply because such models can provide projections for those time periods does not mean those projections are meaningful and reliable enough to establish a rational basis for regulatory decisionmaking. Furthermore, we are unaware of a policy basis that we could use to determine the ''level of proof'' or confidence necessary to determine compliance based upon projections of hundreds-of-thousands of years into the future. The NAS indicated that analyses of the performance of the Yucca Mountain disposal system dealing with the far future can be bounded; however, a large and cumulative amount of uncertainty is

which events are considered very unlikely and need not be considered in performance assessments. We are not otherwise constraining DOE or NRC in identifying bounding limits.

associated with those numerical projections. Setting a strict numerical standard at a level of risk acceptable today for the period of geologic stability would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard. We requested comments regarding the reasonableness of adopting the NAS-recommended compliance period or some other approach in lieu of the 10,000-year compliance period, which we favor and describe below. We also sought comment regarding whether it is possible to implement the NAS-recommended compliance period in a reasonable manner and how that could be done.

The selection of the compliance period for the individual-protection standard involves both technical and policy considerations. It was our responsibility to weigh both during this rulemaking. In addition to the technical guidance provided in the NAS Report, we considered several policy and technical factors that NAS did not fully address, as well as the experience of other EPA and international programs. As a result of these considerations, we are establishing a 10,000-year compliance period with a quantitative limit and a requirement to calculate the peak dose, using performance assessments, if the peak dose occurs after 10,000 years. Under this approach, DOE must make the performance assessment results for the post-10,000-year period part of the public record by including them in the EIS for Yucca Mountain.

In its discussion of the policy issues associated with the selection of the time period for compliance, NAS suggested that we might choose to establish consistent risk-management policies for long-lived, hazardous, nonradioactive materials and radioactive materials (NAS Report p. 56). We previously addressed the 10,000-year compliance period in the regulation of hazardous waste subject to land-disposal restrictions. Although they are subject to treatment standards to reduce their toxicity, some of these wastes, such as heavy metals, can essentially remain hazardous forever. Land disposal, as defined in 40 CFR 268.2(c), includes, but is not limited to, any placement of hazardous waste in land-based units such as landfills, surface impoundments, and injection wells. Facilities may seek an exemption from land disposal restrictions by demonstrating that there will be no migration of hazardous constituents from the disposal unit for as long as the waste remains hazardous (40 CFR 268.6). This period may include not only the operating phase of the facility, but also what may be an extensive period after facility closure. With respect to injection wells, we specifically required a demonstration that the injected fluid will not migrate from the injection well within 10,000 years (40 CFR 148.20(a)). We chose the 10,000-year performance period referenced in our guidance regarding no-migration petitions, in part, to be equal to time periods cited in draft or final DOE, NRC, and EPA regulations (10 CFR part 960, 10 CFR part 60, or 40 CFR part 191, respectively) governing siting, licensing, and releases from HLW disposal systems. With respect to other land-based units regulated under the Resource Conservation and Recovery Act (RCRA) hazardous-waste regulations, we concluded that the compliance period for a no-migration demonstration is specific to the waste and site under consideration. For example, for the WIPP no-migration petition, we found that ''it is not particularly useful to extend this model beyond 10,000 years into the future * * * (However, t)he agency does believe * * * that modeling over a 10,000-year period provides a useful tool in assessing the long-term stability of the repository and the potential for migration of hazardous constituents'' (55 FR 13068, 13073, April 6, 1990). Thus, establishing a 10,000 year compliance period for Yucca Mountain is consistent with risk-management policies that we have established for other long-lived, hazardous materials.

Second, the individual-protection requirements in 40 CFR part 191 (58 FR 66398, 66414, December 20, 1993) have a compliance period of 10,000 years. The 40 CFR part 191 standards apply to the same types of waste and type of disposal system as will be present at Yucca Mountain. Therefore, the use of a 10,000 year time period in this regulation is consistent with 40 CFR part 191. However, as we explained in the *What is the History of Today's Action?* section earlier in this document, by statute the 40 CFR part 191 requirements do not apply to Yucca Mountain (WIPP LWA, section 8(b)). Nevertheless, we deem this consistency appropriate because both sets of standards apply to the same types of waste. Moreover, though the WIPP LWA exempts Yucca Mountain from the 40 CFR part 191 standards, it does not prohibit us from imposing standards on Yucca Mountain that are similar to the 40 CFR part 191 standards, if, as discussed previously, we determine in this rulemaking that the imposition of such standards is appropriate. The question of uncertainties over long time frames and the use of performance projections over those time frames for regulatory decisionmaking has been examined a number of times in our rulemaking (40 CFR parts 191 and 194) with a consistent conclusion that 10,000 years is the appropriate choice for a compliance period.

Although 40 CFR part 191 itself does not directly apply to Yucca Mountain, the necessity to identify a generic compliance period is an important component of the development of radioactive waste standards, including the Yucca Mountain standards. In a regulatory approval process, a judgment is necessary about the technical reliability of repository performance projections. This consensus would involve the applicant, the regulatory authority, and the technical community in general. In the face of increasing uncertainties in projecting repository performance over hundreds-of-thousands of years, the potential for technical consensus on the reliability of these projections would decrease sharply. This decrease would lead to a dramatic increase in the difficulty of making a compliance decision related to such an extended time period. In setting the compliance period in 40 CFR part 191 at 10,000 years, we addressed the issue of increasing uncertainty by having a fixed time period rather than requiring that the time period be determined individually for any repository undergoing evaluation.

Third, we are concerned that there might be large uncertainty in projecting human exposure due to releases from the repository over extremely long periods. We agree with NAS's conclusion that it is possible to evaluate the performance of the Yucca Mountain disposal system and the surrounding lithosphere within certain bounds for relatively long periods. However, we believe that NAS might not have fully addressed two aspects of uncertainty.

One of the aspects of uncertainty relates to the impact of long-term natural changes in climate and its effect upon choosing an appropriate RMEI. For extremely long periods, major changes in the global climate, for example, a transition to a glacial climate, could occur (see Chapter 7 of the BID). We believe, however, that over the next 10,000 years, the biosphere in the Yucca Mountain area probably will remain, in general, similar to present-day conditions due to the rain-shadow effect of the Sierra Nevada Mountains, which lie to the west of Yucca Mountain (see Chapter 7 of the BID). As discussed by NAS, however, for the longer periods contemplated for the alternative of time to peak dose, the global climate regime is virtually certain to pass through several glacial-interglacial cycles, with the majority of time spent in the glacial state (NAS Report p. 91). These longer periods would require the specification of exposure scenarios that would not be based upon current knowledge or cautious, but reasonable, assumptions, but rather upon potentially arbitrary assumptions. The NAS indicated that it knew of no scientific basis for identifying such scenarios (NAS Report p. 96). It is for these reasons that such extremely long-term calculations are useful only as indicators, rather than accurate predictors, of the long-term performance of the Yucca Mountain disposal system (IAEA TECDOC–767, p. 19, 1994, Docket No. A–95–12, Item II-A–5).

The other aspect of uncertainty concerns the range of possible biosphere conditions and human behavior. As IAEA noted, beyond 10,000 years it may be possible to make general predictions about geological conditions; however, the range of possible biospheric conditions and human behavior is too wide to allow ''reliable modeling'' (IAEA–TECDOC–767, p. 19, Docket No. A–95–12, Item II–A–5). It is necessary to make certain assumptions regarding the biosphere, even for the 10,000-year alternative, because 10,000 years represents a very long compliance period for current-day assessments to project performance. For example, it is twice as long as recorded human history (see *What Do Our Standards Assume About the Future Biosphere?,* section III.B.1.f, earlier in this document). For periods approaching the 1,000,000 years that NAS contemplated under the peak-dose alternative, even human evolutionary changes become possible. Thus, reliable modeling of human exposure may be untenable and regulation to the time of peak dose within the period of geologic stability could become arbitrary. Again, the rational basis necessary for regulatory decisionmaking would be difficult or impossible to achieve because of the speculative assumptions that would be involved.

Fourth, many international geologic disposal programs use a 10,000-year period for assessing repository performance (see, *e.g.,* Chapter 3 of the BID, Docket No. A–95–12, Item III–B–2 or GAO/RCED–94–172, 1994, Docket No. A–95–12, Item V–A–7). These disposal programs also have examined this question and have opted to use a fixed time rather than one based only on a site-specific compliance period.

Finally, an additional complication associated with the time to peak dose within the period of geologic stability is that it could lead to a period of regulation that has never been implemented in a national or international radiation regulatory program. Focusing upon a 10,000-year compliance period forces more emphasis upon those features over which humans can exert some control, such as repository design and engineered barriers. Those features, the geologic barriers, and their interactions define the waste isolation capability of the disposal system. By focusing upon an analysis of the features that humans can influence or dictate at the site, it may be possible to influence the timing and magnitude of the peak dose, even over times longer than 10,000 years.

Based on the extensive public comment, consistency with other EPA radioactive and non-radioactive waste disposal programs, and a consideration of the numerous uncertainties associated with projecting repository performance over extended time periods, our final rule establishes the following requirements for the individual-protection standard and the human-intrusion analysis. For the individual-protection standard, a 10,000-year performance assessment is required for comparison against the 15 mrem standard. In addition, a post-10,000-year analysis of peak dose incurred by the RMEI is to be included in the EIS for Yucca Mountain, but is not to be held to a particular dose limit. We view the post-10,000-year analysis as an indicator of long-term performance that provides more complete information. For the human-intrusion analysis, DOE must determine the earliest time at which the human intrusion specified in the standard will occur. Should the intrusion occur at or before 10,000 years after disposal, DOE must demonstrate that the RMEI receives no more than 15 mrem/yr as a result of the intrusion (again, analytical results beyond 10,000 years are not judged against a dose limit, but must be included in the EIS). Should the intrusion occur after 10,000 years, DOE must include the analysis in the EIS for Yucca Mountain as an indicator of long-term disposal system performance.

Public comment supported a compliance period that ranged from 10,000 years to a million years and beyond (i.e., no time limitation). Comments supporting the 10,000-year time period expressed concern that such a time period was the longest time over which it is possible to obtain meaningful modeling results. Some comments agreed with our position on the reliability of dose calculations well in excess of 10,000 years. Other comments noted that, aside from the unprecedented nature of compliance periods exceeding 10,000 years, the greater uncertainties present at such times only serve to complicate the licensing process with no clear cut greater public health benefit. A few comments agreed that, because there likely will be radiation doses to individuals beyond 10,000 years, DOE should calculate peak dose, within the time period of geologic stability, and include these doses in the Yucca Mountain EIS.

Numerous comments suggested that the compliance period should extend to times beyond 10,000 years. Foremost among these comments, NAS suggested a compliance period that would extend to the time of peak dose or risk, within the period of geologic stability for Yucca Mountain (as long as one million years), based on scientific considerations. Though NAS based its recommendation on scientific considerations, it recognized that such a decision also has policy aspects (NAS Report, p. 56), and that we might select an alternative more consistent with previous Agency policy. We believe the unprecedented nature of a compliance period beyond 10,000 years was very persuasive and related strongly to developing a meaningful standard that is reasonable to implement. We also harbored strong concerns related to uncertainty in projecting human radiation exposures over extremely long time periods, for the reasons mentioned earlier.

Some comments suggested that the compliance period of the standard should be comparable to the amount of time that the materials to be emplaced in the Yucca Mountain repository will remain hazardous. While the hazardous lifetime of radioactive waste is important, it is but one of a variety of factors that must be considered in projecting the potential risks from disposal. The ability of the disposal system to isolate such long-lived materials relates to the retardation characteristics of the whole hydrogeological system within and outside the repository, the effectiveness of engineered barriers, the characteristics and lifestyles associated with the potentially affected population, and numerous other factors in addition to the hazardous lifetime of the materials to be disposed.

Thus, for a variety of technical and policy reasons, we believe that a 10,000-year compliance period is meaningful, protective, and practical to implement. We also believe that its use will result in a robust disposal system that will protect public health and the environment for time periods exceeding 10,000 years. We have included a 10,000-year compliance period in regulations for non-radioactive hazardous waste. A 10,000-year compliance period for Yucca Mountain, in conjunction with the requirements of our existing generally applicable standard at 40 CFR part 191, ensures that SNF, HLW, and TRU radioactive wastes disposed anywhere in the United States have the same compliance period. Imposing a compliance period beyond 10,000 years would be unprecedented both nationally and internationally. Further, such an action would carry significant and unmanageable uncertainties. Moreover, provisions to consider radiation dose impacts beyond 10,000 years as a part of the environmental impact review process provide more complete information on long-term disposal system performance. We believe this approach provides the appropriate balance that allows for meaningful consideration of the issues related to 10,000-year and post-10,000-year aspects of disposal system performance.

2. What Are the Requirements for Performance Assessments and Determinations of Compliance? (§§ 197.20, 197.25, and 197.30)

The NRC must decide whether to license the Yucca Mountain disposal system. It must make that decision based upon whether DOE has demonstrated compliance with our 40 CFR part 197 standards. We proposed the quantitative analysis underlying that decision will be a performance assessment (as defined in § 197.12). The DOE and NRC must also make some decisions about what factors to include in the performance assessments, and how extensive those assessments must be to satisfactorily demonstrate compliance. We have addressed some of these performance assessment aspects in our proposal and final rule.

a. What Limits Are There on Factors Included in the Performance Assessments? We proposed that the performance assessment exclude natural features, events, and processes based on the probability of occurrence. We based our proposed requirements for performance assessment on a review of NAS's recommendations, our knowledge regarding the extensive performance assessment work that DOE and NRC have undertaken regarding the Yucca Mountain site, and consistency with 40 CFR part 191 and its application in the WIPP certification. We also require NRC to determine, taking into consideration that performance assessment, whether the disposal system's projected performance complies with § 197.20. Projecting repository performance is the major tool to be used to develop information that will be used to make compliance decisions relative to our standards. To provide the necessary context for these assessments to generate results for regulatory decisionmaking, we must specify sufficient details to assure the standards are implemented as we intend through the use of performance assessments. We have specified only what we believe to be the minimum detail necessary. The remainder we believe should be left to NRC to determine, consistent with its implementing responsibilities and decisionmaking authority.

For repository performance assessments, our standards also require:

(1) That DOE exclude from performance assessments those natural features, events, and processes whose likelihood of occurrence is so small that they are very unlikely, which are those that DOE and NRC estimate to have less than a 1 in 10,000 (1×10^{-4}) chance of occurring during the 10,000 years after disposal. 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) Unlikely events with probabilities higher than stated in (1) above may be excluded from analyses for the human intrusion and ground water protection standards. We leave it to NRC to set the probability limit for these unlikely events in its implementing regulations; and

(3) That the performance assessment need not evaluate the releases from features, events, processes, and sequences of events and processes estimated to have a likelihood of occurrence greater than 1 x 10^{-4} of occurring during the 10,000 years following disposal, if there is a reasonable expectation that the results of the performance assessment would not be changed significantly by such omissions. As necessary, NRC may provide DOE with specific guidance regarding scenario selection and characterization to assure that DOE does not exclude features, events, or processes inappropriately.

We received only a few comments on the question of including low probability events; however, the comments we received supported our proposal. The comments also pointed out some potential confusion in the terms we used in describing unlikely versus very unlikely features, events, and processes. Our intent is to establish that there is no need to include, in the performance assessments used to demonstrate compliance with the individual-protection standard, features, events, and processes, and sequences of events and processes, with probabilities of less than 1 x 10^{-4} chance of occurring in the next 10,000 years. We consider it unlikely that features, events, and processes with such low probabilities of occurrence will occur. We intended to establish another demarcation for excluding unlikely features, events, and processes with a higher probability than stated above but that still have a low probability of occurrence. The DOE must include processes and events in this second category in the assessments for the individual-protection standard, unless NRC determines that excluding them would not affect the results of the assessments. The DOE may, however, exclude them from consideration in demonstrating compliance with the human-intrusion and ground water protection standards. We did not establish a particular probability level for these unlikely features, events, and processes. Instead, we deferred this decision to the implementing authority in § 197.36 of our final rule.

The comments we received on this question supported our contention that 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 that the geologic record is best preserved in the relatively recent past. More specifically, some comments suggested that the Quaternary Period should be the time frame over which DOE should examine evidence for rates and magnitudes of natural features, events, and processes. Because the Quaternary Period includes episodes of glaciation, it provides a means to estimate the potential effects of future climate variations. Further, we believe that the Period's duration (approximately two million years) provides an adequate time frame for estimating the frequency and severity of past seismic activity in the repository area. The NAS in its recommendations indicated that the repository area could be assumed to be "geologically stable" over a period of one million years for the purpose of bounding natural features, events, and processes. We believe that the Quaternary Period is a sufficiently long period of the geologic record to allow DOE to make reasonable estimates of natural features, events, and processes. We chose not to identify a specific time frame in the regulatory language. We leave this choice to the implementing authority.

We allow the exclusion of unlikely natural features, events, and processes from both the ground water and human-intrusion assessments. The approach for the ground water protection requirements is consistent with subpart C of 40 CFR part 191, ''Environmental Standards for Ground-Water Protection.'' The approach for the human-intrusion analysis is consistent with NAS's recommendation (see the *What Is the Standard for Human Intrusion?* section later in this document). We requested public comment regarding whether this approach is appropriate for Yucca Mountain. See the response to Question #10 in section IV later in this document and the Response to Comments document for more information.

b. What Limits Are There on DOE's Elicitation of Expert Opinion? We requested public comment on whether we should include requirements on the use of expert opinion and, if so, what those requirements should be. We consider it likely, given the long time frames involved and the significant uncertainties in the likelihood of features, events, processes, and sequences of events and processes affecting the Yucca Mountain disposal system, that DOE will find it useful to obtain expert opinion to help it arrive at cautious but reasonable estimates of the probability of future occurrence of these features, events, processes, and sequences of events and processes. We also expect DOE to find expert opinion useful in assessing available performance assessment models, or in evaluating the uncertainties associated with the variation of parameter values.

In requesting public comment on this issue, we distinguished between expert judgment, which often is obtained informally, and expert elicitation, in which a more formal process is used. We focused on expert elicitation, and considered including one or all of the following requirements: (1) NRC must consider the source and use of the information so gathered; (2) we would have expected NRC to assure that, to the extent possible, experts with both expertise appropriate for the subject matter and independence from DOE will be on the expert elicitation panel consulted to judge the validity and adequacy of the model(s) or value(s) for use in a compliance assessment; and (3) we would have expected that, when DOE presents information to the expert elicitation panel, it should do so in a public meeting, and qualified experts, such as representatives of the States of Nevada and California, should be given an opportunity to present information.

The comments we received were uniformly opposed to our setting requirements to address expert opinion. There was general agreement among commenters that it would be more appropriate for NRC to use the licensing process to address any requirements relating to expert elicitation. Some commenters referred to NRC's NUREG–1563 (''Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program''), and to the fact that DOE has used it on several occasions. These comments reinforced our opinion that issuing requirements would be an implementation function better left to NRC. We do not expect to issue guidance on this topic, although we reserve the right to do so. We also recognize that such guidance would not be binding, unless it is promulgated by notice and comment rulemaking.

One comment suggested that we restrict the form the expert elicitation could take. The comment stated that it is inappropriate to estimate parameter values using Delphi surveys or other similar techniques that tend to ''exclude the public from vital areas of debate.'' Given that we leave the expert elicitation process to NRC and DOE, we choose not to address only this one particular aspect of that process because we believe that it would be inconsistent to impose any specific requirements on how DOE and NRC should use expert opinion. We believe that NRC and DOE are sufficiently sensitive to public opinion regarding the licensing of Yucca Mountain to avoid the appearance of secrecy or targeted polling of experts to obtain a specific outcome. Therefore, our rule does not address any aspects of DOE's ability to use expert elicitation.

c. What Level of Expectation Will Meet Our Standards? 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). We intend for this term 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 NRC has used a similar qualitative test, ''reasonable assurance,'' for many years in its regulations, and has proposed applying this concept in its Yucca Mountain regulations (proposed 10 CFR part 63). However, the NRC approach was taken from reactor licensing, which focuses on engineered systems with relatively short lifetimes, where performance projections can be verified and if necessary corrective actions are possible. We believe that for very long-term projections where confirmation is not possible, involving the interaction of natural systems with engineered systems complicated by the uncertainties associated with the long time periods involved, an approach that recognizes these difficulties is appropriate. Although NRC has adapted the reasonable assurance approach from the reactor framework and has applied it successfully in regulatory situations related to facility decommissioning and shallow-land waste burial, it has not been applied in a situation as complex as the Yucca Mountain disposal system. We believe that reasonable expectation provides an appropriate approach to compliance decisions; however, with respect to the level of expectation applicable in the licensing process, NRC may adopt its proposed alternative approach. We expect that any implementation approach NRC adopts will incorporate the elements of reasonable expectation listed in § 197.14. A more thorough discussion of our intent concerning the application of reasonable expectation is given below and a more exhaustive discussion of the subject is presented in the Response to Comments document for this regulation. We intend that the information in § 197.14 of the rule and discussions of reasonable expectation presented below and in the Response to Comments document will provide the necessary context for implementation of this concept.

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 timevariable processes and events involved in long-term disposal system performance. Simplifications and assumptions are involved in these modeling efforts out of necessity because of the complexity and time frames involved, and the choices made will determine the extent to which the 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. Inappropriate simplifications can mask the effects of processes that will in reality determine disposal system performance, if the uncertainties involved with these simplifications are not 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. For example, a typical approach to addressing areas of uncertainty is to perform ''bounding analyses'' of disposal system performance. If the uncertainties in site characterization information and the modeling of relevant features, events, and processes are not fully understood, results of bounding analyses may not be bounding at all. The reasonable expectation approach is aimed simply at focusing 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.

We received comments both supporting and opposing the concept of ''reasonable expectation'' and its application to the Yucca Mountain standards. Comments in favor of the approach agreed that the consideration of uncertainty is extremely important to a proper perspective on the degree of confidence possible for projections of disposal system performance over the long time frames involved in assessing repository performance. Comments against the concept voiced variations on three basic concerns: (1) That the concept is ''new,'' ''untested,'' and of ''dubious legal authority'' in the regulatory framework; (2) that it implies that less rigorous, and therefore unacceptable, science and analysis would result from the use of reasonable expectation; and (3) that the choice of approach to compliance decision making is solely an implementation concern that we should leave to NRC.

With respect to the legal authority and use of the reasonable expectation concept in the regulatory process, we believe that the reasonable expectation concept is well established in both the regulatory language in standards, as well as in actual application to deep geologic disposal of radioactive wastes, and has been judicially tested. We developed the ''reasonable expectation'' approach in the context of developing 40 CFR part 191, the generic standards for land disposal of SNF, HLW, and TRU radioactive waste, and more importantly the concept has been applied successfully in the EPA certification of the Waste Isolation Pilot Plant (WIPP), a deep geologic repository for TRU radioactive wastes. The WIPP repository is to date the only deep geologic repository for radioactive wastes in the United States that has been carried through a regulatory approval process. Therefore, we believe that the reasonable expectation concept is neither ''new'' nor ''untried'', nor of ''dubious legal authority'' in the geologic repository regulatory experience. In fact, the use of reasonable expectation for the application to geologic disposal has been upheld in court (*Natural Resources Defense Council, Inc.* versus *U.S. E.P.A.* (824 F.2d 1258, 1293 (1st Cir. 1987))).

In contrast, the reasonable assurance concept was developed and applied many times in the context of reactor licensing—not in the context of deep geologic disposal efforts—and has not been used in a regulatory review and approval process for a deep geologic disposal system. The judicial decision cited in one comment refers to the use of reasonable assurance in the context of reactor licensing, not in the context of deep geologic disposal. While the reasonable assurance concept has an established record of successful application and judicial approval in reactor licensing, it is in fact largely untried in the arena of geologic disposal.

Some comments suggested our approach would allow the use of less rigorous science to the assessment of disposal system performance in licensing. This perception may have arisen from our choice of wording in the proposal, where we stated that NRC may elect to use a more ''stringent'' approach. Such an interpretation was not our intent: the full text of our statement is that NRC may impose requirements that are ''more stringent'' than the ''minimum requirements for implementation'' that our rule establishes; in addition, we clearly stated that reasonable expectation ''is less stringent than the reasonable assurance concept that NRC uses to license nuclear power plants'' (proposed § 197.14(b), emphasis added). However, we will clarify our meaning here. Performance projections for deep geologic disposal require the extrapolation of parameter values (site characteristics related to performance) and performance calculations (projections of radionuclide releases and transport from the repository) over very long time frames that make these projections fundamentally not confirmable, in contrast to the situation of reactor licensing where projections of performance are only made for a period of decades and confirmation of these projections is possible through continuing observation. In this sense, a reasonable expectation approach to repository licensing would be necessarily ''less stringent'' than an approach to reactor licensing. We therefore must disagree with these comments that reasonable expectation requires less rigorous proof than NRC's reasonable assurance approach.

We do not believe that the reasonable expectation approach either encourages or permits the use of less than rigorous science in developing assessments of repository performance for use in regulatory decision making. On the contrary, the reasonable expectation approach takes into account the inherent uncertainties involved in projecting disposal system performance, rather than making assumptions which reflect extreme values instead of the full range of possible parameter values. It requires that the uncertainties in site characteristics over long time frames and the long-term projections of expected performance for the repository are fully understood before regulatory decisions are made. This approach has a number of implications relative to the data and analyses that would be used in making regulatory decisions. Cautious use of bounding assessments is implied since sufficient understanding of uncertainties must be developed to be sure such analyses are truly bounding. Performance scenarios should be developed realistically without omitting important components simply because they may be difficult to quantify with high accuracy, or always assuming worst case values in the absence of information. Elicited values for relevant data should not be substituted for actual field and laboratory studies when they can be reasonably performed, simply to conserve resources or satisfy scheduling demands. The gathering of credible information that would allow a better understanding of the uncertainties in site characterization data and engineered barrier performance that would bear on the long-term performance of the repository should not be subjugated simply for convenience. We do not believe that reasonable expectation in any way encourages less than rigorous science and analysis. In contrast, adequately understanding the inherent uncertainties in projecting repository performance over the time frames required must involve a rigorous scientific program of site characterization studies and laboratory testing.

Some comments expressed the opinion that our use of the reasonable expectation approach intrudes inappropriately into the area of implementation, which is the province of NRC. We do not believe that is the case. We have included the concept of reasonable expectation in the Yucca Mountain standards to provide a necessary context for understanding the standards and as context for the implementation of the licensing process NRC will perform. 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., many 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 problematical over the long-term (see Chapter 7 of the BID). 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 (including the basic guidance given in § 197.14), and not hold out the prospect of a greater degree of ''proof'' than in reality can be obtained.

Relative to implementation, the primary task for the regulatory authority is to examine the performance case put forward by DOE to determine ''how much is enough'' in terms of the information and analyses presented, i.e., implementation involves how regulatory authority determines when the performance case has been demonstrated with an acceptable level of confidence. We have proposed no specific measures in our standards for that judgment. We have not specified any confidence measures for such judgments or numerical analyses, nor prescribed analytical methods that must be used for performance assessments, quality assurance measures that must be applied, statistical measures that define the number or complexity of analyses that should be performed, nor have we proposed any assurance measures in addition to the numerical limits in the standards. We have specified only that the mean of the dose assessments must meet the exposure limit, without specifying any statistical measures for the level of confidence necessary for compliance. We believe that measure is a minimal level for compliance determination, and we selected it to be consistent with the individual protection requirement we applied for the WIPP certification (40 CFR 194.55(f)). For the WIPP certification, EPA was also the implementing agency, and in 40 CFR part 194 we also included implementation requirements, including statistical confidence measures for the assessments and analytical approaches (§§ 194.55(b), (d), (f)) along with quality assurance requirements (§ 194.22), other assurance requirements (§ 194.41), requirements for modeling techniques and assumptions (§§ 194.23 and 25), use of peer review and expert judgment (§§ 194.26 and 194.27). We have not incorporated a similar level of detail in the Yucca Mountain standards because we believe we must specify only what is necessary to provide the context for implementation. We believe that our reasonable expectation approach provides a necessary context for understanding the intent of the standards and for its implementation. We have provided guidance statements in the standards (§ 197.14) relative to the approach that we believe appropriately address the inherent uncertainties in projecting the performance of the Yucca Mountain disposal system. The implementing agency is responsible for developing and executing the implementation process and, with respect to the level of expectation applicable in the licensing process, is free to adopt an approach it believes is appropriate, but we believe whatever approach is implemented must incorporate the aspects of reasonable expectation we have described in the standards and amplified upon in the Response to Comments document.

d. Are There Qualitative Requirements To Help Assure Protection? In the preamble to our proposed standards (64 FR 46998), we requested comment upon whether it is appropriate for us to establish assurance requirements in this final rule and if so, what those requirements should be. The majority of public comments on the issue stated that it was unnecessary for us to include assurance requirements in this rule. The commenters also generally stated that the inclusion of such requirements is an implementation matter that is properly within NRC's jurisdiction. No comments suggested what, if any, assurance requirements we should include in this final rule. Therefore, based upon the public comments we received regarding this rule, the provisions in 40 CFR part 191, and the provisions of NRC's proposed 10 CFR part 63, we did not include assurance requirements in this rule, though we believe we have the authority to do so pursuant to the AEA and the EnPA. For example, our generally applicable standards for the disposal of SNF, HLW, and TRU radioactive wastes (40 CFR part 191, 58 FR 66402, December 20, 1993; 50 FR 38073 and 38078, September 19, 1985) require the consideration of assurance requirements. The assurance requirements in 40 CFR part 191, however, do not apply to facilities that NRC regulates, based upon the understanding between EPA and NRC that NRC would include them in its licensing regulations in 10 CFR part 60. The NRC is the licensing agency for Yucca Mountain; therefore, at first glance it appears that requiring assurance requirements at Yucca Mountain would be inconsistent with our approach in 40 CFR part 191. The EnPA, however, mandates that we set site-specific standards for Yucca Mountain. We believe, therefore, that we could include assurance requirements in this rule. Because NRC's proposed licensing criteria (see 10 CFR 63.102, 63.111, and 63.113; 64 FR 8640, 8674–8677, February 22, 1999) contain requirements similar to the assurance requirements in 40 CFR part 191 for multiple barriers, institutional controls, monitoring, and the retrievability of waste from Yucca Mountain, we believe that it is unnecessary for us to include similar requirements in this rule. We encourage NRC to include the assurance requirements in the proposed 10 CFR part 63 (64 FR 8640), or requirements similar to those in 40 CFR part 191, in its final licensing regulations for Yucca Mountain.

3. What Is the Standard for Human Intrusion? (§ 197.25)

We adopted NAS's suggested starting point for a human-intrusion scenario. As NAS recommends, our standard requires 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 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 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.

We require 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 two exceptions. The first exception is that the human-intrusion analysis would exclude unlikely natural features, events, and processes. The second exception is that the analysis only would address the releases occurring through the borehole (see the *What Are the Requirements for Performance Assessments and Determinations of Compliance?* section earlier in this document).

As noted earlier, our rule uses the same RMEI description for this analysis and scenario as in the assessment for compliance with the individual-protection standard. It is possible that one could postulate that an individual occupies a location above the repository footprint in the future and is impacted by radioactive material brought to the surface during an intrusion event; however, the level of exposure of such an individual would be independent of whether the repository performs acceptably when breached by human intrusion in the manner prescribed in the scenario. Movement of waste to the surface as a result of human intrusion is an acute action. The resulting exposure is a direct consequence of that action. Thus, we interpret the NAS-recommended test of ''resilience'' to be a longer-term test as measured by exposures caused by releases that occur gradually through the borehole, not suddenly as with direct removal. In addition, the effects of direct removal depend on the specific parameters involved with the drilling, not on the disposal system's containment characteristics. We also require that the test of the disposal system's resilience be the dose incurred by the same RMEI used for the individual-protection standard. This approach is consistent with NAS's recommendation.

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. Our review of information about drilling and experiences of drillers indicates that special efforts, such as changing to a specialized drill bit, would likely be necessary to penetrate intact, non-degraded waste packages of the type DOE plans to use. As stated earlier, DOE would determine the timing as part of the licensing process. The DOE's waste-package performance estimates indicate that a waste package would be recognizable to a driller for at least thousands of years (see Chapter 8 of the BID).

We requested comment regarding how much the human-intrusion analysis will add to protection of public health. Also, given current drilling practice in the vicinity of Yucca Mountain, we sought comment regarding whether our stylized, human-intrusion scenario is reasonable.

Comments on our intrusion scenario focused on a number of concerns. Some comment expressed opinions that the intrusion scenario was unrealistic since actual drilling to tap ground water would more probably be done not from the crest of Yucca Mountain but rather from the adjacent valley floors. Other comments stated that multiple drilling intrusions should be assumed rather than only one, and offered alternative scenarios for intrusion frequency and purposes other than tapping ground water. Some comments acknowledged that the scenario was an adequate test of repository resiliency independent of the question of attempting to predict future activities, and that the difficulty of reliably predicting future activities and human intention were unavoidable, as NAS concluded. Some comment stated that the probability of such an intrusion was so remote as to make the scenario useless for any type of repository analysis, while some comment expressed opinions that the entire question of human intrusion was an implementation issue that should be left to the discretion of NRC. Detailed responses to comments we received on the human intrusion question is found in the Response to Comments document accompanying this rule. Our response to some of the most common issues raised in the comments is given below.

A number of comments criticized the stylized definition of the scenario on the grounds it did not address the reality of the site location and resource potential. A convincing case can be made that intrusion is unlikely because of the low resource potential of the immediate Yucca Mountain area (see BID, Chapter 8), and that actual drilling to tap the underlying ground water would most probably be done in the valleys adjacent to Yucca Mountain, as some comments pointed out. We recognize these conditions and the relatively low resource potential; however, as NAS pointed out, there is no scientifically defensible basis to preclude intrusion (NAS Report p. 111). For this reason, the panel recommended that an intrusion scenario should be assessed separately from the expected repository performance case (NAS Report p. 109), and that a stylized intrusion scenario consisting of one borehole penetration should be considered (NAS Report p. 112) as a test of repository resilience to modest intrusion (p. 113). We agree with the NAS conclusions in this regard. As we have pointed out early in the preamble, releases and consequent exposures can come from either the gradual degradation of the disposal system under expected conditions or through disruption, most notably by human activities. Since intrusion cannot unequivocally be ruled out, and exposures can result from intrusions that release radionuclides, we believe it is necessary to consider human intrusion in the context of a repository standard focused on public health protection, even though the resource potential at the site is low. The nature of the intrusion, how it is analyzed and how it should be evaluated in the regulatory context, are the next issues to consider after the basic need to assess a human intrusion scenario is recognized.

The NAS was very specific in its recommendations about assessing human intrusion. The panel recommended that the intrusion scenarios be considered in the EPA's rulemaking process (NAS Report p. 109) and that ''EPA should specify in its standard a typical intrusion scenario to be analyzed'' (p. 108). The panel recommended that a drill hole penetration through a waste package be assumed, which would make a connection from the repository to the underlying saturated zone (pp. 12 and 111). The panel recommended that a ''consequences-only analysis'' be performed (p. 111) and that the standard ''should require such an analysis'' (p. 111), *i.e.,* the analysis should only deal with the fate of releases through the borehole and the potential doses resulting. The NAS recommended that ''the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels * * * acceptable for the undisturbed repository case'' (NAS Report p. 113). We agree with these NAS recommendations and therefore we have constructed the stylized intrusion scenario as described as separate from the individual-protection standard, and imposed a dose limit no greater than the dose limit imposed for the individual-protection standard. We have also followed the NAS recommendation for the time frame for the intrusion (NAS Report p. 112) by linking it to the expected time when the containers first reach a state when a drilling penetration can occur unnoticed by the drillers. This time frame serves as a means of establishing the radionuclide inventory available for release and the transport and dose analysis required by the standard. Comments we received proposing alternative drilling frequencies and intentions, such as deliberately drilling into the repository, did not provide a sufficient rationale to abandon the NAS recommendations and we therefore retained our original framing for the scenario. Additional discussion of the intrusion scenario is to be found in the discussion of comments we received on Question 10 from the proposed rule preamble (see section IV below).

Another line of comment we received stated that framing the intrusion scenario in part, or in any way whatever, should be considered an implementation detail that should be left to NRC. As stated earlier in this document (see section I.A.2, *The Role of 40 CFR part 191 in the Development of 40 CFR part 197*), human intrusion is a process that can contribute to exposures of the public, and it is therefore appropriate to address it in a public health protection standard. In addition, we believe the NAS recommendations as mentioned above were very explicit in stating that human intrusion should be included in the EPA standard and that framing the intrusion scenario should be part of the EPA rulemaking, rather than in implementing regulations. We have followed the NAS recommendations closely, as noted in its comments on our proposed rule. We are also concerned that the implementing authority have some flexibility in implementing the rule and we have framed the standard to allow that flexibility. We have specified in the rule only enough of the details of the scenario to assure it is implemented as we intend. We have in fact not specified enough of the detail to allow an analysis to actually be performed from our description alone. For example, we have not specified the mechanisms by which radionuclides are released from the breached container and make their way down the borehole to the ground water table. Without specifying release and transport mechanisms the analysis cannot be performed. We have left this essential detail for the implementation process. We believe this flexibility is necessary so that the intrusion analyses can consider a range of conditions for the stylized intrusion so it can be an actual test of the repository ''resilience'' for a limited by-passing of the engineered barrier system. Although we have defined the stylized drilling intrusion scenario to closely follow the NAS recommendations, if NRC determines during its implementation efforts that additional intrusion scenarios are necessary to make a licensing decision, NRC can require additional analyses as part of its implementing authority.

We offered for comment two alternatives for the human intrusion standard. The first alternative simply stated that DOE must demonstrate a reasonable expectation that the annual dose incurred by the RMEI would not exceed 15 mrem CEDE as a result of an intrusion event, for 10,000 years after disposal. This parallels the basic individual-protection standard.

The second alternative incorporated our concern that assessments of longer-term performance be made available, if not explicitly used for compliance purposes. Under this alternative, we made a distinction based on how long after disposal the intrusion could occur. If the intrusion were to occur at or earlier than 10,000 years after disposal, DOE must demonstrate a reasonable expectation that annual exposures to the RMEI as a result of the intrusion event would not exceed 15 mrem CEDE. There would be no time limit for this analysis; as our proposal stated, ''[i]f that intrusion can happen within 10,000 years, then DOE must do an analysis which projects the peak dose that would occur as a result of the intrusion within 10,000 years.'' (64 FR 46999, August 27, 1999) However, if the intrusion occurred 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.

We have selected the second alternative for our final human intrusion standard (§ 197.25). However, we are not requiring that DOE calculate a peak dose beyond 10,000 years for comparison against a numerical standard. If the intrusion event occurs earlier than 10,000 years after disposal, DOE need only compare the dose within 10,000 years to the numerical standard. DOE must include post-10,000-year results in its EIS, no matter when the intrusion occurs. We believe this alternative provides assurance that the full effects of an intrusion event will be assessed, regardless of when it occurs. We also believe that the selected alternative is more consistent with the NAS recommendations that a ''consequence-based'' analysis be performed (NAS Report p. 111).

The time frame for the intrusion has implications on how the projected doses are handled and evaluated. We are distinguishing between intrusion events that occur within 10,000 years and those that occur later than 10,000 years after disposal. In assessing events that occur within 10,000 years, we further distinguish the results based on whether exposures are incurred by the RMEI within the 10,000-year period. We have established the 10,000-year compliance period to reflect past precedents and a realization of the inherent uncertainties in long-term performance projections (see section III.(B)(1)(g)). For intrusion events that occur within 10,000 years and exposures are incurred by the RMEI within 10,000 years, doses are compared against the 15 mrem/yr limit given in the standard as part of the compliance case for licensing. For consistency in the treatment of post-10,000-year dose assessments, we are specifying that, when the dose to the RMEI from human intrusion events occurs after the 10,000 year period, the dose assessments are to be included in the EIS, along with the post-10,000 year performance assessments for the individual protection standard. Regardless of when the intrusion occurs, if exposures are incurred later than 10,000 years, they are to be included in the EIS up to the time of peak dose.

We formulated the selected alternative to be responsive to the NAS recommendations, in addition to addressing our concern regarding the availability of post-10,000 year analyses. A key factor in evaluating an intrusion scenario is predicting when such an event might take place. However, as NAS concluded, ''there is no scientific basis for estimating the probability of intrusion at far-future times' but that ''we believe it is useful to assume that the intrusion occurs during a period when some of the canisters will have failed * * *'' NAS Report p. 107, 112. Therefore, we specify that DOE must assume the intrusion occurs at ''the earliest time after disposal that the waste package would degrade sufficiently that a human intrusion could occur without recognition by the drillers' (proposed § 197.25). This time would be determined through the licensing process, presumably by assessing the expected performance of the engineered barrier system. This provides DOE the flexibility to demonstrate that its engineered barrier system is sufficiently robust to withstand intrusion for a predictable time period, which then determines the nature of the waste inventory used in the analysis, *i.e.,* the relative proportions of long-and short-lived radionuclides.

4. How Does Our Rule Protect Ground Water? (§ 197.30)

The inclusion of separate ground water protection standards in today's rule continues a longstanding Agency policy of protecting ground water resources and the populations who may use such resources. This policy is articulated in our primary ground water protection strategy document titled ''Protecting the Nation's Ground Water: EPA's Strategy for the 1990's'' (Docket No. A–95–12, Item V-A–13). We designed today's standards to protect the ground water in the vicinity of Yucca Mountain to benefit the current and future residents of the area who could use this ground water as a resource for drinking water and other domestic, agricultural, and commercial purposes. The following sections discuss the Agency's general approach to ground water protection, the NAS comments regarding ground water protection at Yucca Mountain, and some of the legal and regulatory issues associated with our final ground water protection standards.

Policy and Technical Rationales for Separate Ground Water Protection Standards

Our General Approach to Ground Water Protection

Ground water is one of our nation's most precious resources because of its many potential uses. A significant portion (over 50 percent in the early 1990s) of the U.S. population draws on ground water for its potable water supply (''Protecting the Nation's Ground Water: EPA's Strategy for the 1990's,'' Docket No. A–95–12, Item II–A–3). In addition to serving as a source of drinking water, people use ground water for irrigation, stock watering, food preparation, showering, and various industrial processes. When that water is radioactively contaminated, each of these uses completes a radiation exposure pathway for people. Ground water contamination is also of concern to us because of potential adverse impacts upon ecosystems, particularly sensitive or endangered ecosystems (''Protecting the Nation's Ground Water: EPA's Strategy for the 1990's,'' Docket No. A–95–12, Item II–A–3). For these reasons, we believe it is a resource that needs protection. Therefore, we require protection of ground water that is a current or potential source of drinking water to the same level as the maximum contaminant levels (MCLs) for radionuclides that we established previously under the authority of the Safe Drinking Water Act (SDWA).

In January 1990, the Agency completed a strategy to guide future EPA and state activities in ground water protection and cleanup. The Agency-wide Ground Water Task Force developed two papers, which it issued for public review: an EPA Statement of Ground Water Principles and an options paper covering the issues involved in defining the Federal/State relationship in ground water protection. We combined these papers and other Task Force documents into an EPA Ground Water Task Force Report: ''Protecting The Nation's Ground Water: EPA's Strategy for the 1990's'' (''the Strategy,'' EPA 21Z–1020, July 1991 (Docket No. A–95–12, Item II–A–3)). Our approach in this rule is consistent with this strategy.

Key elements of our ground water protection and cleanup strategy are the strategy's overall goals of preventing adverse effects on human health and the environment and protecting the environmental integrity of the nation's ground water resources. Our strategy also recognizes, however, that our efforts to protect ground water must consider the use, value, and vulnerability of the resource, as well as social and economic values. We believe it is important to protect ground water to ensure the preservation of the nation's currently used and potential underground sources of drinking water (USDWs) for present and future generations. Also, we believe it is important to protect ground water to ensure that where it interacts with surface water it does not interfere with the attainment of surface-water-quality standards; these standards are also necessary to protect human health and the integrity of ecosystems. We employ MCLs to protect ground water in numerous regulatory programs. Our regulations pertaining to hazardous-waste disposal (40 CFR part 264); municipal-waste disposal (40 CFR parts 257 and 258); underground injection control (UIC) (40 CFR parts 144, 146, and 148); generic SNF, HLW, and TRU radioactive waste disposal (40 CFR part 191); and uranium mill tailings disposal (40 CFR part 192) reflect this approach. These programs have demonstrated that such protection is scientifically and technically achievable, within the constraints that each program applies (''Progress In Ground Water Protection and Restoration,'' EPA 440/6–90–001, Docket No. A–95–12, Item V–A–6).

Another critical issue in ground water protection is that ground water generally is not directly accessible. Thus, it is much more difficult to monitor and/or decontaminate ground water than is the case with other environmental media (''Ground-Water Protection Strategy'' p. 11, August 1984, Docket No. A–95–12, Item V–A–13). Because of the expenses and difficulties associated with remediation of contaminated ground water, it is prudent and cost-effective to prevent the occurrence of such contamination (*Id.*). It is possible for large amounts of contaminants to enter a body of ground water and remain undetected until the contaminated water reaches a water well or surface-water body. Moreover, ground water contaminants, unlike contaminants in other environmental media such as air or surface water, generally move in plumes with limited mixing or dispersion into uncontaminated water surrounding the plume. These plumes of relatively concentrated contaminants can move slowly through aquifers. They may persist, and thus may make the contaminated resource unusable, for extended periods of time (*Id.*). Because an individual plume may underlie only a very small part of the land surface, it can be difficult to detect by aquifer-wide or regional monitoring. Also, monitoring is unlikely to occur over greatly extended time periods, during which time an aquifer may become dangerously contaminated (*Id.*). Further, the affected area may become quite large over long time periods. Thus, we believe that it is prudent and responsible to protect ground water resources from contamination through pollution prevention rather than to rely on clean-up of preventable pollution. The pollution prevention approach to protecting ground water resources we are adopting for Yucca Mountain avoids requiring present or future communities to implement expensive clean-up or treatment procedures. This approach also protects individual ground water users. Moreover, absent the protection we have built into the rule, the ground water in aquifers around the repository itself could be subject to expensive clean-up by future generations if releases from the repository contaminate the surrounding ground water to levels that exceed legal limits. A guiding philosophy in radioactive waste management, as well as waste disposal in general, has been to avoid imposing burdens on future generations for clean-up efforts as a result of disposal approaches that would knowingly result in pollution in the future (see, for example, IAEA Safety Series No. 111–F, ''The Principles of Radioactive Waste Management,'' Docket No. A–95–12, Item V–A–10). With respect to radioactive waste disposal, we believe the fundamental principle of inter-generational equity is important. We should not knowingly impose burdens on future generations that we ourselves are not willing to assume. Disposal technologies and regulatory requirements are developed with the aim of preventing pollution from disposal operations, rather than assuming that clean-up in the future is an unavoidable cost of disposal operations today. Designing a disposal system, and imposing performance requirements that avoid polluting resources that reasonably could be used in the future, therefore, is a more appropriate choice than imposing clean-up burdens on future generations. The approach to ground water protection in today's standards is consistent with our overall approach to ground water protection: it prevents the contamination of current and potential sources of drinking water downgradient from Yucca Mountain.

NAS Comments on Ground Water Protection

In its report, NAS clearly identified the ground water pathway as the significant pathways of to the biosphere in the vicinity of Yucca Mountain(NAS Report pp. 52 and 81). The NAS also recognized that ground water modeling for the Yucca Mountain site is complex. Because the modeling for Yucca Mountain involves water movement through pore spaces (the matrix) and fractures in the rocks, as well as the degree of interconnectedness between the water moving in the two pathways, there is uncertainty regarding which model or models to use in the analysis:

> Because of the fractured nature of the tuff aquifer below Yucca Mountain, some uncertainty exists regarding the appropriate mathematical and numerical models required to simulate advective transport * * * [E]ven with residual uncertainties, it should be possible to generate quantitative (possibly bounding) estimates of radionuclide travel times and spatial distributions and concentrations of plumes accessible to a potential critical group. (NAS Report p. 90)

In its report, NAS did not recommend specifically that we include a separate ground water protection provision in our environmental protection standards for Yucca Mountain. Neither, however, did NAS state that we should not include such a provision.

However, in its comments on the proposed rule, NAS specifically addressed our decision to include separate ground water protection standards for the Yucca Mountain site:

> ''(i)n the preamble (to the proposed rule), EPA implies that there is a scientific basis for inclusion of separate ground-water limits in the standards '' for example, EPA provides a detailed analysis of approaches to calculating such limits * * * The (NAS) respectfully disagrees and does not believe that there is a basis in science for establishing such limits for the reasons described above. The (NAS) recognizes EPA has the authority under the Energy Policy Act to establish separate ground-water limits as a matter of policy, but if it does so it should explicitly state the policy decisions embedded in the proposed standard and ask the public to comment on those decisions.
>
> ''If EPA wishes to establish such standards on the basis of science, it must make more cogent scientific arguments to justify the need for this standard''
>
> (NAS Comments, p. 11, Docket No. A–95–12, Item IV–D–31).

EPA's Review of the Ground Water Standards

For the reasons discussed above (see *Our General Approach to Ground Water Protection*), we believe that separate ground water protection standards designed to protect the ground water resource are necessary elements of our Yucca Mountain standards. Our decision to include separate ground water standards is a policy decision that we make pursuant to our statutory authority under the Energy Policy Act. Regarding the protectiveness of the standards, 40 CFR part 197 incorporates the current MCLs. We believe that this approach is necessary to provide stability for NRC and DOE in the licensing process. We based these MCLs on the best scientific knowledge regarding the relationship between radiation exposure and risk that existed in 1975 when they were developed. Scientific understanding has evolved since 1975. We recently concluded a review of the existing MCLs based on a number of factors, including the current understanding of the risk of developing a fatal cancer from exposure to radiation; pertinent risk management factors (such as information about treatment technologies and analytical methods); and applicable statutory requirements. See 65 FR 76708–76753, December 7, 2000. Our analyses indicate that, when the risks associated with the individual radionuclide concentrations derived from the MCLs are calculated in accordance with the latest dosimetry models described in Federal Guidance Report 13, they still generally fall within the Agency's current risk target range for drinking water contaminants of 10^{-4} to 10^{-6} lifetime risk for fatal cancer. Therefore, the MCLs for the radionuclides of concern at Yucca Mountain have not changed.

Our analyses, and those of NAS, indicate that, of all the potential environmental pathways for radionuclides, travel through ground water is the most likely pathway to lead to human exposure to radiation from the Yucca Mountain disposal system (see Chapters 7 and 8 of the BID). The ground water protection standards in this rule protect ground water that is being used or that might be used as drinking water by restricting potential future contamination. Water from the aquifer beneath Yucca Mountain currently serves as a source of drinking water 20 to 30 km south of Yucca Mountain in the communities directly protected by the individual-protection standard. It is also a potential source of drinking water for more distant communities. As noted by NAS, the available ground water supply in the vicinity of Yucca Mountain could sustain a substantially larger population than that presently in the area (NAS Report p. 92).

Technical Approach for Protecting Ground Water at Yucca Mountain

As noted above, NAS asserted in its comments regarding the proposed rule, that we implied that there was a scientific basis for including separate ground water limits in the regulations. The NAS urged us to clearly state the policy reasons for including such limits. We believe that we clearly articulated in the preamble to the proposed rule that we included a ground water protection provision in the proposal based upon our long-standing policy.

In keeping with the site-specific nature of these standards, we believe that it is appropriate to outline an approach to determining compliance with the ground water standards consistent with the geologic conditions along the anticipated ground water flow path for releases from the repository. The approach that we have devised consists of several components. The first component is to define a ground water resource use common for the current population making use of the ground water along the potential path of releases. The population living downgradient from the repository typically uses the ground water for domestic consumption and for agricultural activities. The dominant agricultural activity is alfalfa cultivation (see Chapter 8 of the BID). The next component of the approach is to define a method for assessing the extent of potential contamination in the aquifer that can be used for comparison against established limits. To address the unique setting of the repository, we are defining a ''representative volume'' of ground water consistent with the uses of the resource (see § 197.31(b)). The third component is to propose alternatives to defining how DOE could use the representative volume in making assessments of potential ground water contamination (see § 197.31). See the *Representative Volume of Ground Water* discussion later in this section for our responses to comments on the representative volume approach.

We proposed to use the MCLs as appropriate standards against which to measure compliance. Comment upon our proposal was mixed. Some comments claimed that we misapplied the MCL concept in the Yucca Mountain standards compared with how we apply MCLs in other situations, such as the use of MCLs to define when drinking water from public water supplies is acceptable. Some comments supported the use of MCLs. Other comments pointed out that the dosimetry system used for the current MCLs has been superceded by newer approaches to assessing dose and risk from ground water use and that we should, therefore, not use the MCLs. A number of comments claimed that the use of separate ground water standards is completely unnecessary because the individual-protection standard includes the drinking water exposure pathway and, therefore, the ground water standards are unnecessary as a health protection measure.

Retaining separate ground water protection standards is consistent with both our national policy to protect ground water resources and with previous Agency regulations for geologic disposal facilities. Our generic standards in 40 CFR part 191, which apply to the same kinds of wastes contemplated for disposal at Yucca Mountain, contain separate ground water protection provisions. We believe that there is no question that separate ground water protection standards are appropriate for deep geologic disposal facilities. We believe that the use of contaminated ground water for purposes that could result in exposures to individuals should be of concern, and that avoiding contaminating useable ground water resources is in the general interest of the public at large. More specifically, contamination of water resources could result in the exposure of individuals well removed from the repository location. Also, if ground water were withdrawn from the repository sub-basin, and transported to other locations to supply water needs, a larger population would be exposed than if the water were used only locally. We commonly apply MCLs to water treatment facilities to assure that exposures to the subsequent users of the water are acceptable and the users are protected. The intent of using the MCLs as a compliance measure for the Yucca Mountain disposal system is to encourage a robust containment and isolation design that will not result in unacceptable contamination during the regulatory time frame, which would require future generations to shoulder the burden of water treatment due to contamination from the wastes. We also included ground water protection requirements in our certification process for WIPP, which is the only deep geologic disposal facility in the country that has actually gone through a regulatory review and approval process. We see no reason why we should not apply the same approach to protection for the Yucca Mountain disposal facility as we afforded to the population around WIPP. In fact, the Yucca Mountain disposal system will be located above aquifers that are the ground water supply for the residents living downgradient from the repository, whereas the aquifers potentially subject to contamination at the WIPP facility are highly saline, non-potable water sources. We recognize that the individual-protection standard includes a drinking water exposure pathway; however, from a policy perspective it is appropriate and consistent for us to provide separate protection for ground water resources in the Yucca Mountain area. As illustrated by the examples above, the protection of ground water resources is in the general interest of the public at large, because it is easily conceivable that uses of the resource could result in exposures well beyond the immediate vicinity of the repository. From a more practical perspective, it would be extremely difficult to predict with any reliability what the total range of potential exposures (and consequent health effects) would be for all possible uses of the resource, because such predictions would involve considerable speculation. It makes more sense to assure the resource is not contaminated in the first place. We are taking the more prudent course of attempting to prevent ground water contamination above the MCLs by imposing separate ground water protection requirements.

The NRC's determination of compliance with the ground-water protection standards will be based largely upon DOE's projections of potential future contaminant concentrations. The DOE will include these projections in the license application it submits to NRC. These projections, by their very nature, inevitably will contain uncertainty. An important cause of uncertainty, as NAS recognized, is the choice of conceptual site models (NAS Report p. 75). The conceptual models used for Yucca Mountain can differ fundamentally. For example, water can be presumed to flow through either pores in the rock or conduits through the rock (such as discrete fractures or a network of fractures that can act as preferential pathways for faster ground water flow), or a combination of the two. To further complicate the situation, any of these flow scenarios, with the possible exception of flow through conduits, can occur at Yucca Mountain whether or not the rock is saturated completely with water.

We believe that adequate data and the choice of models will be critical to any compliance calculation or determination because such data and models are the backbone of the performance assessment used to show compliance. The NAS examined the use of ground-water flow and contaminant-transport models in regulatory applications (''Ground Water Models: Scientific and Regulatory Applications,'' 1990, Docket No. A–95–12, Item V-A–26). In that report, NAS concluded that data inadequacy is an impediment to the use of unsaturated fracture flow models for Yucca Mountain. However, NAS noted that data inadequacy also was an impediment to using models that assume the pores in the rock are either saturated or unsaturated or that assume flow through fractures that are filled completely with water. However, despite the recognition of the importance of the choice of the site conceptual model, we believe that the need for sufficient quantity, types, and quality of data to adequately analyze the site, because of its hydrogeologic complexity, is even more important. In other words, the complexity of the ground water flow system requires adequate site characterization to justify the choice of the conceptual flow model.

The choice of modeling approaches to address the ground water system in the area of Yucca Mountain, based upon the conceptual model of the site developed from site characterization activities, is important to characterize contaminant migration, particularly the mixing of uncontaminated water with water that has been contaminated with radionuclides released from breached waste packages. The extent of the dilution afforded by mixing contaminated water with other ground water moving through the rocks below the repository but above the water table and the dispersion of the plume of contamination within the saturated zone as the ground water system carries radionuclides downgradient are critical elements of the dose assessments.

At one end of the spectrum of approaches to modeling the Yucca Mountain area's ground water system is the assumption that it is possible to model the system based upon flow through pores over a large area (tens of square kilometers). At the other extreme is the assumption that radionuclides are carried through fast-flow fractures in the unsaturated zone separately from uncontaminated ground water also passing through the repository footprint. Those radionuclides then are assumed to be carried through the saturated zone in fractures that allow little or no dispersion within, or mixing with, uncontaminated water in the saturated zone. This scenario is essentially ''pipe flow'' from the repository to the receptor. Although the flow of ground water at the site is influenced strongly by fractures, which the models should reflect, we believe that it is unreasonable to assume that no mixing with uncontaminated ground water would occur along the radionuclide travel paths because such mixing is a natural process, and would be governed by the degree of interconnection between individual fractures in the rocks. We requested comment upon this approach, including consideration of the practical limitations on characterizing the flow system over several or tens of square kilometers.

Comments varied from statements that we should not allow DOE to consider mixing of contaminated water from the repository with uncontaminated water along potential flow paths, that such dilution is an expected process in the natural system, and that these decisions about the flow system modeling are implementation details which we should defer to NRC. We agree that some degree of mixing along the ground water flow paths is to be expected and, if supported by the hydrogeologic characterization, should be considered in modeling approaches used to make projections of radionuclide migration from repository releases. We also agree that detailed decisions about the approach to modeling the ground water flow system at the site are an implementation concern for NRC. We therefore make no specific requirements in this regard. We do believe that whatever specific modeling approach and attendant assumptions that DOE or NRC make should attempt to model realistically the expected behavior of the actual flow regime downgradient from the repository. Recalling the ''pipe-flow'' scenario described above, we believe it would be highly unrealistic to assume that no mixing of the contaminated water with ground water along the flow path occurs along the distance from the repository to the furthest allowable boundary of the controlled area. Although the actual dispersion effects for the fractured rock geohydrologic setting are anticipated to be small (see Chapter 7 of the BID), ignoring such processes is still inappropriately over-conservative because it would neglect a natural process that is expected to occur. Consistent with this perspective, we specify two alternative methods that DOE could use for determining radionuclide concentrations in the representative volume of ground water. We believe these two alternatives provide appropriate direction for making the compliance determination while allowing ample flexibility for the implementation decisions concerning the details of characterizing the ground water flow and modeling approaches that DOE ultimately must select and defend in the licensing process.

Our intent was to develop ground water protection standards that NRC can reasonably implement. In this regard, NAS indicated that quantitative estimates of ground water contamination should be possible (NAS Report p. 90). We thus require DOE to project the level of radioactive contamination it expects to be in the representative volume of ground water. The representative volume could be calculated to be in a contaminated aquifer that contains less than 10,000 mg/L of TDS and that is downgradient from Yucca Mountain. Through the use of this method, we intend to avoid requiring DOE and NRC to project the contamination in every small, possibly unrepresentative amount of water because we believe that this approach is not scientifically defensible considering the inherent uncertainties in hydrologic data and the limitations of modeling calculations. For example, we do not intend that NRC must consider whether a few gallons of water in a single fracture would exceed the standards. Thus, we allow use of a larger volume of water that must, on average, meet the standards. See below for a discussion of this larger volume, the ''representative volume.''

Because the purpose of the engineered and natural barriers of the geologic repository at Yucca Mountain is to contain radionuclides and minimize their movement into the general environment, we anticipate that radionuclide releases from the repository will not occur for a long period of time. With this assumption in mind, we believe that ground water protection for the Yucca Mountain site should focus upon the protection of the ground water as a resource for future human use. It is the general premise of this rule that the individual-protection standard will adequately protect those few current residents closest to the repository. The intent of the ground water standards is protecting 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. To implement this conceptual approach and develop an approach for compliance determinations, we believe that the ground water standards currently used, the MCLs, should apply to public water supplies downgradient from the repository in aquifers at risk of contamination from repository releases. There is presently no public water supply providing treatment to meet MCLs before the water reaches consumers downgradient of Yucca Mountain, and there is no guarantee that such a system will be in place to protect future users from contamination caused by releases from the disposal system. Applying the MCLs in the ground water assures that the level of protection currently required for public water supplies elsewhere in the nation also is maintained for future communities using the water supply downgradient from the Yucca Mountain disposal system.

Representative Volume of Ground Water

To implement the standards in § 197.30, we require that DOE use the concept of a ''representative volume'' of ground water. Under this approach, DOE and NRC will project the concentration of radionuclides released from the Yucca Mountain disposal system, for comparison against the MCLs, that would be present in the representative volume in the accessible environment over the 10,000-year period of the standards. The representative volume will be a volume of water projected to supply the annual water demands for defined resource uses. We believe that water demand estimates for calculation of the representative volume should reflect the current resource demands for the general lifestyles and demographics of the area, but not be rigidly constrained by current activities, because potential contamination would occur far into the future. In the area south of Yucca Mountain, people currently use ground water for domestic purposes, commercial agriculture (for example, dairy cattle, feed crops, other crops, and fish farming), residential gardening, commercial, and municipal uses (see Chapter 8 of the BID). The ground water resources, as reflected by estimates of current usage and aquifer yields, indicate that there is theoretically enough water to support a substantially larger population than presently exists at each of the four alternative locations we proposed for the point of compliance (*Id.*). The representative volume approach sets an upper bound on the size of the hypothetical community and its water demand. On the other hand, the SDWA defines the minimum size for a public water system as a system with 15 service connections or that regularly supplies at least 25 people. The SDWA was designed to address, and typically is applied to, situations where contamination can be monitored in the present and where monitoring is done close to the disposal facility rather than many kilometers away. If necessary, corrective actions can be taken if contamination limits are exceeded. In contrast, the geologic disposal application involves potential contamination releases that are expected to occur no sooner than far into the future. It simply is not reasonable to assume that monitoring for the purpose of detecting radionuclide contamination around the repository will be performed continually far into the future. Consequently, it is not prudent to assume that corrective actions would be taken to reduce contamination levels. As noted by NAS, active institutional controls (including active monitoring and maintenance) can play an important role in assuring acceptable repository performance for some initial period, not exceeding a time scale of centuries (NAS Report p. 106). Another approach to protecting the ground water resource into the future is necessary. Projecting repository performance, and consequently assessing potential repository releases to the surrounding ground waters, can only be based upon mathematical modeling of the repository's engineered and natural barrier performance. A method of assessing potential contamination must be developed that involves ground water modeling capabilities. The approach we have developed to assess ground water contamination (described previously) is the use of a representative volume of ground water in modeling calculations.

We believe that, ideally, the representative volume should be fully consistent with the protection objectives of the ground water protection strategy; however, we also recognize the unusual features of these standards. That is, the 10,000-year compliance period introduces unresolvable uncertainties that make this situation fundamentally different from the situations of clean-up or foreseeable, near-term potential contamination to which the SDWA ground water protection strategy ordinarily applies. The size of the area that must be modeled (tens of km^2) around the site and the complexity of the site characteristics introduce fundamental limitations on the size of the water volume that it is possible to model with reasonable confidence. It is Agency policy to protect ground water as a resource and we intend our ground water protection standards to accomplish that policy goal. We intend the representative volume concept we have incorporated into the standards to serve as context for the application of our ground water protection policy to the Yucca Mountain site, which differs from the more common application of the SDWA as described above. The representative volume concept addresses two needs in this respect. First, the size of the representative volume (measured as an annual volume in acre-feet) must be sufficiently large that the uncertainties in projecting site characteristics (such as the hydrologic properties along the flow paths) that control ground water flow are not so great that performing calculations to determine radionuclide concentrations in that volume becomes meaningless from an analytical perspective. That is, we should not expect a higher level of confidence and exactness than the scientific tools and available data are capable of providing. Second, the representative volume should be an appropriate measure of the resource to be protected. From both perspectives, analytical limitations and resource characterization, the representative volume of 1,285 acre-feet that we proposed is the potential choice that could satisfy those needs. As described in the preamble to the proposed rule, we preferred the 1,285 acre-feet alternative because we believed it reflected both perspectives. The major resource use for ground water in the area downgradient from the repository is agriculture, and the most water intensive agricultural activity in the area is alfalfa farming. The 1,285 acre-feet representative volume (including 10 acre-feet for domestic use for the farm community) is the water demand for an average alfalfa farm in the Amargosa Valley area (see Chapter 8 of the BID). From consideration of the inherent limitations of modeling the geohydrologic setting at the site, we believe that approximately a 100 acre-feet representative volume is the smallest volume for which it is possible to perform reasonably reliable calculations (Memo to Docket from Frank Marcinowski, EPA, Docket No. A–95–12, Item II–E–10). The 1,285 acre-feet volume is sufficiently above this limit; therefore, questions about the scientific capabilities of performance modeling to assess radionuclide concentrations in the 1,285 acre-feet volume should not be a concern. While still feasible to model, 120 acre-feet is much closer to the lower limit of defensible modeling, and uncertainties at this volume are potentially unwieldy and overwhelming. We requested comment regarding both our use of a representative volume of ground water and possible alternatives for the size of the representative volume. We based these alternative volumes upon variations in possible lifestyles for residents downgradient from the repository and upon current and near-term projections of population growth and land use in the area.

We specifically requested comment upon whether 1,285 acre-feet is the most appropriate representative volume of ground water, or whether other values within the ranges discussed below are more appropriate. We believe that there may be significant technical, policy, or practical obstacles with the use of either very small or very large water volumes. Modeling capabilities limit the volumes of ground water for which it is possible to make meaningful and scientifically defensible calculations. At the other extreme, excessively large volumes of water allow artificially high dilution of radionuclide releases, and do not actually simulate the natural process that would occur along the radionuclide ground water travel path from the repository to the compliance point. The selection of the representative volume must consider both modeling limitations and realistic approaches to modeling, and must be both a reasonable representation of the resource to be protected and be possible to implement from a modeling perspective.

Comments on our alternatives for the representative volume size varied from agreement with our preferred volume of 1,285 acre-ft to favoring larger and smaller volumes. We believe that the larger volume mentioned in the proposed rule, 4,000 acre-ft, is not a suitable choice for a number of reasons. This number is an estimate of the perennial yield in the sub-basin containing Yucca Mountain. It is an estimate of the amount of ground water that can be removed annually without seriously depleting the aquifer. Because there are relatively few wells in this sub-basin, the 4,000 acre-ft estimate is not highly reliable and is difficult to justify. This is one reason why we did not select this number. Perhaps more importantly, the perennial yield is not a physical location in the aquifer and the challenge of projecting repository performance is to project the path of potential contamination from the repository. The perennial yield concept is not consistent with the idea that the modeling of potential contamination from the repository should use an actual volume of water, the representative volume, to determine compliance with the standards. Small volumes of ground water would be difficult to model with confidence over the long time frames and distances appropriate for the Yucca Mountain repository. More specifically, we believe it is not possible to model for the 10 acre-ft representative volume (see the Response to Comments document for more detail). Comment on the 120 acre-ft volume was generally that this volume was too small for defensible modeling, which agrees with our assessment. As stated above, we consider 120 acre-ft to be within the range of feasible modeling, but very close to the lower limit of scientifically defensible modeling capabilities. It also does not reflect the typical use of the ground water resource, which is better represented by the agricultural scenario we have selected.

There are a number of fundamental limitations involved in modeling the flow of ground water over long distances that are direct functions of the variability of the hydrologic properties in the aquifers along its dimensions. Averaging assumptions are used in modeling to greater and lesser extents to address these limitations, as a function of the information available regarding the natural variability of hydrologic properties along the flow paths. Our approach to calculating ground water contaminant concentrations (the well capture zone or slice-of-the-plume methods described in § 197.31(b)) centers the representative volume to include the highest concentration portion of the projected plume. If the representative volume is too small, it does not capture a volume large enough to reflect the natural processes that will occur along the flow path. Therefore, the concentrations will be unrealistically high and will not be a reasonable representation of the variations that should be expected in the actual situation. The exact limit on the lowest size of the representative volume adequately reflecting modeling limitations and the data base of hydrologic information about the site is a difficult expert judgment. An exact lower limit is not possible to identify because of the inherent limitations in gathering site data and performing modeling. Our opinion after extensive discussions with qualified experts is that a representative volume on the order of 100 acre-ft or below is the lower limit of modeling capability for the Yucca Mountain ground water flow regime (Yucca Mountain Docket, A–95–12, Item II–E–10).

We based the 1,285 acre-ft representative volume on a hypothetical small farming community of 25 people and an alfalfa farm with 255 acres under cultivation. This approach assumes a small community whose water needs include domestic consumption and an agricultural component comparable to present water usage in the vicinity of the repository. We based the size of the average area of alfalfa cultivation, 255 acres, on site-specific information for the nine existing alfalfa-growing operations in Amargosa Valley in 1998, which ranged in size from about 65 acres to about 800 acres (see Chapter 8 of the BID). Using a water demand for alfalfa farming in Amargosa Valley of 5 acre-feet per acre per year, we estimate that the annual water demand for the average operation is 1,275 acre-ft (Chapter 8 of the BID). An average value of 0.4 acre-ft per person for domestic water use is typical of the area (Chapter 8 of the BID), which for the small community of 25 people would add 10 acre-ft for domestic uses, resulting in a total representative volume of 1,285 acre-ft. Comments on the derivation of the 1,285 acre-ft representative volume supported this size as being technically feasible for modeling and consistent with water resource demands in the area downgradient from the repository.

To implement the standards in § 197.30, we require that DOE use the concept of a ''representative volume'' of ground water. Under this approach, DOE will project the concentration of radionuclides or the resultant doses within a ''representative volume'' of ground water for comparison against the standards. We have selected a value of 3,000 acre-ft/yr as the representative volume. This value is a ''cautious, but reasonable'' figure for protecting users of the ground water downgradient of the repository, as described below. Our approach focuses on the anticipated water use immediately downgradient of the repository, and is closely aligned with the alternatives offered for public comment in our proposed rule.

The preamble to the proposed rule noted that the representative volume should reflect the water usage of a hypothetical community that may exist in the future. The preamble also noted that the water usage should reflect the current general lifestyles and demographics of the area, but not be rigidly constrained by current activities. Using current activities and near-term projections of planned activities in the downgradient area leads us to three types of water demands that can be identified for the downgradient area: Water demand for individual domestic and municipal uses, water demand for commercial/industrial uses, and water demand for agricultural uses.

In deciding how to make this projection, we have concluded in the final rule that our focus in developing an appropriate representative volume should be to consider the spectrum of likely downgradient uses of the ground water resources, as well as the site-specific hydrologic characteristics of the disposal system itself. To avoid speculation on all possible uses of ground water, we have been guided by the premise that current uses in the immediate downgradient area, as well as short-term projections for water uses reflecting growth projections for the area, should be considered in defining an appropriate representative volume for the ground water standard. We believe that the most likely future uses will in fact take place where they are currently located, since there is no reason to anticipate that they will cease occurring.

Deriving a representative volume involves identifying water demands for the spectrum of likely uses, and includes an examination of projected plume characteristics. This leads us to focus primarily on projected uses occurring downgradient of the repository. As noted above, the current and anticipated water demands downgradient of the repository consist of residential/municipal uses, commercial/industrial uses and agricultural uses.

Currently, the population at the Lathrop Wells is small, about ten people (BID Chapter 8), however near-term projections for the area between Lathrop Wells and the NTS boundary indicate that a science museum and industrial park are under development (Docket No. A–95–12, Items V–A–16, V–A–19). There are also growth projections for the Amargosa Valley area (Docket No. A–95–12, Items V–A–14, 15), leading us to believe that residential/municipal water demands as well as commercial/industrial water demands are likely in the near-term for the area between Lathrop Wells and the NTS boundary.

Projected water demand for the science museum and industrial park are on the order of 100 acre-ft/yr (Docket No. A–95–12, Item V–A–19). Based upon the growth projections, we believe that some residential population growth should be anticipated for the area in addition. In the preamble for the proposed rule, we included a representative volume of 120 acre-ft/yr for a small residential community of approximately 150 persons, which included water uses for individuals and municipal uses. We believe that these water demands should be incorporated into the representative volume, so that the representative volume addresses all potential water users. Limiting the water demand to only one of these uses, we believe, would not be representative of the spectrum of potential users that might be exposed to contaminated water from repository releases. For example, the water demand for the small population at Lathrop Wells would be on the order of less than 10 acre-ft/yr. Our evaluations of representative volume options in the proposed rule (Docket No. A–95–12, Item II–E–10), and the responses we received concerning these options, consistently concluded that such small volumes would not allow credible scientifically defensible projections to be made.

The contribution of agricultural activities to the representative volume can be derived from a consideration of current farming activities in Amargosa Valley. In the Town of Amargosa Valley, agricultural activities consume the largest volumes of ground water, but are largely confined to the location approximately 25–30 km downgradient from the repository location. However, the ground water used for these activities could be contaminated if radionuclide releases from the disposal system were sufficiently high to exceed the limits given in § 197.30. To protect the agricultural resource use, we have used alfalfa farming as a measure of water demand. Although there is no alfalfa farming currently at the compliance location, and no near-term planning for it, our approach to protecting the resource is to include the appropriate water demand in the representative volume at the compliance location. By protecting this volume upgradient of where the actual resource is anticipated to be tapped, we will be protecting the larger actual volume of water that will be used for agricultural purposes downgradient from the compliance location.

As described previously, alfalfa cultivation is the largest water consumer in the agricultural sector, and this activity is anticipated to continue (BID Chapter 8). We have defined an average-sized alfalfa farm based upon current information about acreage under cultivation in Amargosa Valley (BID Chapter 8). We have retained this value to avoid speculation about the future of this particular activity for the following reasons. The demand for alfalfa cultivation to support the local dairy industry in Amargosa Valley is anticipated to be strong for the near-term. The hydrologic basin in which this activity takes place is fully allocated, suggesting that dramatic increases in alfalfa cultivation are unlikely since the water allocations necessary for dramatic increases are not readily available (BID Chapter 8). Therefore, we are using the value of 1,275 acre-feet/yr for an average-sized farm for developing a representative volume figure (this represents the proposed value of 1,285 acre-feet, less the 10 acre-feet assumed for purely domestic use).

The anticipated behavior of the ground-water flow system from Yucca Mountain is important in determining the total contribution of the agricultural water demand to the representative volume, since the width of potential contamination plumes will determine how large a volume of contaminated ground water could be tapped for agricultural purposes and consequently should be protected from unacceptable contamination. Projections of ground water flow, from particle-tracking analyses, have been performed by DOE to determine the path of possible contaminant flow from advective transport (ground water movement) alone (Docket No. A–95–12, Items V–A–5, V–A–27). The particle tracks near the compliance boundary, the southwesternmost corner of NTS (a distance of approximately 18 km from the southern end of the repository), indicate that the width of a potential contamination plume at the compliance location is about 1.8–2.0 kilometers. Farther downgradient, the width of the particle-track ground water travel path widens slightly to a width of between 2 and 3 km. This width does not consider dispersive effects that will occur, which contribute to uncertainty in projecting the actual size of a potential contamination plume. The actual width will be a function of a number of other factors, including the location of failed waste packages over time within the repository and the particular values of dispersion parameters chosen for analyses. Somewhat smaller or larger contamination plume widths could result, but the particle track approach results offer a satisfactory approximation.

The average alfalfa farm we have defined (255 acres in a square shape) is only approximately one kilometer on an edge. Since the exact location of a contamination plume and the variations in radionuclide contaminant concentrations within it are uncertain and cannot be projected with high confidence, we are using two average sized alfalfa farms across the path of the contamination plume to increase confidence that the highest concentration portions of a potential contamination plume will be included in the representative volume, giving a total contribution of 2,550 acre-ft/yr for the agricultural component of the representative volume. Again, we are not assuming the existence of actual farms at the compliance location, but we are assessing the effects of radionuclide contamination on the water volume that they could use at more distant locations.

In total, the contributions to the representative volume consist of the agricultural use water demand for two average size alfalfa farms (2,550 acre-ft/yr), the commercial/industrial water demand for the Lathrop Wells development projections (100 acre-ft/yr), and individual/municipal use water demand for a small community consistent with the near-term growth projections for the area (120 acre-ft/yr). These three components amount to 2,770 acre-ft/yr. As mentioned above, there is significant uncertainty in the exact location and radionuclide concentrations in potential contamination plumes from the repository, and therefore we cannot be absolutely certain that two average-sized alfalfa farms will cover the total possible width of a contamination plume, but we believe including the water demand from more than two farms would not be entirely justified. Our intent in using the two alfalfa farms (each 1 km in width) is to assure that the highest concentration portion of any contamination plume is tapped by the wells supplying this water demand. We have also modified § 197.31 to allow the use of multiple pumping wells (rather than a single well as described in the proposed rule) to tap the representative volume so that technical limitations on constructing a well withdrawal scenario can be eliminated or minimized, should DOE elect this alternative for calculating radionuclide concentrations in the representative volume.

There is, of course, uncertainty in projecting the size and shape of contamination plumes from the repository as well as projecting human activities into the future, and we have limited this source of uncertainty by considering only near-term projections for growth and development in the area, but some degree of inherent uncertainty will always remain. To address these residual uncertainties in this approach, we increase the representative volume by about 10%, to a total 3,000 acre-ft/yr. We believe that this figure represents a cautious, but reasonable, estimate of the representative volume to protect the ground water resource downgradient of the repository.

We considered an alternative way of evaluating the representative volume concept for application to the ground water protection standards. This approach considers the larger scale ground water flows and uses in the larger basin (Basin 230) which receives outflow from the basin where the repository is located (Basin 227A). The primary water use in this region is in the Amargosa Desert hydrographic basin (Basin 230, see BID Chapter 8), where farming, mining, and other industrial uses occur. This water comes from four basins that have an estimated total water budget of about 43,800 acre-feet, which represents ground water that flows into the Amargosa Desert basin.

The Jackass Flats basin (Basin 227A, which includes Yucca Mountain and the point of compliance location) is one of four basins that flow from the north into the Amargosa Desert basin and provide the ground water that is used for these activities. It is the only one of these basins into which it is reasonable to anticipate that water contaminated by releases from the repository would flow. The Jackass Flats basin contributes about 8,100 acre-feet to the total Amargosa Valley water budget (Table 8–6, BID). Considering the approximate nature of these values, it is reasonable to approximate the contribution of the Jackass Flats to flow into the Amargosa Desert basin and to current water uses at 20%.

Although the Amargosa Desert basin has a water appropriation limit of about 41,093 acre-feet, in 1997, the reported ground water use in the Amargosa Desert basin was about 13,900 acre-feet (BID Chapter 8). That is, the use was less than appropriated. Moreover, actual water use fluctuates significantly, depending primarily on the level of irrigation and mining activities in a given year (BID Chapter 8). To estimate the actual contribution of flow from Jackass Flats, we again refer to the largest water use in the area downgradient from the repository, which is for irrigation, particularly for the cultivation of feed for livestock (primarily alfalfa). There are nine alfalfa farms in the affected area, ranging from approximately 65 to 800 acres (BID Chapter 8). Estimates of acreage under cultivation for feedstock has shown a steady increase from 1994 to 1999 (Table 8–6, BID), with an increase of 50% from 1997 to 1999. Assuming that it also increased by 50%, the 1997 irrigation use of 9,379 acre-feet (Table 8–4, BID) could have increased by approximately 4,700 acre-feet in 1999. This assessment gives a range of water use from approximately 13,900 acre-feet in 1997 to an estimate of 18,600 acre-feet in 1999, placing the corresponding 20% contribution from Jackass Flats in a range of approximately 2,800 to 3,700 acre-feet. From this range of possible values, we again selected 3,000 acre-feet as a value that is conservative (toward the low end of the range), but also makes an allowance for the uncertainty inherent in these estimates.

In summary, both approaches to deriving a ''cautious, but reasonable'' representative volume for the purpose of ground water protection converge on a value of 3,000 acre-ft/yr. Our approach to developing an appropriate representative volume considered the size of the ground water resource and its current and projected uses. Accordingly, we have selected a representative volume of 3,000 acre-feet for this rule. This volume is within the 10 to 4,000 acre-feet range described in the proposed rule and addressed in the public comments and represents a reasonable and site-specific approach to protecting groundwater resources in the vicinity of Yucca Mountain.

Our standards require DOE to assume that the entire representative volume is drawn at the compliance point, that is, 18 km south of the repository, rather than in the Amargosa Valley itself, at 25 to 30 km south of the repository. Therefore, it is adequate not only to protect downgradient uses, but also to protect all of these reasonably projected uses, should the representative volume be withdrawn at the compliance point. As noted above, we believe that given the uncertainties of projecting any particular future and the difficulties of modeling that using the small volumes that would be required by relying only on current projected uses, this is a reasonable approach for determining how ground water should be protected at this particular site.

There are two basic approaches that DOE must choose between for calculating the concentrations of radionuclides in the accessible environment. The DOE may perform this analysis by determining how much contamination is in: (1) A ''well-capture zone;'' or (2) a ''slice of the plume'' (see immediately below for explanations of these approaches). For either approach, the volume of water used in the calculations is equal to the representative volume, *i.e.,* the annual water demand for the future group using the ground water.

The ''well-capture zone'' is the portion of the aquifer containing a volume of water that one or more water supply wells, pumping at a defined rate, withdraw from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval. If DOE uses this approach, it must assume that the:

(1) Wells have characteristics consistent with public water supply wells in Amargosa Valley, for example, well bore size and length of the screened interval;

(2) Screened interval includes the highest concentration in the plume of contamination at the point of compliance; and

(3) Pumping rate is set to produce an annual withdrawal equal to the representative volume.

To include an appropriate measure of conservatism in the compliance calculations for the well-withdrawal approach, for the purpose of the analysis, DOE should assume that pumping wells that tap the highest concentration within the projected plume of contamination would supply the community water demand. This approach achieves conservatism by requiring that the entire water demand is withdrawn from wells intercepting the center of the plume of contamination so that the highest radionuclide concentrations in the plume are included in the volume used for the compliance calculations. The well-capture zone concept is described in more detail in Bakker and Strack, ''Capture Zone Delineation in Two-Dimensional Groundwater Flow Models,'' (1996) (Docket No. A–95–12, Item V–A–25).

The ''slice of the plume'' is a cross-section of the plume of contamination centered at the point of compliance with sufficient thickness parallel to the prevalent flow of the plume such that it contains the representative volume. If DOE uses this approach, it must:

(1) Propose to NRC, for its approval, where the edge of the plume of contamination occurs, for example, where the concentration of radionuclides reaches 0.1% of the level of the highest concentration at the point of compliance;

(2) Assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(3) Set the volume of ground water contained within the slice of the plume equal to the representative volume.

Both alternatives require DOE to determine the physical dimensions and orientation of the representative volume during the licensing process, subject to approval by NRC. Factors that would go into determining the orientation of the representative volume would include hydrologic characteristics of the aquifer and the well.

The DOE must demonstrate compliance with the ground water protection standards (§ 197.30) assuming undisturbed performance of the disposal system. The term ''undisturbed performance'' means that human intrusion or the occurrence of unlikely, disruptive, natural processes and events do not disturb the disposal system. The intent of the ground water protection standards is to assess whether the expected performance of the repository system will lead to contamination of the ground water resource above the MCLs. The assessment of resource pollution potential is based upon the engineered design of the repository being sufficiently robust under expected conditions to prevent unacceptable degradation of the ground water resource over time. Disruption of the disposal system is inconsistent with that intent. For this reason we have specified that the ground water standards apply to undisturbed performance. Our approach also recognizes that human behavior is difficult to predict and, if human intrusion occurs, that individuals may be exposed to radiation doses that would be more attributable to human actions than to the quality of repository design (NAS Report p. 11). The requirement that DOE project performance for comparison with the ground water protection standards based on undisturbed-performance scenarios is consistent with our generally applicable standards for SNF, HLW, and TRU radioactive waste in 40 CFR part 191 (58 FR 66402, December 20, 1993; 50 FR 38073 and 38078, September 19, 1985).

We also require that DOE combine certain estimated releases from the Yucca Mountain disposal system with the pre-existing naturally occurring or man-made radionuclides to determine the concentration in the representative volume. This requirement means that DOE must show a reasonable expectation that the releases of radionuclides from radioactive material in the Yucca Mountain disposal system will not cause the projected level of radioactivity in the accessible environment to exceed the limits in § 197.30.

We requested public comment regarding these approaches to ground water protection (*i.e.,* the use of the MCLs, the concept of representative volume and the alternatives for its size and modeling approaches, and calculational approaches for the representative volume application). We also requested comments regarding whether it is desirable and appropriate for us to provide additional detail for the representative volume in the final standards.

Comments generally approved of the idea of providing alternate approaches for determining the concentration of contaminants in the representative volume. Other comments requested additional clarification of the approaches. We developed these approaches to measuring the representative volume in the plume of contamination to provide conservative but reasonable methods of assessing contaminant concentrations. We intend both methods to avoid extreme assumptions that would involve using only the highest potential area of contamination in a contamination plume for comparison against the standards and to allow reasonable consideration of the expected behavior of the flow regime downgradient of the repository. For example, the well capture-zone approach has conservative aspects consistent with our general approach to regulations (a ''cautious, but reasonable'', approach). These aspects include locating the well in the path of the plume and requiring it to have characteristics similar to water supply wells in the area, while also allowing DOE to consider well-bore dilution effects for the water supply wells that realistically would be expected in actual practice. To keep the modeling analyses from becoming too complicated to perform and assess with a reasonable degree of confidence, we specify that DOE use average hydrologic properties to avoid the problem of summing up possibly thousands of individual model runs. We attempt to specify only the most important specifics for the two methods to provide a necessary context to assure the standards are understood as we intend, but still to provide flexibility for NRC in its implementation of the standards. For example, we neither established requirements nor made recommendations regarding models to be used for the plume modeling methods. We left the applicant (DOE) and the implementing authority (NRC) the decision on defining the outer boundary of the contamination plume for this approach.

We received some comment asking for additional clarification concerning the two methods proposed for calculating radionuclide concentrations in a contamination plume, and in response we have made some wording changes in the final standards. We proposed that the screened interval for the withdrawal well be centered in the middle of the contamination plume (proposed § 197.36 (b)(1)(ii)). The intent was to take a conservative approach and assume that the well taps the contamination plume where the highest contamination occurs, rather than being positioned such that only a portion of the lower concentration margin of the plume is included in the representative volume—such a situation would allow a high dilution of the contamination from pumping effects. For a physical situation where the contamination plume is very narrow and located at the top of the aquifer, a physically unrealistic situation could occur if the well's screened interval must be centered on the middle of the contamination plume, *i.e.,* the screened interval could extend into the unsaturated zone above the aquifer making calculations of well capture zones unrealistic since a water supply well would not be deliberately screened in that way. To remove this unrealistic physical situation from consideration, we have modified the language describing the location of the screened interval to state that it must include the highest concentration portion of the plume, with the intent being that the screened interval should cross as much of the plume diameter as possible so that the conservative approach is taken to calculating radionuclide concentrations in the ground water (final § 197.31(b)(1)(ii)).

Another clarifying change we have made addresses the ''averaging'' of hydrologic properties (§ 197.31(a)(2)) in the downgradient portions of the ground water flow system for the purpose of making calculations for comparison against the ground water protection standards. In the proposed standards, we used the phrase ''average hydrologic characteristics''. We did not intend to imply that a simple arithmetic averaging process would adequately represent the expected variation in hydrologic properties that results from heterogeneity of the flow system at the site (Chapter 7 and Appendix VI of the BID), or that simple arithmetic averaging would be an allowable approach. We believe that a simple arithmetic averaging approach would mask the expected heterogeneity of the flow system. The values for hydrologic properties of the aquifers along the flow path used in calculations should be conservative but reasonable values, which are representative of the expected heterogeneity in the aquifers. Heterogeneity can be accounted for by using spatial statistical averaging methods that can limit extrapolation of data obtained from field measurements in one locale and which are applied to other locations represented by fewer or poorer quality data. By using such techniques, conservative but reasonable data can be developed that adequately represent the heterogeneity of the aquifers for modeling purposes. We have modified the proposed language to reflect that the ''averaged'' values should be conservative but reasonable representations of the aquifer's hydrologic properties.

a. Is the Storage or Disposal of Radioactive Material in the Yucca Mountain Repository Underground Injection? As we discussed in detail in the preamble to the proposed rule, we do not believe that the disposal of radioactive waste in geologic repositories is underground injection for purposes of the SDWA (42 U.S.C. 300f to 300j–26). We received one comment supporting our position and one comment disagreeing with us. See 64 FR 47004–47007 (August 27, 1999) for our comprehensive discussion of this issue.

b. Does the Class-IV Well Ban Apply? We previously indicated that we would review whether the Class-IV injection-well ban would apply to Yucca Mountain. See 64 FR 47006–47007 for our previous discussion of this issue. This rulemaking does not apply the Class-IV injection-well ban to the Yucca Mountain repository. We believe this approach is appropriate in light of the statutory and regulatory provisions, discussed above and in the preamble to the proposed rule, relating to ''underground injection,'' and the differences in the purposes of the Underground Injection Control (UIC) program and the authority delegated to us under the EnPA to establish public health and safety standards for Yucca Mountain.

It is important to emphasize that our decision not to apply the Class-IV well ban to Yucca Mountain does not affect other disposal systems that dispose of hazardous or radioactive waste into or above a formation which, within one-quarter (1/4) mile of the disposal system, contains a USDW. We based today's rule upon site and facility-specific characteristics of the Yucca Mountain disposal system. Today's rule is limited to the Yucca Mountain disposal system.

c. What Ground Water Does Our Rule Protect? Although we find that the Yucca Mountain disposal system is not underground injection as contemplated by the SDWA, we nevertheless consider the ground water protection principles embodied in the SDWA to be important. Therefore, although we do not apply all aspects of the SDWA, we are establishing separate ground water protection standards consistent with the levels of the radionuclide MCLs under the SDWA.

We requested public comment upon our approaches designed to protect ground water resources in the vicinity of the repository. We are concerned that ground water resources in the vicinity of Yucca Mountain receive adequate protection from radioactive contamination. The primary purpose of our ground water standards is to prevent contamination of drinking-water resources. Because the compliance period is 10,000 years after disposal, references to levels of contamination mean those levels projected to exist at specific future times, unless otherwise noted. However, these projections will be made at the time of licensing. This approach prevents placing the burden upon future generations to decontaminate that water by implementing expensive clean-up or treatment procedures. We believe it is prudent to protect drinking water from contamination through prevention rather than to rely upon clean-up afterwards. Absent the protection this prevention provides, future generations might find it necessary to intrude into the sealed repository to remediate radionuclides released from waste packages inside the repository, in addition to treating contaminated ground water along the ground water flow path. Thus, our ground water protection standards stress pollution prevention and provide protection from contamination of sources of drinking water containing up to 10,000 mg/L of total dissolved solids (TDS). We emphasize that the individual-protection standard (§ 197.20) covers all ground water pathways, including drinking water.

The definition of USDW received extensive discussion in the legislative history of the SDWA as reflected in the report of the House Committee on Interstate and Foreign Commerce. To guide the Agency, the Committee Report suggested inclusion of aquifers with fewer than 10,000 mg/L of TDS (H.R. Rep. No. 1185, 93d Cong., 2d Sess. 32, 1974). We have reviewed the current information regarding the use of aquifers for drinking water which contain high levels of TDS. This review found that ground water containing up to 3,000 mg/L of TDS that is treated is in widespread use in the U.S. In the Yucca Mountain vicinity, with few exceptions (one being the Franklin Playa area), ground water contains less than 1,000 mg/L of TDS. Our review also found that ground water elsewhere in the nation, containing as much as 9,000 mg/L of TDS, currently supplies public water systems. Based upon this review and the legislative history of the SDWA, we are proposing that it is reasonable to protect the aquifers potentially affected by releases from the Yucca Mountain disposal system. Therefore, the provisions in § 197.30 would apply to all aquifers, or their portions, containing less than 10,000 mg/L of TDS. We took the definitions associated with § 197.30 directly from our UIC regulations (40 CFR parts 144 through 146).

One comment suggested that we change the definition of ''aquifer'' in the final rule to exclude perched water bodies. A perched water body is a static area of ground water, usually above the water table, that is unconnected to an aquifer but that may infiltrate into an aquifer over time. Based upon our review of this comment, typical definitions of ''aquifer'' in the technical literature, and the available site-specific information regarding the existence of perched water bodies in the vicinity of Yucca Mountain, we decided to make the suggested change. This comment argued for this change based upon the fact that perched water would be of little value to future residents because few such formations exist in the area and because of abundant water in the aquifer underlying Yucca Mountain. The comment also argued that it would be difficult to make specific predictions regarding the location and characteristics of perched water bodies. Finally, the comment stated it would not be meaningful to attempt to model perched water bodies in any performance assessment. There are only a few, small perched water bodies known to be in the vicinity of Yucca Mountain (see Chapter 7 of the BID). Also, traditional definitions of ''aquifer'' usually do not include perched water bodies (see the Glossary in the BID). Our intent also is to provide protection to water resources of sufficient size to supply water on a continuing basis to targeted uses. Perched water bodies, particularly as they have been observed in the Yucca Mountain area, are relatively small and would not provide a continual source of water to wells used for irrigation or for community water demands. Based upon this information, we believe that it is unnecessary to include these bodies in the definition of ''aquifer'' because it is extremely unlikely that they could serve as a consistent source of drinking water. Therefore, we amended the definition of ''aquifer'' to exclude perched water bodies.

d. How Far Into the Future Must DOE Project Compliance With the Ground Water Standards? We are establishing a 10,000-year compliance period for ground water protection. The primary rationale for establishing a 10,000 year compliance period is that we are significantly concerned about the uncertainty associated with projecting radiation doses over periods longer than 10,000 years. The NAS indicated that beyond 10,000 years it is likely that uncertainty will continue to increase (NAS Report p. 72). As a result, it will become increasingly difficult to discern a difference between the radiation dose from drinking water containing radionuclides (limited by the MCLs) and the total dose arriving through all pathways (limited by the individual-protection standard). Moreover, this approach is consistent with the 10,000-year compliance period we are establishing for the individual-protection standard. Therefore, it provides internal consistency within the standards. It is also consistent with regulations covering long-lived chemically hazardous wastes, which present potential health risks similar to those from radioactive waste, and with the compliance period that we established in our generally applicable radioactive waste disposal standards at 40 CFR part 191.

We requested comment regarding our proposal to impose the ground water protection standards during the first 10,000 years following disposal. Question 14 in the preamble to our proposal specifically asked: ''Is the 10,000-year compliance period for protecting the RMEI and ground water reasonable or should we extend the period to the time of peak dose?'' (64 FR 47010–47011) Comments related to the compliance period applied to both the RMEI and ground water. See the discussion of issues pertaining to both the RMEI and ground water protection in section III.B.1.g (*How Far Into the Future Is It Reasonable to Project Disposal System Performance?*) along with our rationale for adopting a 10,000-year compliance period.

e. How Will DOE Identify Where to Assess Compliance With the Ground Water Standards? To provide a basis for determining projected compliance with the ground water protection standards in § 197.30, it is necessary to establish a geographic location where DOE must project the concentrations of radionuclides in the ground water over the compliance period. This location is the ''point of compliance.''

Our understanding, based upon current knowledge, of the flow of ground water passing under Yucca Mountain is as follows (except where noted otherwise, Chapter 7 and Appendix VI of the BID are the sources for the information in this paragraph). The general direction of ground water movement in the aquifers under Yucca Mountain is south and southeast. The major aquifers along the flow path are in fractured tuff, alluvium, and, underlying both of these, the deeper carbonate rocks. At the edge of the repository, the tuff aquifer is relatively (several hundred meters) thick. The tuff aquifer gets closer to the surface toward its natural discharge points. Potential releases of radionuclides from the engineered barrier system into the surrounding rocks would be highly directional and would reflect the orientation of fractures, rock unit contacts, and ground water flow in the area downgradient from Yucca Mountain. Directly under the repository, we anticipate that any waterborne releases of radionuclides will move through the unsaturated zone and downward into the tuff aquifer, in an easterly direction, between layers of rocks that slant to the east, and downward along generally vertical fractures in the rock units until reaching the saturated zone. The layer of tuff gradually thins proceeding south (downgradient) from Yucca Mountain. As the tuff aquifer thins, the overlying alluvium becomes thicker until the tuff disappears and the water in the aquifer moves into the alluvium to become the ''alluvial aquifer.'' Along the flow path, there might be movement of water between the carbonate aquifer and either the tuff or alluvial aquifers. If there is significant upward flow from the carbonate aquifer, contamination in overlying aquifers could be diluted. It is generally believed, however, that any such flow would not significantly affect the concentration of radionuclides in the overlying aquifers. Conversely, downward movement of ground water from the tuff aquifer could contaminate the carbonate aquifer. Limited information currently available indicates that ground water from the lower carbonate aquifer moves upward into the overlying aquifer; however, this interpretation may not be correct for the entire flow path from beneath the repository to the compliance points southward from Yucca Mountain. Today, most of the water for human use is withdrawn between 20 and 30 km away from the repository footprint (that is, at Lathrop Wells and farther south through the Town of Amargosa Valley) where it is more easily and economically accessed for agricultural use and human consumption. It is likely that the alluvial aquifer is the major source of this water (see Chapter 8 and Appendix V of the BID).

Another basis of our understanding is the historical record of water use in the region. The record indicates that significant, long-term human habitation has not occurred in the southwestern area of NTS, or for that matter anywhere in the vicinity of Yucca Mountain, except where ground water is very easily accessed (for example, in Ash Meadows) (see Chapter 8 of the BID). This observation coincides with current practice whereby the number of wells generally decreases with greater depth to ground water (see Chapter 8 of the BID). The difficulty in accessing ground water in the tuff aquifer in the near vicinity of Yucca Mountain increases because of the rough terrain, the relative degree of fracturing of the tuff formations containing the aquifer, and the great depth to ground water there. As described earlier, the ground water flow from under Yucca Mountain is thought to be generally south and southeast. In those directions, the ground water gets progressively closer to the Earth's surface the farther away it gets from Yucca Mountain until it is thought to discharge to surface areas 30–40 km away (the southwestern boundary of NTS is about 18 km from Yucca Mountain). This means that access to the upper aquifer is easier at increasing distance from Yucca Mountain.

Because of DOE's ongoing site characterization studies, it is possible that, at the time of licensing, data not now available will reveal important inaccuracies in the preceding conception of the ground water flow under, and downgradient from, Yucca Mountain. We intend compliance with the ground water standards to be assessed where DOE and NRC project the highest concentrations of radionuclides in the representative volume of ground water in the accessible environment. The DOE will determine this location by modeling releases into the saturated zone beneath the repository and the subsequent movement of radionuclides downgradient from Yucca Mountain. After selecting a location, however, DOE must continue to evaluate new information regarding ground water flow. If this new information indicates that the highest concentrations would occur at a location in the accessible environment different from the one selected by DOE and NRC, DOE must propose a new compliance location to NRC. The new location is subject to NRC's approval. The next section discusses the concept of accessible environment as it relates to the controlled area.

f. Where Will Compliance With the Ground Water Standards be Assessed? We presented four alternatives for comment prior to determining the location of the point of compliance. See the preamble to the proposed rule (64 FR 47000–47004) for a detailed discussion of these four alternatives. We asked commenters to address the effectiveness of these or other alternatives for protecting ground water, including consideration of site-specific characteristics and reasonable methods of implementing the alternatives.

After reviewing and evaluating the public comments, various precedents, the EnPA, and NAS's recommendations, we adopted the concept of a controlled area as an essential precondition to assessing compliance with the ground water standards. The ground water standards must be met in the accessible environment where the highest radionuclide concentrations in the representative volume of ground water are projected to occur during the compliance period (10,000 years). The highest projected concentrations will be compared to the regulatory limits established in today's rule. The accessible environment includes any location outside the controlled area. The controlled area may extend no more than 5 km in any direction from the repository footprint, except in the direction of ground water flow. In the direction of ground water flow, the controlled area may extend no farther south than latitude 36°40′13.6661″ North, which corresponds to the latitude of the southwest corner of the Nevada Test Site, as it exists today (Department of Energy submittal of Public Land Order 2568, dated December 19, 1961, Docket No. A–95–12, Item V–A–29). The size of the controlled area may not exceed 300 km^2 (see below for further discussion). Such a limitation is derived by combining the concept of the controlled area as used in 40 CFR part 191 and the requirement for a site-specific standard in the case of Yucca Mountain. If fully employed by DOE, and based on current repository design, the controlled area could extend approximately 18 km in the direction of ground water flow (presently believed to be in a southerly direction) and extend no more than 5 km from the repository footprint in any other direction. Allowing for a nominal repository footprint of a few square kilometers, this results in a rectangle with approximate dimensions of 12 km in an east-west direction and 25 km in a north-south direction, or approximately 300 km^2. The DOE may define the size and shape of the controlled area, but the boundaries cannot extend farther south than latitude 36°40′13.6661″ North in the direction of ground water flow and 5 km in any other direction.

The alternatives for the ground water standards' compliance point presented in the proposed rule correspond to downgradient distances of approximately 5, 18, 20, and 30 km from the repository footprint. The first alternative mirrored the approach used in 40 CFR part 191. This approach incorporates the concept of a controlled area, not to exceed 100 km2, and not to extend more than 5 km in any direction from the repository footprint. The second alternative also incorporated the concept of a controlled area, not to extend more than 5 km in any direction from the footprint, except that DOE could include any contiguous area within the boundary of NTS. The last two alternatives described specific points of compliance at distances of about 20 and 30 km, respectively, from the repository footprint. We also intended these controlled areas and points of compliance to be in the predominant direction of ground water movement from the repository. Consequently, they would reflect the transport path for radionuclides released from the repository. We intended the controlled area options to describe that area of land dedicated to the sole use of serving as the natural barrier portion of the disposal system. Compliance with the standards within the controlled area is not an issue in regulatory decision making because this area is considered part of the overall disposal system and is dedicated to limiting radionuclide transport by means of the natural processes operative within it. Rather, compliance will be judged at the location where projected concentrations are highest and that is no closer to the repository than the edge of the controlled area. The controlled area also serves as the basis for institutional control measures intended to limit access around the repository site. This use of the controlled area, to limit access to the site, is an assurance measure we have left to the discretion of NRC as the implementing authority. Our rule does not require any specific institutional controls to be applied to the controlled area. As part of the licensing process, DOE will propose the specific shape and size of the controlled area. The NRC's proposed rule establishing licensing criteria for the Yucca Mountain facility specifically requires that DOE have permanent control of the land. We anticipate that Congress and the President will authorize a legislative withdrawal of an area within which the site is located. The DOE will determine the extent of land that will be requested of Congress to legislatively withdraw from all other public or private use. For its DEIS (Docket No. A–95–12, Item V–A–4), DOE analyzed a potential land withdrawal area of 600 km2 in the context of site characterization needs. The legislative land withdrawal represents the societal decision on the area of land to be dedicated to the characterization and operation of a disposal system. Although the land withdrawal may exceed 300 km^2, we limit the controlled area to 300 km^2 for the purpose of defining the maximum geological volume which may be included in the disposal system.

We adopted the concept of a controlled area from the generic standards in 40 CFR part 191. Those standards state that the maximum size of the controlled area is 100 km^2 (40 CFR 191.12). After examining the available information concerning the characteristics of the Yucca Mountain site, the current understanding of the expected performance of the disposal system and the repository engineered barrier system design, and comments received on our proposed approach to ground water protection, we believe that a controlled area of up to 300 km² will adequately address the site-specific conditions at Yucca Mountain.

It would be unreasonable for us to limit DOE's flexibility while site characterization and disposal system design are continuing, or to issue standards that do not account for the uncertainties of ground water flow in the region. Therefore, today's rule provides that the size of the controlled area may be up to 300 km².

In reaching this decision regarding the maximum size of the controlled area, we must draw a contrast between the approach used in 40 CFR part 191 and today's rule. As mentioned earlier, although the WIPP LWA exempted the Yucca Mountain site from licensing under the provisions of 40 CFR part 191, the radiation protection principles in 40 CFR part 191 are still applicable, and we examined them while developing site-specific standards for Yucca Mountain. Throughout this preamble, we note where and why we have carried some of the concepts forward from 40 CFR part 191 if we believe they are necessary for protective standards at Yucca Mountain, and how we have applied them in ways consistent with the site-specific information and understanding of the Yucca Mountain site. Part 191 established a controlled area with a maximum distance in any direction of 5 km from the repository footprint to provide a location for judging compliance with the individual-protection (§ 191.15), ground water protection (§ 191.24), and containment requirements (§ 191.13). Thus, the controlled-area concept in 40 CFR part 191 links a 5 km maximum distance from the repository footprint to a limit on the size of the controlled area (100 km² maximum). Within this area, compliance with the standards is not required because the geologic media therein comprise an essential part of the disposal system. This combination of controlled area and protection of individuals and ground water is appropriate for generic standards because generic standards' provisions must account for the wide variety of possible site conditions (e.g., releases could move in many directions from the repository toward the population), engineered alternatives, and population characteristics. Note that in the 1980s, when 40 CFR part 191 was being developed, DOE was considering nine candidate HLW repository sites. It is also important to recognize that 40 CFR part 191 contained a mechanism for substituting alternative provisions, should they be deemed necessary.

By contrast, 40 CFR part 197 is site-specific. The 1987 NWPA amendments specified Yucca Mountain as the only potential repository site where DOE may conduct characterization activities. Therefore, since passage of the 1987 amendments, the Yucca Mountain site has been under an intense characterization effort. Because of these efforts, a significant amount of information has been generated regarding past, present, and planned population patterns, land use, engineered design, and the hydrogeological characteristics of the host rock and ground water systems at the Yucca Mountain site. Based upon information currently available, it appears that contaminated ground water will flow predominantly in a relatively narrow path from the Yucca Mountain repository. See the Yucca Mountain DEIS, Chapter 3 (DOE/EIS–0250 D, July 1999, Docket No. A–95–12, Item V–A–4, and the Viability Assessment, Docket No. A–95–12, Item V–A–5). In addition to the extensive data base compiled over the years, we have the recommendations of NAS. Significantly, NAS endorsed the use of present knowledge using ''cautious, but reasonable'' assumptions in defining exposure scenarios (NAS Report p. 100).

Concerning the size of the controlled area, though we have a general understanding of the primary direction of ground water flow, our present knowledge continues to evolve through site characterization. As a result, we believe the ''cautious, but reasonable'' approach allows DOE the flexibility to utilize a controlled area up to a maximum of 300 km². Given the uncertainty in ground water flow paths, and the fact that releases could occur anywhere within the repository, we believe it is prudent to ensure that any potential contamination plumes from repository releases are contained within the controlled area, and to ensure that access to and human activity within the area of potential contamination is limited, thereby minimizing the potential for human exposure. We recognize that 300 km² represents an increase in the maximum size of the controlled area, and is larger than we allow in 40 CFR part 191. However, for site-specific reasons, we are increasing the maximum extent of the controlled area only in the direction of ground water flow to no farther south than latitude 36° 40′ 13.6661″ North, while simultaneously limiting the extent of the controlled area in any other direction to no greater than 5 km from the repository footprint.

The size and shape of the controlled area proposed by DOE in the licensing process will depend upon two fundamental elements: (1) The dimensions of the repository layout for the waste inventory and thermal loading, as defined in the final repository design; and (2) uncertainty in ground water flow directions. Both of these aspects are evolving since studies for both site characterization and repository design are still in progress. However, DOE provides some indication in its DEIS of the range of repository-design layouts under various assumed waste inventories and thermal loading alternatives. Combining these repository alternatives in the DEIS, with projected ground water flow paths to the southern most extension of the controlled area at latitude 36° 40′ 13.6661″ North, gives potential controlled area sizes from 100 km² or less to around 300 km². These estimates are based upon the uncertainties in ground water flow directions and repository designs that currently exist. When characterization and design studies are completed, a well-defined controlled area size can be determined during the licensing process, where the uncertainties will be examined in closer detail and a final controlled area size can be determined. However, uncertainties can only be reduced, not eliminated completely, even when site characterization is completed—some residual uncertainty will remain. As stated earlier, we believe it is important to allow flexibility for DOE and NRC at this time to continue the characterization and design work, and allow the licensing process to operate within certain bounds while knowledge of the site is evolving.

In addition to ground water flow path uncertainties, the size and shape of the controlled area also depend upon understanding how and where (in relation to the repository layout) radionuclides could be introduced into the ground water. Failed waste packages during the regulatory time-frame supply the releases carried into the ground water system. While DOE has adopted a new highly engineered waste package anticipated to have containment lifetimes into the tens of thousands of years (TRW Environmental Safety Systems Inc., ''Repository Safety Strategy: Plan to Prepare the Postclosure Safety Case to Support Yucca Mountain Site Recommendation and Licensing Considerations'', TDR–WIS–RL–000001, January 2000, Docket No. A–95–12, Item V–A–24), some small number of waste packages can be anticipated to fail within the regulatory period due to undetected manufacturing defects. While these failures can be minimized through rigorous quality control efforts during manufacturing, the potential cannot be totally eliminated. The location of such ''premature failures'' in the repository is, however, unpredictable. Other unpredictable disruptive events and processes, such as roof falls that damage waste packages and accelerate corrosion processes, could also result in releases in advance of the anticipated containment lifetime of the containers under expected conditions. The location of these types of waste package failures is also not amenable to reliable prediction. Therefore, releases from such failures could originate anywhere within the repository footprint and would consequently enter the ground water flow envelope at any location. Recognizing this, the process of defining the controlled area would focus upon the two factors discussed above, the repository footprint, which will reflect the waste inventory and the repository design choices, and the envelope of potential ground water flow paths around that footprint. ''Cautious, but reasonable'' assumptions regarding these factors can then be applied to define a controlled area that will include potential releases from a small number of premature waste package failures. A more detailed discussion of the influence of these factors on the potential size of the controlled area may be found in ''Considerations for Defining a Site-Specific Controlled Area for the Yucca Mountain Proposed Repository Location'' (Docket No. A–95–12, Item V–B–7).

Regarding the alternatives we proposed for the ground water point of compliance, none of the information we have reviewed suggests that it is likely or reasonable to assume that year-round residents will live within 5 km of the repository footprint. As discussed in Chapter 8 and Appendix IV of the BID, it would be extremely difficult to farm that close to Yucca Mountain, partly because extracting ground water at that location would be both technically challenging and very expensive for an individual or small group. In addition, much of this area has rough terrain and soils not conducive to farming. Our understanding of projections of future land use does not indicate significant population growth much farther north of Lathrop Wells, *i.e.*, closer than about 18 km from the repository footprint (see Appendix I of the BID, Docket No. A–95–12, Items V–A–14, 15, 16). Given the small likelihood of a year-round resident at 5 km, we chose not to select a distance of 5 km as the limiting distance from the repository footprint to the controlled area boundary.

As one goes farther away from Yucca Mountain in the direction of ground water flow, it is easier to drill for ground water because the water table is closer to the ground surface and the geologic medium changes from tuff to alluvium. In addition, the soil characteristics improve such that agricultural pursuits become more feasible, as evidenced by the widespread agricultural activity in Amargosa Valley some 30 km from Yucca Mountain. There are approximately 10 residents at about 20 km (Lathrop Wells) and hundreds of residents at a distance of 30 km. Current projections of population growth indicate southern Nevada as one of the fastest growing areas in the country (see the Yucca Mountain DEIS, Chapter 3 (DOE/EIS–0250D, July 1999, Docket No. A–95–12, Item V–A–4), and reports prepared for Nye County and Amargosa Valley (Docket No. A–95–12, Items V–A–14, V–A–15, and V–A–16)). We selected latitude 36° 40′ 13.6661″ North, which corresponds to the southwest corner of NTS as it exists today (Docket No. A–95–12, Item V–A–29), as the maximum distance that the controlled area may extend in the direction of ground water flow (south). Given the expected population growth in southern Nevada, it is reasonable to project that some population growth may occur slightly north of Lathrop Wells, although the boundaries of NTS are likely to remain and restrict population expansion in this direction, at least for the near future. As indicated previously, the representative volume of ground water used to demonstrate compliance would reflect a small community including alfalfa cultivation and some residential and light industrial development. At distances progressively closer than 18 km to the repository, it becomes more difficult to drill for water, soil conditions become less favorable for agriculture, and more land is subject to restricted access by the Federal government. We believe, based upon the site-specific information now available, and using cautious, but reasonable assumptions, the southwest corner of NTS, or an equivalent distance in the direction of ground water flow, would be the closest location for a small group to be accessing ground water.

Several comments suggested that we should locate the point of compliance for ground water protection purposes at the boundary of the Yucca Mountain repository footprint. As discussed above, 40 CFR part 191 established the concept that a certain amount of geology surrounding a repository is part of the overall disposal system. The controlled-area concept limited considerations of radiation dose to individuals or contamination of ground water to areas outside of this controlled area. The controlled area in 40 CFR part 191 applies at a distance from the repository, to be determined by the implementing agency, but not to exceed 5 km from the footprint. We continue to support the concept of a compliance point at some distance beyond the repository footprint. In the case of Yucca Mountain, most of the land within the repository footprint is rugged terrain, with extreme depths to ground water, and land unsuitable for agricultural pursuits (see Chapter 8 of the BID). Therefore, we did not choose a compliance point at the edge of the Yucca Mountain repository footprint.

A number of comments suggested we locate the point of compliance, or limit the distance to the boundary of the controlled area, at distances ranging from 5 km to 30 km from the repository footprint. As we indicated previously, we adopted NAS's recommendations to use present knowledge and cautious, but reasonable, assumptions in making regulatory decisions. For the reasons discussed earlier, we did not choose to base compliance with the standards upon a uniform 5 km distance from the repository. Other comments supported placing the compliance point at 30 km, citing the volume of water currently withdrawn at that distance. Indeed, most of the agricultural activities in the vicinity of Yucca Mountain currently take place in this area, and it is home to hundreds of residents. This situation occurs because of the easy accessibility of ground water and soil conditions conducive to a variety of agricultural activities. However, a distance of 30 km would effectively ignore the existence of populations who presently access ground water closer to the repository. Given the prospect of future population growth as well, at distances of about 20 to 30 km from the repository footprint, it would appear more reasonable to protect ground water resources at distances closer than 30 km. Therefore, we did not choose the ''30 km'' alternative as the compliance point.

Distances approximating 20 km appear more reasonable to consider to assess compliance with the ground water standards. As described in Chapter 8 of the BID, no farming currently occurs closer than about 23 km from the repository footprint. Also, as one gets closer than about 18 km to the repository footprint, the depth to water begins to increase dramatically from about 100 m at a distance of 20 km to a few hundred meters at a distance of

5 km. Given the expectation of future population growth and the precious nature of ground water resources in the area, it is reasonable to assume that a small group may annually extract the representative volume of ground water at a distance slightly closer than 20 km, namely, latitude 36° 40′ 13.6661″ North, which corresponds to the southwest corner of NTS as it exists today (Docket No. A–95–12, Item V–A–29). This approach is protective of the ground water resources reasonably anticipated to be accessed in the vicinity of Yucca Mountain. To determine compliance with the ground water standards, DOE must define the controlled area and calculate the concentrations of radionuclides in the representative volume of ground water at a location outside the controlled area where the concentrations are the highest. The controlled area may encompass no more than 300 km^2 and may extend no farther south, in the direction of ground water flow, than latitude 36° 40′ 13.6661″ North, which corresponds to the southwest corner of NTS (Docket No. A–95–12, Item V–A–29). In any other direction, the controlled area may extend no more than 5 km from the repository footprint. We emphasize that these dimensions describe the maximum size of the controlled area. In defining the actual dimensions of the controlled area, DOE may extend the southern boundary of the controlled area as far as latitude 36° 40′ 13.6661″ North, which corresponds to the southwest corner of the NTS (Docket No. A–95–12, Item V–A–29). The DOE could place the boundary of the controlled area anywhere along that distance. Therefore, when we say we did not base compliance with the standard upon a distance of 5 km from the repository footprint, we mean that we neither selected the alternative that would have set the maximum dimension of the controlled area as 5 km in any direction, nor did we identify a specific point of compliance at that distance. The DOE is free to define the controlled area such that it extends only 5 km, or less than 5 km, in any direction (*i.e.*, DOE is not required to extend the controlled area as far as latitude 36° 40′ 13.6661″ North in the direction of ground water flow, or as far as 5 km from the repository footprint in any other direction), and to assess compliance at the location outside the controlled area where concentrations are highest. In the context of waste disposal, the ground water protection standards do not apply inside the controlled area, consistent with the approach in 40 CFR part 191.

IV. Responses to Specific Questions for Public Comment

In addition to requesting comments regarding all aspects of this rulemaking, many of which we have highlighted in the preceding sections of this document, we also requested comment based upon sixteen specific questions. These specific questions appear below, along with brief summaries of the comments we received and our responses to those comments. As with each of the comments discussed elsewhere in this document, we present detailed and comprehensive responses in the accompanying Response to Comments document.

1. The NAS Recommended That We Base The Individual-protection Standard Upon Risk. Consistent With This Recommendation and the Statutory Language of the EnPA, We are Proposing a Standard in Terms of Annual CEDE Incurred by Individuals. Is Our Rationale for This Aspect of Our Proposal Reasonable?

Comments/Our Responses. Many of the comments we received on this issue supported the promulgation of a standard stated in terms of dose. Moreover, section 801(a)(1) of the EnPA specifically provides that EPA shall ''promulgate, by rule, public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site. Such standards shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases from radioactive materials stored or disposed of in the repository.'' Consistent with the specific statutory language of the EnPA, and the numerous comments supporting the use of a standard stated in terms of dose, we choose to use dose as the form of the individual-protection standard. See section III.B.1.a above for a discussion of our rationales for making this choice. As discussed to some extent in section III.B.1.c, and in more detail in the preamble to the proposed standards (beginning on 64 FR 46984), the primary basis of the dose limit, 150 microsieverts (15 mrem), is the risk of fatal cancer. This level equates to an annual risk of about 8.5 in one million of developing a fatal cancer. This level is within the risk range recommended by NAS. Thus, the 15 mrem CEDE standard is consistent with NAS's recommendation.

2. We Are Proposing an Annual Limit of 150 μSv (15 mrem) CEDE To Protect the RMEI and the General Public From Releases From Waste Disposed of in the Yucca Mountain Disposal System. Is Our Proposed Standard Reasonable To Protect Both Individuals and the General Public?

Comments/Our Responses. As noted in section III.B.1.c above, we are establishing an individual-protection standard for Yucca Mountain that limits the annual radiation dose incurred by the RMEI to 150 μSv (15 mrem) CEDE. See section III.B.1.c for a discussion of the comments regarding the appropriateness of the level of protection. We chose not to adopt a separate limit on radiation releases for the purpose of protecting the general population. There is a full description of our reasoning in section III.B.1.e, above. However, in summary, we based this decision upon several factors. The first factor is NAS's estimate of extremely small doses to be received by individuals resulting from air releases from the Yucca Mountain disposal system. The projected level of these doses is well below the risk level corresponding to our individual-protection standard for Yucca Mountain. It also is well below the level that we have regulated in the past through other regulations. We also declined to establish a negligible incremental dose (NID) level below which doses would not have to be calculated. The second factor is that, based upon current, site-specific conditions near Yucca Mountain, it is unlikely that there will be great dilution and wide dispersal of radionuclides transported in ground water leading to exposure of a large population. This means that the individual-dose standard will suffice to protect the general population. There should be no confusion between establishment of this standard and our establishment of ground water protection standards intended to protect that water for future use. The final factor is that we require all of the pathways, including air and ground water, to be analyzed by DOE and considered by NRC under the individual-protection standard.

Regarding the concepts of negligible incremental dose or risk, though we have recognized elsewhere in this preamble that individual doses from ^{14}C are below the level at which the Agency has historically regulated individual doses, we have declined to establish an NID or NIR level for the reasons enumerated in section III.B.1.e in this preamble. As described by NCRP, the concepts of NID and NIR relate to individual-dose assessments, not collective dose assessments (Docket A–95–12, Item II–A–8). Therefore, we are not prepared to accept the NIR concept as discussed by NAS.

We also disagree with NAS when it states on page 120 of its report: ''On a collective basis, the risks to future local populations are unknowable.'' There is no question that there will be uncertainty in the estimate; however, even without our recommendation, DOE has already published projected collective doses for Yucca Mountain (see Table 4–34 on p. 4–39 of the Yucca Mountain DEIS, Docket No. A–95–12, Item V–A–4), and is likely to refine these estimates. These estimates could fulfill the NCRP recommendation to use collective dose in a non-regulatory fashion to assess acceptability of a facility (Docket No. A–95–12, Item II–A–8).

Most comments on this issue supported not establishing a collective-dose limit for Yucca Mountain. Two other comments supported our decision to not establish an NIR or NID level. One comment went further by opposing our suggestion that DOE use estimated collective dose to examine design alternatives on the grounds that such action is unnecessary to protect the general public. That comment also stated that we have not provided guidance on what to do with the collective dose estimates and that we are making policy judgments with respect to collective dose estimation. Upon consideration of those comments, we are not recommending that DOE estimate collective dose, primarily because we believe that the individual-protection standard will adequately protect the general population.

3. To Define Who Should Be Protected by the Proposed Individual-protection Standard, We Are Proposing To Use an RMEI as the Representative of the Rural-residential CG. Is Our Approach Reasonable? Would it be More Useful to Have DOE Calculate the Average Dose Occurring Within the Rural-residential CG Rather Than the RMEI Dose?

Comments/Our Responses. We decided that the RMEI in the individual-protection scenario will have a rural-residential lifestyle. A number of comments supported the use of the CG approach. One commenter suggested specifically that it preferred a rural-residential CG to the rural-residential RMEI because it is possible to estimate exposures with much greater confidence. However, in general, we decided to use the rural-residential RMEI rather than a rural-residential CG for the same reasons that we selected RMEI instead of the CG (see section III.B.1.d above, and Docket No. A–95–12, Item V–B–3).

In summary, those reasons are that the RMEI approach:

(1) Is consistent with widespread practice, current and historical, of estimating dose and risk incurred by individuals even when it is impossible to specify or calculate accurately the exposure habits of future members of the population (as in this case where it is necessary to project doses for very long periods);

(2) Is sufficiently conservative and fully protective of the general population;

(3) Provides protection similar to the probabilistic CG approach recommended by NAS for small groups—it has the same goal and purpose as does NAS's recommended probabilistic CG approach, *i.e.*, to protect the vast majority of the public while ensuring that the acceptability of the repository is not driven by unreasonable and extreme cases. It accomplishes this by employing some maximum parameter values and some average parameter values (similar to the NAS's concept of using ''cautious, but reasonable'' assumptions) for the factors most important to estimating the dose to arrive at a conservative, but reasonable, projection of future dose;

(4) Allows the desired degree of conservatism to be built but within the site-specific limits and the framework which we have established.

(5) Is straightforward and relatively simple to understand, and is more appropriate than the probabilistic CG for the situation at Yucca Mountain. It is less speculative to implement than is the probabilistic CG approach given the unique conditions present at Yucca Mountain (and is a cautious, but reasonable, approach). For example, given the known characteristics of ground water flow at Yucca Mountain, locating the receptor in the direct path is more protective, and easier to implement, than assessing an average dose incurred by a randomly-located group of receptors; and,

(6) Has been used by us in the past (whereas we have not used the CG concept).

A number of other comments suggested other groups or individuals that would represent more appropriately the individual to be protected by the individual-protection standard. The suggestions included a fetus, the elderly and infirm, and subsistence farmers. Regarding the various ages and stages of development, the risk value used for the development of cancer is an overall average risk value (see Chapter 6 of the BID for more details) that includes all exposure pathways, both genders, all ages, and most radionuclides. However, it does not cover the ''unborn within the womb'' (see Chapter 6 of the BID). It is thought that the risk per unit dose for prenatal exposures is similar to the average risk per unit dose for postnatal exposures; however, the exposure period is very short compared to the rest of the individual's average lifetime. (See Chapter 6 of the BID for a discussion of cancer risk from *in utero* exposure). Therefore, the risk is proportionately lower and would not have a significant impact upon the overall risk incurred by an individual over a lifetime (see Chapter 6 of the BID). On the other end of the age spectrum, radiation exposure of the elderly at the levels of the individual-protection standard would be less than the overall risk value because they have fewer years to live and, therefore, fewer years for a fatal cancer to develop (see Chapter 6 of the BID). Finally, we did not use subsistence farmers because we do not believe that they are representative of the current lifestyle in Amargosa Valley and that, therefore, they would not constitute a cautious, but reasonable, assumption in relation to the guidance from NAS to use current technology and lifestyle.

4. Is it Reasonable To Use RMEI Parameter Values Based Upon Characteristics of the Population Currently Located in Proximity to Yucca Mountain? Should We Promulgate Specific Parameter Values in Addition To Specifying the Exposure Scenarios?

Comments/Our Responses. The basis of the RMEI dose calculations will be the current population downgradient from Yucca Mountain. This approach is consistent with NAS's recommendation to use current lifestyles to avoid the endless speculation that could result from trying to project future human activities. See section III.B.1.d above for a discussion of this issue. Most commenters supported this approach. However, a number of commenters preferred using a subsistence-farmer lifestyle. We have been unable to identify this lifestyle in the area around the Yucca Mountain site. Also, a few commenters stated that we should take future changes in population, land use, climate, and biota into consideration. Again, with the exception of climate and geologic processes, these factors are subject to the potentially endless speculation of which NAS spoke in its report. We do require DOE and NRC to take climate change and probable variations in geologic conditions into account because they are factors that scientific study can reasonably bound.

5. Is it Reasonable To Consider, Select, and Hold Constant Today's Known and Assumed Attributes of the Biosphere for Use In Projecting Radiation-related Effects Upon the Public of Releases From the Yucca Mountain Disposal System?

Comments/Our Responses. The comments we received on this question generally favored our position of holding present biosphere conditions constant for the purpose of making performance projections for the disposal system. Some comments pointed to the unexpected dynamic population growth in the southern Nevada area, or stated that current conditions were not a reliable means to predict future conditions. Some comments also pointed out that the target receptor for dose assessments could not be defined independently of assumptions about the biosphere. The tenor of these comments is a general agreement that unreasonably speculative assumptions about biosphere conditions are inappropriate and should be avoided. We agree with this general theme of not making unreasonably speculative assumptions about the future. The NAS also made this point in its recommendations for a reference biosphere. We made some fundamental assumptions in this rule about biosphere conditions to assure that dose assessments for the RMEI are cautious, but reasonable. For example, we require that DOE assume that the RMEI consumes 2 liters/day of drinking water and that DOE base food consumption patterns on surveys of the current residents in the area downgradient from Yucca Mountain. We have left it to NRC to establish other details of the biosphere dose assessment calculations for Yucca Mountain, such as details of pathway-specific dose conversion factors and details necessary for assessing all potential exposure pathways. For additional discussion of these issues, see section III.B.1.f above.

A related aspect of fixing biosphere conditions for dose assessments is the question of potential variations in climate and geologic conditions because these factors play an important part in developing the ground water contaminant concentrations that serve as input for the biosphere dose assessments. We specify that DOE should vary climate and geologic conditions over a reasonable range of values based on an examination of evidence in the geologic record for conditions in the area. The evidence preserved in the relatively recent geologic record provides a means to reasonably bound the range of possible conditions.

6. In Determining the Location of the RMEI, We Considered Three Geographic Subareas and Their Associated Characteristics. Are There Other Reasonable Methods or Factors Which We Could Use to Change the Conclusion We Reached Regarding the Location of the RMEI? For Example, Should We Require an Assumption That for Thousands of Years Into the Future People Will Live Only in the Same Locations That People do Today? Please Include Your Rationale for Your Suggestions

Comments/Our Responses. See section III.B.1.d above for a further discussion of this subject. The many comments we received on this topic suggested a variety of locations, some closer and some farther than Lathrop Wells. A few commenters thought that the Lathrop Wells location is appropriate. However, a number of others stated that the location should be at the repository footprint. One commenter stated that the current farming area in southern Amargosa Valley would be a reasonable location for the RMEI.

Based on further review of site-specific information, we decided to locate the RMEI in the accessible environment above the highest concentration of radionuclides in the plume of contamination. The accessible environment begins at the edge of the controlled area, which may extend no farther south than the southern boundary of NTS (latitude 36° 40′ 13.6661'' North), which is approximately 18 km south of the repository (roughly 2 km closer than the Lathrop Wells location we proposed). We do not believe that an RMEI likely would live much closer to the Yucca Mountain repository because of the increasing depth to ground water and the increasing roughness of the terrain (see Chapter 8 of the BID), although the RMEI would still have rural-residential characteristics described in § 197.21 if the controlled area does not extend as far south as the NTS boundary. In addition, we believe that, at 18 km, a rural resident likely will receive the highest potential doses in the region because, as we have defined the RMEI, the potential dose at this location will be from drinking water, as well as through ingestion of food grown with contaminated ground water. With the RMEI eating food grown using contaminated water, the rural resident at 18 km will have a higher dose than an individual would have living much closer than 18 km because the cost of water likely would preclude a garden and likely would allow only drinking the water and domestic uses (see Chapter 8 of the BID). Likewise, we do not think that hypothesizing that the RMEI lives 30 km away is a cautious or reasonable assumption because: (1) At 30 km, the RMEI likely would use water in which contaminants would be much more diluted; (2) the downgradient residents closest to Yucca Mountain are currently near Lathrop Wells; and (3) Nye County projects short-term (20 years) growth between U.S. Route 95 and the southern boundary of NTS; therefore, population there is not an ephemeral phenomenon. Therefore, placing the RMEI at about 18 km from the repository footprint reflects the location of existing residents, is reasonably conservative, and provides more protection of public health, relative to one commenter's suggested location of 30 km.

There were a few other comments related to the location of the RMEI. For example, one comment suggested that, in selecting the location, we should consider the geology and hydrology of the site rather than choosing the location in advance. Another comment stated that we should base the location of the RMEI on the ability of the RMEI to sustain itself consistent with topography and soil conditions. This comment also stated that depth to ground water should not be a factor because it is impossible to predict either human activities or economic imperatives.

We determined the point of compliance for the individual-protection standard using site-specific factors and NAS's recommendation to use current conditions (NAS Report p. 54). In preparing to propose a location for the RMEI, we collected and evaluated information on the natural geologic and hydrologic features such as topography, geologic structure, aquifer depth, aquifer quality, and the quantity of ground water, that may preclude drilling for water at a specific location (see Chapters 7 and 8, and Appendices IV and VI, of the BID). We also considered geologic conditions, for example, we do not believe that a rural-residential individual would occupy areas much closer to Yucca Mountain because of the increasing rough terrain and the increasing depth to ground water (see Chapter 8 of the BID). With increasing depth to ground water come higher costs: (1) To explore for water; (2) to drill for water; and (3) to pump the water to the surface (see Appendix IV of the BID). Our final standard requires DOE and NRC to consider other, more appropriate locations based upon potential, future site characterization data. We agree that it is impossible to predict either human activities or economic imperatives. Therefore, we followed NAS's recommendation to use current conditions. This approach allows us to avoid forcing the use of potentially excessive speculative assumptions as the bases of regulatory decisionmaking. It also leads us to consider the depth to ground water as a key factor in determining the location and activities of the RMEI and the current location of people living downgradient from the repository as a reflection of this key factor. We note that some wells providing drinking water are located less than 18 km from the repository footprint; however, those wells have been installed by the Federal government to serve the needs of NTS, and we do not consider them typical of wells that would serve, or be installed by, a rural-residential RMEI. See Chapter 8 (Table 8–5) of the BID.

Finally, one comment stated that the proposed RMEI concept forces DOE to assume the RMEI will withdraw water from the highest concentration within the plume without consideration of the likelihood. According to this comment, forcing such an assumption neglects the low probability that a well will intersect the highest concentration within the plume.

This comment's approach, which would utilize a probabilistic method to determine the radionuclide concentration withdrawn by the RMEI, is similar to one of the example critical group approaches that NAS provided in its report (NAS Report, Appendix C). The NAS's approach would use statistical sampling of various parameters, i.e., considering the likelihood (probability) of various conditions existing, to arrive at a dose for comparison to the standard. However, we did not use this CG approach for the following reasons: (1) There is no relevant experience in applying the probabilistic CG approach, (2) the probabilistic CG approach is very complex and is difficult to implement in a manner that assures it would meet the requirements of defining a CG (i.e., a small group of people who are homogeneous in regards to exposure characteristics, including receiving the highest doses among the general population), and (3) we are concerned that this approach does not appear to identify clearly which individual characteristics describe who is being protected. A probabilistic approach for CG dose assessment could include members that would receive little or no exposure and members that would receive much higher exposures. An RMEI is a more conservative approach, based upon site-specific conditions, because the RMEI serves to represent those individuals in the community who would receive the highest doses, based on cautious, but reasonable, assumptions. Finally, a significant majority of the comments on the NAS Report opposed the use of the probabilistic CG approach. We further believe that prudent public health policy requires that our approach be followed to provide reasonable conservatism. To allow the probability of any particular location being contaminated is not a prudent approach to the ultimate goal of testing acceptable performance.

7. The NAS Suggested Using an NIR Level to Dismiss From Consideration Extremely Low, Incremental Levels of Dose to Individuals When Considering Protection of the General Public. For Somewhat Different Reasons, We are Proposing To Rely Upon the Individual-Protection Standard To Address Protection of the General Population. Is This Approach Reasonable in the Case of Yucca Mountain? If Not, What is an Alternative, Implementable Method To Address Collective Dose and the Protection of the General Population?

Comments/Our Responses. A number of commenters agreed with us that the general population is protected by the individual-protection standard in the site-specific case of Yucca Mountain. Nearly all commenters agreed with our position that a collective-dose limit is unnecessary, again, in the site-specific case of Yucca Mountain. Some commenters stated that EPA should not use an NIR level. One commenter stated that we should not suggest that DOE use a collective-dose estimate in the consideration of design alternatives. We decided not to include a collective-dose limit (see section III.B.1.e), and are not recommending that DOE estimate collective doses.

Regarding the NIR, we decline to set such a level. We agree with NAS's conclusion that '' * * * an individual risk standard [will] protect the public health, given the particular characteristics of the site * * *'' (NAS Report p. 7). However, we do not accept the remainder of that statement: '' * * * provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk'' (NAS Report p. 7). We do not agree that collective doses made up of very small individual doses are necessarily negligible. We base our decision on the site-specific characteristics of Yucca Mountain and the levels of individual risk that we previously have used. See the preamble to the proposed rule (64 FR 46991) for the full discussion of our reasoning. We summarize this discussion immediately below.

The NAS based its recommendations upon guidance from NCRP in which NCRP proposed a ''Negligible Incremental Dose'' level of 1 mrem/yr. Dose levels below 1 mrem/yr would be considered ''negligible'' for any source or practice (see the NAS Report pp. 59–61 and NCRP Report No. 116, p. 52, Docket No. A–95–12, Item II–A–7). The IAEA has made similar recommendations to define an ''exempt practice'' (see IAEA Safety Series No. 89, p. 10, Docket No. A–95–12, Item II–A–6). However, it is not clear to us that an exemption for whole sources or practices, such as waste disposal in general, should apply to such specific situations such as gaseous releases from a particular repository because gaseous releases comprise only one category of releases from a repository; other releases are projected via the ground water pathway. In addition, we believe that it is inappropriate to avoid calculating a radiation dose merely because it is small on an individual basis (NCRP Report No. 121, p. 62, Docket No. A–95–12, Item II–A–8). Finally, we do not believe that it is appropriate to apply the NIR concept to population doses (NCRP Report No. 121, p. 62, Docket A–95–12, Item II–A–8). In its Report No. 121, NCRP stated: ''[a] concept such as the NID (Negligible Incremental Dose) * * * is not necessarily a legitimate cut-off dose level for the calculation of collective dose. Collective dose addresses societal risk while the NID and related concepts address individual risk'' (NCRP Report No. 121, p. 62, Docket No. A–95–12, Item II–A–8).

Despite our belief that it is inappropriate to set an NID level, we acknowledge that the extremely low levels of individual risk from the doses that NAS cited (NAS Report p. 59) (i.e., 0.0003 millirem/yr, for airborne releases) are well below those levels that we have used for other regulations.

In addition, the standards in 40 CFR part 191 provide both release limits, which act as a form of collective dose protection, and individual-protection limits. The release limits act to restrict the potential of dilution being used by disposal system designers to meet the individual-protection limit. However, the potential for large-scale dispersal of radionuclides through ground water and into surface water does not exist at Yucca Mountain.

Therefore, for the reasons enumerated above, we believe that we do not need to include a general population-protection provision in our Yucca Mountain standards. See the Response to Comments document for a fuller discussion of our responses to comments we received on these issues.

8. Is Our Rationale for the Period of Compliance Reasonable in Light of the NAS Recommendations?

Comments/Our Responses. Public comments supported a compliance period that ranged from 10,000 years to a million years and beyond (i.e., no time limitation). Most of the comments supporting the 10,000-year period were concerned that such a period was the longest time over which it would be possible to obtain meaningful modeling results. Comments noted that just because performance assessment models may be set to run dose calculations to times well in excess of 10,000 years does not necessarily mean that at this time the level of confidence in the reliability of these calculations remains the same. Other comments noted that because of the unprecedented nature of compliance periods exceeding 10,000 years, the greater uncertainties at such times only serves to complicate the licensing process without providing a clearly identifiable increased benefit to public health. A few commenters suggested that because there will likely be radiation doses incurred by individuals beyond 10,000 years, DOE should calculate peak dose, within the time period of geologic stability, and include these doses in the Yucca Mountain Environmental Impact Statement. These comments essentially supported the rationale upon which we based our final rule.

On the other hand, numerous comments suggested that a compliance period of 10,000 years is not reasonable. They urged us to extend the compliance period beyond 10,000 years for a variety of reasons. Foremost among these reasons is that NAS suggested a compliance period that would extend to the time of peak dose or risk, within the period of geologic stability for Yucca Mountain, which it estimated could be as long as one million years. The NAS based its recommendations on scientific considerations. The NAS concluded that it is possible to assess the performance of the repository over times during which the geologic system is ''relatively stable'' or varies in a ''boundable manner'' (NAS Report p. 9). It also noted that policy considerations could act to shorten this period. Other comments suggested that the compliance period of the standard should be comparable to the hazardous lifetime of the materials to be emplaced in the Yucca Mountain repository.

It is unclear whether an assessment of the disposal system based on NAS's recommendation for a standard that would apply to time of peak dose within the period of geologic stability (about one million years) would be meaningful given the expected rigor of a licensing process. As discussed above in section III.B.1.g, we believe that the substantial uncertainty in projecting human radiation exposures over extremely long time periods, such as a million years, is unacceptable. For example, analyzing long-term natural changes would require unprecedented performance assessment modeling of numerous and different climate regimes including several glacial-interglacial cycles. This situation could require the specification of exposure scenarios based on arbitrary assumptions rather than ''cautious, but reasonable'' assumptions rooted in present-day knowledge. In fact, NAS indicated it knew of no scientific basis for identifying such scenarios (NAS Report p. 96). Another concern relates to the possible biosphere conditions and human behavior. Even for a period as ''short'' as 10,000 years, it is necessary to make certain assumptions. For periods on the order of one million years, even natural human evolutionary changes become a consideration. Regulating to such long time periods could become arbitrary. Moreover, NAS based its time-frame recommendation on scientific considerations; however, it recognized that such a decision also has policy aspects (NAS Report p 56). The NAS recognized that the existence of these policy aspects might lead us to select an alternative more consistent with previous Agency policy. Indeed, we considered the longest practical regulatory periods associated with other Agency programs, as well as 40 CFR part 191. We believe the unprecedented nature of a compliance period beyond 10,000 years argues against imposing such a long regulatory period here. Also, numerous international disposal programs use a 10,000-year compliance period. Many of these same programs have committed to consider more qualitative evaluations beyond 10,000 years. (See GAO/RCED–94–172, 1994, Docket No. A–95–12, Item V–A–7. Chapter 3 of the BID also contains information on international programs.) Of course, as knowledge and technical capabilities grow, this situation could change over time.

The hazardous lifetime of radioactive waste is important; however, it is but one of several factors that a regulator must consider in projecting the potential risks from disposal. Indeed, some of the radionuclides expected to be in the waste inventory at Yucca Mountain have half-lives extending to thousands or hundreds of thousands of years (and even a million years or more in a few cases). The ability of the repository to isolate such long-lived materials relates to the retardation characteristics of the whole hydrogeological system within and outside the repository, the effectiveness of engineered barriers, the characteristics and lifestyles associated with the potentially affected population, and numerous other factors in addition to the hazardous lifetime of the materials to be disposed.

With respect to uncertainty in the projected peak dose, one commenter suggested that NRC should deny the license application if modeling results show an uncertainty range of five orders of magnitude above the dose limit in our individual-protection standard. Modeling results, and their associated uncertainties, are but a part of the complete record on which NRC will determine whether the disposal system complies with 40 CFR part 197. For the reasons cited above, we consider a 10,000-year compliance period, and the additional requirement that DOE calculate the peak dose beyond 10,000 years and include this assessment in the Yucca Mountain Environmental Impact Statement, to be the most appropriate approach, given the state of technology and knowledge today. In addition, we require DOE to provide a ''reasonable expectation'' that disposal system performance will meet the standard. Calculation of doses to the RMEI involves projecting doses that are within a reasonably expected range rather than projecting the most extreme case. This approach is in concert with NAS's recommendations to use ''cautious, but reasonable'' assumptions to define who is to be protected (NAS Report pp. 5–6). The degree of uncertainty in the dose assessments considered acceptable in the licensing process is, in our opinion, an implementation decision that should be the responsibility of NRC. We believe that we have provided sufficient detail in the standard to provide the context needed to assure the standard is applied as we intend (see, e.g., our discussions of ''reasonable expectation'' in section III.B.2.c and in the Response to Comments Document that accompanies this rule); however, the final decision regarding the acceptable degree of uncertainty is NRC's responsibility.

For a variety of technical and policy reasons, we believe that a 10,000-year compliance period is meaningful, protective, practical to implement, and will result in a robust disposal system protective for periods beyond 10,000 years. In other programs we have regulated non-radioactive hazardous waste for as long as 10,000 years. Having a 10,000-year compliance period for Yucca Mountain, in conjunction with 40 CFR part 191, ensures that SNF, HLW, and TRU radioactive wastes disposed anywhere in the United States must be regulated for a 10,000-year compliance period.

9. Does Our Requirement That DOE and NRC Determine Compliance with § 197.20 Based Upon the Mean of the Distribution of the Highest Doses Resulting From the Performance Assessment Adequately Address Uncertainties Associated With Performance Assessments?

Comments/Our Responses. Comments on this question ranged from advocating that we should use the maximally exposed individual and ''worst-case'' measures to expressing general agreement with the proposed approach. Some comments stated that any measure applied to the performance assessments should be considered an implementation decision that we should leave to NRC. See the Response to Comments document for additional discussion of comments we received regarding performance assessments.

We specify a compliance measure we believe is reasonable but still conservative: the mean of the distribution of projected doses from DOE's performance assessments. The primary reason we impose this requirement is that it provides a necessary context for implementation of the standard. In addition, we note that it is also consistent with the approach we implemented in certifying WIPP.

We consider it necessary to supply context for understanding the intent of the standard to constrain and direct the otherwise unbounded range of approaches to demonstrating compliance that could be justified in the absence of such context. For example, it would be possible to use only a small number of assessments to demonstrate compliance if the standard specified only an exposure limit. In such a case, the full range of relevant site conditions and processes might not be considered. Further, the analyses and the regulatory decision making might not capture the uncertainties in projecting long-term performance. At the other extreme, without a defined performance measure, endless and exhaustive site characterization studies and analyses could be required. The impetus for these endless and exhaustive studies and analyses would be a perceived need to identify the most extreme ''worst-case'' scenarios (regardless of their actual likelihood of occurring). We believe that a thorough assessment of repository performance expectations should examine the full range of reasonably foreseeable site conditions and relevant processes expected during the regulatory time frame. In making quantitative estimates of repository performance, we believe that unrealistic or extreme situations or assumptions should not dominate estimates of expected performance (see additional discussions about ''reasonable expectation'' in this preamble and the Response to Comments Document). With these considerations in mind, we believe that specifying a performance measure is necessary to supply the proper context for implementing the standard in the regulatory process, as well as providing the applicant (DOE) a focus for its efforts to build the compliance arguments and supporting calculations.

In line with our use of the term ''reasonable expectation,'' the fundamental compliance measure consistent with a literal mathematical interpretation of this term would be the mean value of the distribution of calculated doses. However, as the only alternative for a compliance measure, the mean may in some cases be interpreted too restrictively. In actuality, some situations may result in very high dose estimates for situations that have low probabilities. Simply averaging these ''outliers'' into the distribution of calculated dose estimates can bias the mean levels that may be unrealistically high. Although this is certainly a conservative (and therefore desirable) approach, its effects can be unrealistically conservative (not a desirable situation). The result of overly conservative effects is to drive regulatory decision making on the basis of very low probability and potentially unrealistic situations.

Because of these potential situations, we also proposed using the median of the expected range of calculated values as another interpretation of the ''expected'' situation. The median (reflecting a value exceeded half of the time) may be more conservative if some of the variables involved in the performance calculations have skewed distributions. However, we conclude that, in the case of Yucca Mountain, the mean is an appropriate measure.

By specifying the mean as the performance measure and probability limits for the processes and events to be considered (§ 197.36), and in concert with the intent of our ''reasonable expectation'' approach in general, we have implied that probabilistic approaches for the disposal system performance assessments are expected. The probabilistic approach is well established in DOE's approach to performance projections (see the DEIS and Vol. 3 of the Viability Assessment, Docket No. A–95–12, Items V–A–4 and V–A–5). Based on DOE's past actions and stated intent, we believe that DOE will continue to follow this approach and that, therefore, it is unnecessary for us to specify additional requirements in the standard to assure that DOE continues to follow this approach. We also believe that specifying such requirements could be interpreted to exclude the use of deterministic analyses. These analyses can be useful for carefully focused bounding analyses and sensitivity studies. For these reasons we have specified only the fundamental performance measures to provide the context for understanding, without additional qualifications, the intent of the standard for implementation efforts.

A number of comments stated that, though they agreed with our selection of performance measures, the choice should be left as an implementation detail for NRC. Relative to the implementation question, we believe that specifying the fundamental compliance measure is necessary as a means to supply the proper context for understanding the intent of the rule and for implementation guidance as explained above. We feel this is distinctly different than the implementation responsibility of NRC, as explained below.

We do not believe that setting the fundamental compliance measure intrudes into NRC's implementation authority because the primary task for the regulatory authority is to examine the performance case put forward by DOE to determine ''how much is enough'' in terms of the information and analyses presented (i.e., how will the regulatory authority determine when the performance case has been demonstrated with an acceptable level of confidence). Our standard contains no specific measures for that judgment. We do not specify any confidence measures for such judgments or numerical analyses. Also, we do not prescribe analytical methods that must be used for performance assessments, quality assurance measures that must be applied, statistical measures that define the number or complexity of analyses that should be performed, or any assurance measures in addition to the numerical limits in the standard. We specify only that the mean of the dose assessments must meet the exposure limit. There are many other considerations and decisions that describe the extent of the assessments or level of rigor necessary to ensure that the mean is a meaningful measure upon which a licensing decision can rest. These considerations and decisions properly belong to the implementing authority. For example, we believe setting a confidence level clearly is an implementation function that should be left to NRC; therefore, we make no requirements in the standard to foreclose NRC's flexibility in setting appropriate confidence measures. In the development of the WIPP certification criteria, where we had both the standard-setting and implementing authority, we did establish a confidence measure (40 CFR 194.55 (d) and (f)) in addition to the basic performance measure. We also included implementation requirements in the WIPP certification criteria, including analytical approaches (§ 194.55(b)), quality assurance requirements (§ 194.22), other assurance requirements (§ 194.41), requirements for modeling techniques and assumptions (§§ 194.23 and 194.25), and use of peer review and expert judgment (§§ 194.26 and 194.27). These requirements go well beyond the simple statement of a compliance measure. We did not incorporate a similar level of detail in the Yucca Mountain standards because we believe we must specify only what is necessary to provide the context for implementation that NRC will execute. We therefore agree with comments that support our choice of the performance measure, but disagree for the reasons described above that this choice is an intrusion into the implementation responsibilities of NRC.

For the WIPP certification, the compliance measure selected for the individual-protection standard was the higher of the mean or median of the calculated distributions of doses from releases (40 CFR 194.55(f)). The mean or median are reasonably conservative measures because they are influenced by high exposure estimates found when analyzing the full range of site conditions and relevant processes, without being geared to exclusively reflect high-end results, as would be the case if we selected as the measure a high-end percentile of the calculated dose distribution (such as the 95th or 99th percentile). Our final rule for Yucca Mountain specifies only that the mean be used, as we believe that it is appropriately conservative in this situation.

10. Is the Single-borehole Scenario a Reasonable Approach To Judge the Resilience of the Yucca Mountain Disposal System Following Human Intrusion? Are There Other Reasonable Scenarios Which We Should Consider, for Example, Using the Probability of Drilling Through a Waste Package Based Upon the Area of the Package Versus the Area of the Repository Footprint or Drilling Through an Emplacement Drift but not Through a Waste Package? Why Would Your Suggested Scenario(s) be a Better Measure of the Resilience of the Yucca Mountain Disposal System than the Proposed Scenario?

Comments/Our Responses. Comments upon this question varied from agreement that the proposed intrusion scenario is an adequate test of repository resiliency to opinions that the analysis of any human-intrusion scenario would be irrelevant to the Yucca Mountain setting. Some comments proposed alternative intrusion scenarios, most commonly the use of multiple drilling intrusions. Some comments also proposed alternative ways of treating the intrusion scenario relative to repository requirements. We also received comments concerning other aspects of the intrusion scenario as well as in response to the specific questions asked above. Discussion on all the issues raised in comments about the human-intrusion scenario appears in the Response to Comments document.

Comments in favor of the intrusion scenario as we framed it in the proposed rule focused upon the difficulties in defending any predictions about the probability of drilling intrusions through the repository and in reliably predicting a hypothetical drilling intrusion in any detail. These comments echoed NAS's conclusions about the reliability of post-closure institutional controls to prevent intrusion, and the inability to make scientifically supportable predictions of the probability of human-intrusion events over the regulatory period (NAS Report pp. 104–109). The NAS reasoned that because it is not possible to reliably eliminate the potential for human intrusion, the only reasonable approach would be to assume an intrusion occurs and assess the consequences on disposal system performance. In this light, NAS recommended that a simple stylized drilling intrusion through the repository to the underlying ground water table be assessed as a test of the resiliency of the disposal system (NAS Report Chap. 4). Because it is impossible to scientifically exclude the potential for an intrusion, and because proposing the nature of an intrusion is at best speculative, these comments agreed that the stylized approach that assumes an intrusion and assesses the consequences is appropriate. We have followed the NAS's recommendations closely in framing the human intrusion standard.

Some comments on the framing of the intrusion scenario proposed that, for various reasons, multiple intrusions should be considered, rather than simply assuming one borehole penetration through the repository. Because of certain site-specific considerations with respect to Yucca Mountain, and in light of the rationale underlying the NAS recommendations, it is not appropriate to modify the scenario to include multiple penetrations through the repository. It is impossible to accurately predict the potential for intrusion in the distant future. Therefore, postulating multiple intrusions is just as speculative as postulating a single intrusion at any given time or specific location over the repository. For this reason, NAS recommended that we develop a stylized intrusion in our rulemaking (NAS Report p. 111). We agree with this recommendation because disruption of the engineered and natural barriers is a means through which radionuclides can escape the repository and be transported to the accessible environment where exposures of individuals can result. Therefore, an evaluation of human-intrusion consequences is appropriate for a repository standard. The NAS also recommended that we define a typical intrusion scenario for analysis (NAS Report p. 108) and recommended a stylized approach to framing the scenario (NAS Report p. 111) and a consequence analysis of the scenario (NAS Report p. 111). The intent of this approach is that the disposal system should be resilient ''to at least moderate inadvertent intrusions'' (NAS Report p. 113). Scenarios ranging from single penetrations to many penetrations through the repository over the regulatory time period would give a very wide range of results—none more or less defensible than any other, making their use in regulatory decision making ambiguous at best. To avoid the speculative aspects of defining intrusion scenarios, we believe the stylized single intrusion recommended by NAS is sufficient and would provide a suitable test of the Yucca Mountain disposal system's performance.

Related comments offered opinions that the prospect of drilling for water resources at the top of Yucca Mountain is not a credible scenario because drilling for water would be more sensible in the adjacent valleys. These comments, however, did not offer alternatives for the drilling intrusion. Rather, they stated or implied that the intrusion scenario was unnecessary. We agree that drilling for water, or any other mineral resources at Yucca Mountain, is unlikely because of the very limited resource potential at the site (see Chapter 8 of the BID). However, as NAS concluded, it is impossible to totally eliminate the possibility of intrusion (see Chapter 4 of the NAS Report). This question again goes back to the difficulty in making defensible predictions about the probability of human activities over very long time periods and the fact that intrusion is a means through which releases, and consequent exposures, can occur. Therefore, it is necessary to consider the consequences of inadvertent intrusions in a health-based standard. Some comments suggested that there is a strong possibility for deliberate intrusion into the repository to access its contents as possible resources. We believe that there is no useful purpose to assessing the consequences of deliberate intrusions because in that case the intruders would be aware of the risks and consequences and would have decided to assume the risks. This is consistent with NAS's conclusion regarding intentional intrusion (NAS Report p. 114).

Some comments stated that defining the stylized scenario as we did effectively makes the human-intrusion dose assessment results into design constraints for the repository. We do not believe the stylized scenario imposes any design constraints because the waste package penetration is assumed to occur regardless of the particular design chosen for the waste package. Here again, none of these comments proposed alternative scenarios. Rather, they simply questioned the basic relevance of a human intrusion standard. For the reasons mentioned previously, however, we reiterate our belief that an analysis of human-intrusion is necessary, and we also note that NAS (NAS Report p. 108) stated that ''EPA should specify in its standard a typical intrusion scenario...''. We do not believe it should be regarded as a design constraint unless the results of the consequence analyses indicate that the limited breaching of the natural and engineered barriers would result in the standard being exceeded. Even though the probability of drilling intrusions may be low, it is impossible to unequivocally eliminate them. Therefore, we agree with NAS's conclusion that the ''repository should be resilient to at least modest inadvertent intrusions'' (NAS Report p. 113).

11. Is it Reasonable To Expect That the Risks to Future Generations Be No Greater Than the Risks Judged Acceptable Today?

Comments/Our Responses. Comments we received upon this question strongly favored the position that we should not allow greater risks for future generations than what is judged to be acceptable today. Some comments speculated that with advances in medical technology and other areas, the risks assessed today most likely would be less in the future because society would be more effective in mitigating the effects of radiation exposures. Some comments advised that risks from the disposal effort should be reviewed periodically so that decisions could be made about their acceptability at a future date. We believe we have set the standards conservatively, but reasonably, and consistent with our policies for radiation exposure from radioactive waste disposal applications and NAS's recommendations. In this regard, our standards apply over the entire regulatory period of 10,000 years. Our standards thus protect future generations for a very significant time period. In addition, we require DOE to calculate the peak dose to the RMEI beyond 10,000 years. Although our standards do not apply to the results of this calculation, this post-10,000-year analysis will provide more complete information regarding disposal system performance beyond 10,000 years. This approach to the post-10,000-year period is consistent with our understanding of the limits imposed by inherent uncertainties in making such long-term performance projections. The question of periodic re-evaluation of repository performance is an implementation question that should be left to the discretion of NRC.

12. What Approach Is Appropriate for Modeling the Ground Water Flow System Downgradient From Yucca Mountain at the Scale (Many Kilometers to Tens of Kilometers) Necessary for Dose Assessments Given the Inherent Limitations of Characterizing the Area? Is it Reasonable To Assume That There Will be Some Degree of Mixing With Uncontaminated Ground Water Along the Radionuclide Travel Paths From the Repository?

Comments/Our Responses. Comments on this question shared a general theme that we should not be prescriptive in indicating a preference or requirement for any specific modeling approach that should be used. Rather, the bulk of the comments suggested that DOE (the organization responsible for developing the license application) and NRC (the authority responsible for the approval of the disposal facility) should make these decisions. We agree with this general theme; therefore, our rule does not specify that DOE must use a particular modeling approach to demonstrate compliance with the standards. We believe that DOE and NRC should avoid extreme assumptions and approaches and should identify and consider the inherent uncertainties in projecting performance in the regulatory process. More specifically for Yucca Mountain, we believe that it is necessary to avoid extreme modeling approaches. One example of an extreme modeling approach is assuming the transportation of releases from the repository through the natural barriers without mixing with other ground waters. In this regard we retained our recommendation that ''reasonable expectation'' be the standard used to assess repository performance. We have provided detail in the standards only to the extent needed to provide the context necessary to assure that the components of the standards are implemented in the manner we intended when we developed the standards. Ultimately, it is NRC's task to select and apply the appropriate measure to determine compliance with our standards.

13. Which Approach for Protecting Ground Water in the Vicinity of Yucca Mountain is the Most Reasonable? Is There Another Approach Which Would be Preferable and Reasonably Implementable? If so, Please Explain the Approach, Why It Is Preferable, and How It Could Be Implemented

Comments/Our Responses. We received public comments advising us of a variety of approaches towards protecting ground water in the vicinity of Yucca Mountain. Two primary approaches emerged. One group of public comments suggested that an all-pathways, individual-dose standard, with no separate or specific ground water protection provisions, would be fully protective of the public health. On the other hand, a second set of public comments suggested that we should promulgate separate ground-water protection standards applicable to the Yucca Mountain disposal system. The final rule reflects the latter approach.

We believe as a matter of prudent policy that ground water protection standards are neither redundant nor unnecessary because they address specific aspects of natural resource protection not covered by the individual-protection standard. Rather, such standards are complementary to the public health and safety standards applicable to the Yucca Mountain disposal system. In particular, we consider ground water that is, or that could be, drinking water to be the most valuable ground water resource. We believe that it deserves the highest level of protection. At Yucca Mountain, water from the aquifer beneath the proposed repository currently serves as a source of drinking water in communities 20 to 30 km south of Yucca Mountain. This aquifer has the potential to supply drinking water to a substantially larger population than that presently in the area (NAS Report p. 92).

Over the years, many of our regulatory programs have incorporated the MCLs as an important part of our regulations related to both radioactive and non-radioactive wastes. This approach grew out of the development and implementation of our ground water protection strategy, ''Protecting the Nation's Ground-Water: EPA's Strategy for the 1990s'' (''the Strategy,'' Docket No. A–95–12, Item II-A–3). The use of ground water protection requirements, including the use of MCLs, is reflected in our regulations pertaining to hazardous waste disposal (40 CFR part 264), municipal waste disposal (40 CFR parts 257 and 258), underground injection control (UIC) (40 CFR parts 144, 146, and 148), and uranium mill tailings disposal (40 CFR part 192). We also have incorporated the MCLs into our generally applicable standards for the disposal of SNF, HLW, and TRU radioactive waste (40 CFR part 191). These generic regulations apply to the land disposal of these materials everywhere in the United States except at Yucca Mountain. Extending comparable ground-water protection standards to the proposed Yucca Mountain disposal system will assure reasonable and similar protections wherever the disposal of SNF, HLW, or TRU radioactive waste occurs in this country.

In our response to Question 15, we note our concerns related to adopting only an all-pathways individual-protection standard with no specific ground-water protection provisions. For a more detailed discussion of the issues associated with these two options (all-pathways with and without separate ground water protection), please see the Response to Comments document.

14. Is the 10,000-year Compliance Period for Protecting the RMEI and Ground Water Reasonable or Should we Extend the Period to the Time of Peak Dose? If We Extend it, How Could NRC Reasonably Implement the Standards While Recognizing the Nature of the Uncertainties Involved in Projecting the Performance of the Disposal System Over Potentially Extremely Long Periods?

Comments/Our Responses. As discussed in the response to Question 8 above, comments both supported and questioned our compliance period for the RMEI and ground water protection standards. Commenters who supported the 10,000-year compliance period thought that this time period was ''sufficient'' and that it represented an appropriate balance between long-term coverage and implementability. These commenters agreed with us that, though it is possible to make longer-term calculations, such calculations should be used only for regulatory insight because of the considerable uncertainty involved in making the calculations. These comments support our rationale and choice of a 10,000-year compliance period for protecting the RMEI and ground water.

Numerous commenters suggested that we should extend the compliance period beyond 10,000 years for a variety of reasons. Foremost is that NAS suggested a compliance period extending up to the time of peak dose or risk, within the period of geologic stability for Yucca Mountain (i.e., up to one million years). Other commenters suggested that the compliance period should be comparable to the hazardous lifetime of the materials to be emplaced in the Yucca Mountain repository. As indicated in our response to Question 8 above and in section III.B.1.g, we have significant concerns relating to making meaningful projections of repository performance over the time periods implied by NAS's recommendations. These concerns extend to modeling the time to peak concentration to judge compliance with the ground water standards, which NAS did not explicitly consider. Modeling of exposure scenarios and climatic conditions very different from those experienced over the last 10,000 years, coupled with the potential for human evolutionary changes over such extended time frames, introduces tremendous uncertainties. This situation may result in making arbitrary assumptions in performance assessment modeling, rather than making informed choices based upon cautious, but reasonable, assumptions rooted in present-day knowledge. Regarding the hazardous lifetime of the materials to be emplaced in the Yucca Mountain repository, it is true that there will be radioactive materials remaining after the end of the 10,000-year regulatory period. Nevertheless, the ability of a repository to isolate such long-lived radionuclides depends upon a variety of other factors, including the retardation characteristics of the whole hydrogeological system within and outside of the repository, the effectiveness of the engineered barriers, the characteristics and lifestyles associated with the potentially affected population, as well as the hazardous lifetime of the materials to be emplaced in the repository.

Although we received numerous comments suggesting that 10,000 years was insufficient as a compliance period, we received little in the way of suggestions regarding on how to reasonably implement standards covering these potentially very extended time periods. For example, one commenter suggested that we put the burden on NRC and DOE to develop methods to estimate, with some degree of certainty, the effects after 10,000 years without explaining how the agencies could achieve these results. Please note that NAS specifically addressed this matter (NAS Report, pp. 12–13):

> ''It might be possible that some of the current gaps in scientific knowledge and uncertainties that we have identified might be reduced by future research * * *. Conducting such an appraisal, however, should not be seen as a reason to slow down ongoing research and development programs, including geologic site characterization, or the process of establishing a standard to protect public health.''

We agree with NAS's conclusion. We expect more information will be developed in the time between the promulgation of this rule and the NRC licensing decision to address some of the remaining uncertainties.

15. As Noted by NAS, Some Countries Have Individual-Protection Limits Higher Than We Have Proposed. In Addition, Other Federal Authorities Have suggested Higher Individual-dose Iimits With No Separate Protection of Ground Water. Therefore, We Request Comment Upon the Use of an Annual CEDE of 250 μSv (25 mrem) With No Separate Ground Water Protection, Including the Consistency of Such a Limit With Our Ground Water Protection Policy

Comments/Our Responses. Our promulgation of only an all-pathways, individual-protection standard, such as 25 mrem/yr, with no ground-water protection provisions, would provide no assurance that ground water resources will be protected adequately. The separate ground water protection standards in our rule will preserve the integrity of the ground-water resources in the vicinity of Yucca Mountain for present and future generations.

The all-pathways, individual-protection standard is the primary mechanism to protect public health from releases of radioactivity from the Yucca Mountain repository. We believe that an all-pathways limit, supplemented with ground water protection standards, provides complete public health protection and assures that ground water resources will be safe for use by future generations. In addition, the ground water resources in the vicinity of Yucca Mountain support a diverse agricultural community and important ecological systems (e.g., the endangered Devil's Hole pupfish).

We believe that separate ground water protection standards designed to protect the ground water resource in the vicinity of Yucca Mountain is a necessary element of our Yucca Mountain standards. Our decision to include separate ground water protection standards is a policy decision. As explained in section III.B.4 (*How Does Our Rule Protect Ground Water?*), we developed a ground water protection strategy to guide Agency programs in their efforts to prevent adverse effects on human health and the environment and in protecting the environmental integrity of the nation's ground water resources (see ''The Strategy,'' Docket No. A–95–12, Item II-A–3). We have employed ground water protection programs and standards in a variety of regulatory programs for hazardous and non-hazardous waste. We also have incorporated ground water protection standards in our generally applicable disposal regulations for SNF, HLW, and TRU radioactive wastes (see 40 CFR part 191), and implemented them at WIPP. Incorporation of ground water standards in our overall Yucca Mountain standards provides consistency with other Agency programs and assures consistent protection wherever SNF, HLW, and TRU radioactive waste may be disposed of in this country.

We believe that both ground-water protection standards, incorporating the MCLs to protect ground-water resources, and an individual-protection standard, as embodied in an all-pathways standard, are complementary and necessary to provide adequate public health protection and protection of an invaluable national natural resource. For a more detailed discussion of the issues associated with the options for the individual-protection standard and the ground-water protection standards, please see the Response to Comments document.

16. We Are Proposing To Require, in the Individual-Protection Standard, That DOE Must Project the Disposal System's Performance After 10,000 Years. Are the Specified Uses of the Projections Appropriate and Adequate?

Comments/Our Responses. Some comments supporting our 10,000-year compliance period also endorsed the idea that projections of the disposal system's performance beyond 10,000 years would, among other things, be fraught with greater uncertainties and would not necessarily provide greater public health protection. A few comments supported our requirement that DOE project doses beyond 10,000 years and include the results of these projections in the Yucca Mountain EIS. In addition, a few comments suggested that any post-10,000-year projection should serve only to provide ''regulatory insight.''

Comments supporting the use of a post-10,000-year projection for regulatory purposes cited the long-term hazard posed by the wastes planned for Yucca Mountain, the need to protect future generations, and the possibility that the individual doses would exceed our standard in the post-10,000-year time frame. As indicated in our response to Question 8 above, we considered these and other issues in determining that a 10,000-year compliance period is most appropriate. This compliance period is protective, meaningful, and practical to implement. By also including a post-10,000-year dose assessment in the EIS, which provides more complete information on long-term performance, we believe a robust disposal system protective for time periods beyond 10,000 years will result.

In considering the appropriate use of the post-10,000-year dose assessment, we have had to balance these very difficult issues. It is possible to set computer models to run for time periods beyond 10,000 years; however, this approach does not necessarily result in an equal or higher level of confidence that the exposed individuals will be protected. As numerous comments pointed out, it is likely that such results will contain greater uncertainties. We agree with these comments. Yet, despite these greater uncertainties, such assessments can be somewhat informative though not necessarily reliable dose predictions. We note, for example, the considerations that supported Sweden's proposed regulations for SNF and nuclear waste (''The Swedish Radiation Protection Institute's Proposed Regulations Concerning the Final Management of Spent Nuclear Fuel or Nuclear Waste,'' SSI Report 97:07, May 1997, Docket No. A–95–12, Item V–A–11). Regarding long-term assessments (beyond 1,000 years), such studies ''do not mean that the full protective capacity of the repository can be forecasted, e.g., on the scale of a million years into the future. However, studies of such (repository) subsystems can provide valuable information without actually being considered as a prediction of doses to living organisms' (Id. at 11). We believe that requiring DOE to include a post-10,000-year dose assessment in the EIS is an appropriate means to address the issues associated with such long-term impacts. We note that in our proposal, we stated that ''NRC is not to use'' post-10,000-year results in assessing compliance with the individual-protection standard. However, in its comments on our proposal, NRC stated that, if DOE uses post-10,000-year results to bolster its compliance case, ''the Commission should not be constrained from considering such information'' (Docket No. A–95–12, Item II–D–92). We agree. At the very least, more complete information on long-term disposal system performance will be available. In addition, during this time, the repository design will become more clearly defined by new information. For more extensive discussions of this issue, please see our response to Question 8 above and the Response to Comments document.

VI. Severability

As discussed above at Section III.B.1, the purpose of the Individual Protection Standard is to protect public health and safety. As discussed in Section III.B.4, the Ground Water Protection Standard serves two purposes. First, it protects the ground water resource. Second, by protecting that resource, the Ground Water Protection Standard also furthers the goal of public health and safety. Consistent with the recommendations of the National Academy of Sciences, the Individual Protection Standard is adequate in itself to protect public health and safety. In addition, EPA is adopting the Ground Water Protection Standard in its discretion in order to provide additional protection to the vital ground water resource, and in so doing, is also providing an extra measure of public health and safety protection. Thus, notwithstanding that the Individual Protection and Ground Water Standards have coincident compliance points and, as implemented by NRC, may have other similarities, these two provisions are wholly severable.

VI. Regulatory Analyses

A. Executive Order 12866

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 review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Executive Order 12866 defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect upon 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.

In accordance with the terms of Executive Order 12866, EPA 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. Thus, this action was submitted to OMB for review.

In accordance with the terms of Executive Order 12866, EPA 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. Thus, this action was submitted to OMB for review. Any changes to the rule that were made in response to OMB suggestions or recommendations have been documented in the public record.

B. Executive Order 12898

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations And Low-income Populations (Environmental Justice),'' directs us to incorporate environmental justice as part of our overall mission by identifying and addressing disproportionately high and adverse human health and environmental effects of programs, policies, and activities upon minority populations and low-income populations.

We find no disproportionate impact in the outcome of this rulemaking. No plan has thus been devised to address a disproportionate impact.

C. Executive Order 13045

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 we have reason to believe may have a disproportionate effect upon children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the planned rule upon children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives that we considered.

As discussed in the preamble in sections II.C and III.B.1.a, the primary risk factor considered in our risk assessment is incidence of fatal cancer. We have derived a risk value for the onset of fatal cancer that considers children, since it is an overall average risk value (see Chapter 6 of the BID for more details) that includes all ages from birth onward, all exposure pathways, both genders, and most radionuclides. We do note that the risk factor does not include the fetus. However, we believe that the risk of fatal cancer per unit dose incurred by the unborn is similar to that for those who have been born, but the exposure period is very short compared to the rest of the individual's average lifetime, so the risk of fatal cancer to the unborn is proportionately lower and does not have a significant impact upon the overall risk of fatal cancer incurred by an individual over a lifetime. (See Chapter 6 of the BID for more discussion of the risk of fatal cancer resulting from in utero exposure.)

Therefore, this final rule is not subject to Executive Order 13045 because we do not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

D. Executive Order 13084

On January 1, 2001, Executive Order 13084 was superseded by Executive Order 13175. However, this rule was developed when Executive Order 13084 was still in force, and so tribal considerations were addressed under Executive Order 13084.

Under Executive Order 13084, ''Consultation and Coordination with Indian Tribal Governments,'' we may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs upon those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or we consult with those governments. If we comply by consulting, Executive Order 13084 requires us to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of our prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires us to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

The radiological protection standards promulgated by today's rule are applicable solely and exclusively to the Department of Energy's potential storage and disposal facility at Yucca Mountain. Therefore, this rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose any direct compliance costs on such communities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Executive Order 13132

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

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule. Nonetheless, in developing its proposed rule EPA held public meetings in Nevada and Washington, D.C. during which comment was received from and discussions were had with representatives from the State of Nevada and various county officials. EPA also had informal meetings with State and local officials to apprise them of the status of the rulemaking.

F. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs us to use voluntary consensus standards in our 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 us to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

In our proposal, 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 today are site-specific standards developed solely for application to the Yucca Mountain disposal facility.

G. Paperwork Reduction Act

We have determined that this rule contains no information collection requirements within the scope of the Paperwork Reduction Act, 42 U.S.C. 3501–20.

H. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq

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

I. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Public Law 104–4) establishes requirements for Federal agencies to assess the effects of their regulatory actions upon state, local, and tribal governments and the private sector. Under section 202 of UMRA, we generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before we promulgate a rule for which a written statement is needed, section 205 of UMRA generally requires us 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 us to adopt an alternative other than the least costly, most cost-effective, or least burdensome if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before we establish any regulatory requirements that significantly or uniquely affect small governments, including tribal governments, we must develop, under section 203 of 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 into the development of regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's 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 final rule promulgates 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.

J. Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," (66 FR 28355 (May 22, 2001)), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

We have not prepared a Statement of Energy Effects because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, we have determined that it is not likely to have an adverse effect on the supply, distribution, or use of energy.

List of Subjects in 40 CFR Part 197

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

Dated: June 5, 2001.

Christine Todd Whitman,

Administrator.

The Environmental Protection Agency is adding a new part 197 to Subchapter

F of Chapter I, title 40 of the Code of Federal Regulations, as follows:

Subchapter F—Radiation Protection Programs

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

Subpart A—Public Health and Environmental Standards for Storage

Subpart B—Public Health and Environmental Standards for Disposal

Individual-Protection Standard

Human-Intrusion Standard 197.25 What standard must DOE meet?

Ground Water Protection Standards

Additional Provisions

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

Subpart A—Public Health and Environmental Standards for Storage

§ 197.1 What does subpart A cover?

This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site.

§ 197.2 What definitions apply in subpart A?

Annual committed effective dose equivalent means the effective dose equivalent received by an individual in one year from radiation sources external to the individual plus the committed effective dose equivalent.

Committed effective dose equivalent means the effective dose equivalent received over a period of time (e.g., 30 years,), as determined by NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides.

DOE means the Department of Energy.

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.

EPA means the Environmental Protection Agency.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

High-level radioactive waste means:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and

(2) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

Member of the public means anyone who is not a radiation worker for purposes of worker protection.

NRC means the Nuclear Regulatory Commission.

Radioactive material means matter composed of or containing radionuclides subject to the Atomic Energy Act of 1954, as amended (42 U.S.C. 2014 *et seq.*). Radioactive material includes, but is not limited to, high-level radioactive waste and spent nuclear fuel.

Spent nuclear fuel means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated by reprocessing.

Storage means retention (and any associated activity, operation, or process necessary to carry out successful retention) of radioactive material with the intent or capability to readily access or retrieve such material.

Yucca Mountain repository means the excavated portion of the facility constructed underground within the Yucca Mountain site.

Yucca Mountain site means:

(1) The site recommended by the Secretary of DOE to the President under section 112(b)(1)(B) of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10132(b)(1)(B)) on May 27, 1986; or

(2) The area under the control of DOE for the use of Yucca Mountain activities at the time of licensing, if the site designated under the Nuclear Waste Policy Act is amended by Congress prior to the time of licensing.

§ 197.3 How is subpart A implemented?

The NRC implements this subpart A. The DOE must demonstrate to NRC that normal operations at the Yucca Mountain site will and do occur in compliance with this subpart before NRC may grant or continue a license for DOE to receive and possess radioactive material within the Yucca Mountain site.

§ 197.4 What standard must DOE meet?

The DOE must ensure that no member of the public in the general environment receives more than an annual committed effective dose equivalent of 150 microsieverts (15 millirems) from the combination of:

(a) Management and storage (as defined in 40 CFR 191.2) of radioactive material that:

(1) Is subject to 40 CFR 191.3(a); and

(2) Occurs outside of the Yucca Mountain repository but within the Yucca Mountain site; and

(b) Storage (as defined in § 197.2) of radioactive material inside the Yucca Mountain repository.

§ 197.5 When will this part take effect?

The standards in this part take effect on July 13, 2001.

Subpart B—Public Health and Environmental Standards for Disposal

§ 197.11 What does subpart B cover?

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE.

§ 197.12 What definitions apply in subpart B?

All definitions in subpart A of this part and the following:

Accessible environment means any point outside of the controlled area, including:

(1) The atmosphere (including the atmosphere above the surface area of the controlled area);

(2) Land surfaces;

(3) Surface waters;

(4) Oceans; and

(5) The lithosphere.

Aquifer means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

Barrier means any material, structure, or feature that, for a period to be determined by NRC, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

Controlled area means:

(1) The surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(a) South than 36° 40′ 13.6661″ north latitude, in the predominant direction of ground water flow; and

(b) Than five kilometers from the repository footprint in any other direction; and

(2) The subsurface underlying the surface area.

Disposal means the emplacement of radioactive material into the Yucca Mountain disposal system with the intent of isolating it for as long as reasonably possible and with no intent of recovery, whether or not the design of the disposal system permits the ready recovery of the material.

Disposal of radioactive material in the Yucca Mountain disposal system begins when all of the ramps and other openings into the Yucca Mountain repository are sealed.

Ground water means water that is below the land surface and in a saturated zone.

Human intrusion means breaching of any portion of the Yucca Mountain disposal system, within the repository footprint, by any human activity.

Passive institutional controls means:

(1) Markers, as permanent as practicable, placed on the Earth's surface;

(2) Public records and archives;

(3) Government ownership and regulations regarding land or resource use; and

(4) Other reasonable methods of preserving knowledge about the location, design, and contents of the Yucca Mountain disposal system.

Peak dose means the highest annual committed effective dose equivalent projected to be received by the reasonably maximally exposed individual.

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 during 10,000 years after disposal;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates the annual committed effective dose equivalent incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

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.

Plume of contamination means that volume of ground water in the predominant direction of ground water flow that contains radioactive contamination from releases from the Yucca Mountain repository. It does not include releases from any other potential sources on or near the Nevada Test Site.

Repository footprint means the outline of the outermost locations of where the waste is emplaced in the Yucca Mountain repository.

Slice of the plume means a cross-section of the plume of contamination with sufficient thickness parallel to the prevalent direction of flow of the plume that it contains the representative volume.

Total dissolved solids means the total dissolved (filterable) solids in water as determined by use of the method specified in 40 CFR part 136.

Undisturbed performance means that human intrusion or the occurrence of unlikely natural features, events, and processes do not disturb the disposal system.

Undisturbed Yucca Mountain disposal system means that the Yucca Mountain disposal system is not affected by human intrusion.

Waste means any radioactive material emplaced for disposal into the Yucca Mountain repository.

Well-capture zone means the volume from which a well pumping at a defined rate is withdrawing water from an aquifer. The dimensions of the well-capture zone are determined by the pumping rate in combination with aquifer characteristics assumed for calculations, such as hydraulic conductivity, gradient, and the screened interval.

Yucca Mountain disposal system means the combination of underground engineered and natural barriers within the controlled area that prevents or substantially reduces releases from the waste.

§ 197.13 How is subpart B implemented?

The NRC implements this subpart B. The DOE must demonstrate to NRC that there is a reasonable expectation of compliance with this subpart before NRC may issue a license. In the case of the specific numerical requirements in § 197.20 of this subpart, and if performance assessment is used to demonstrate compliance with the specific numerical requirements in §§ 197.25 and 197.30 of this subpart, NRC will determine compliance based upon the mean of the distribution of projected doses of DOE's performance assessments which project the performance of the Yucca Mountain disposal system for 10,000 years after disposal.

§ 197.14 What is a reasonable expectation?

Reasonable expectation means that NRC is satisfied that compliance will be achieved based upon the full record before it. Characteristics of reasonable expectation include that it:

(a) Requires less than absolute proof because absolute proof is impossible to attain for disposal due to the uncertainty of projecting long-term performance;

(b) Accounts for the inherently greater uncertainties in making long-term projections of the performance of the Yucca Mountain disposal system;

(c) Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence; and

(d) Focuses performance assessments and analyses upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 197.15 How must DOE take into account the changes that will occur during the next 10,000 years after disposal?

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 over the next 10,000 years.

Individual-Protection Standard

§ 197.20 What standard must DOE meet?

The DOE must demonstrate, using performance assessment, that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed individual receives no more than an annual committed effective dose equivalent of 150 microsieverts (15 millirems) from releases from the undisturbed Yucca Mountain disposal system. The DOE's analysis must include all potential pathways of radionuclide transport and exposure.

§ 197.21 Who is the reasonably maximally exposed individual?

The reasonably maximally exposed individual is a hypothetical person who meets the following criteria:

(a) Lives in the accessible environment above the highest concentration of radionuclides in the plume of contamination;

(b) Has a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada. The DOE must use projections based upon surveys of the people residing in the Town of Amargosa Valley, Nevada, to determine their current diets and living styles and use the mean values of these factors in the assessments conducted for §§ 197.20 and 197.25; and

(c) Drinks 2 liters of water per day from wells drilled into the ground water at the location specified in paragraph (a) of this section.

Human-Intrusion Standard

§ 197.25 What standard must DOE meet?

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. The DOE must:

(a) If complete waste package penetration is projected to occur at or before 10,000 years after disposal:

(1) Demonstrate that there is a reasonable expectation that the reasonably maximally exposed individual receives no more than an annual committed effective dose equivalent of 150 microsieverts (15 millirems) as a result of a human intrusion, at or before 10,000 years after disposal. The analysis must include all potential environmental pathways of radionuclide transport and exposure; and

(2) If exposures to the reasonably maximally exposed individual occur more than 10,000 years after disposal, include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance; and

(b) Include the results of the analysis and its bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance, if the intrusion is not projected to occur before 10,000 years after disposal.

§ 197.26 What are the circumstances of the human intrusion?

For the purposes of the analysis of human intrusion, DOE must make the following assumptions:

(a) There is a single human intrusion as a result of exploratory drilling for ground water;

(b) The intruders drill a borehole directly through a degraded waste package into the uppermost aquifer underlying the Yucca Mountain repository;

(c) The drillers use the common techniques and practices that are currently employed in exploratory drilling for ground water in the region surrounding Yucca Mountain;

(d) Careful sealing of the borehole does not occur, instead natural degradation processes gradually modify the borehole;

(e) Only releases of radionuclides that occur as a result of the intrusion and that are transported through the resulting borehole to the saturated zone are projected; and

(f) No releases are included which are caused by unlikely natural processes and events.

Ground Water Protection Standards

§ 197.30 What standards must DOE meet?

The DOE must demonstrate that there is a reasonable expectation that, for 10,000 years of undisturbed performance after disposal, releases of radionuclides from waste in the Yucca Mountain disposal system into the accessible environment will not cause the level of radioactivity in the representative volume of ground water to exceed the limits in the following Table 1:

TABLE 1.—LIMITS ON RADIONUCLIDES IN THE REPRESENTATIVE VOLUME

Radionuclide or type of radiation emitted	Limit	Is natural background included?
Combined radium-226 and radium-228	5 picocuries per liter	Yes.
Gross alpha activity (including radium-226 but excluding radon and uranium).	15 picocuries per liter	Yes.
Combined beta and photon emitting radionuclides	40 microsieverts (4 millirem) per year to the whole body or any organ, based on drinking 2 liters of water per day from the representative volume.	No.

§ 197.31 What is a representative volume?

(a) It is the volume of ground water that would be withdrawn annually from an aquifer containing less than 10,000 milligrams of total dissolved solids per liter of water to supply a given water demand. The DOE must project the concentration of radionuclides released from the Yucca Mountain disposal system that will be in the representative volume. The DOE must then use the projected concentrations to demonstrate a reasonable expectation to NRC that the Yucca Mountain disposal system complies with § 197.30. The DOE must make the following assumptions concerning the representative volume:

(1) It includes the highest concentration level in the plume of contamination in the accessible environment;

(2) Its position and dimensions in the aquifer are determined using average hydrologic characteristics which have cautious, but reasonable, values representative of the aquifers along the radionuclide migration path from the Yucca Mountain repository to the

accessible environment as determined by site characterization; and

(3) It contains 3,000 acre-feet of water (about 3,714,450,000 liters or 977,486,000 gallons).

(b) The DOE must use one of two alternative methods for determining the dimensions of the representative volume. The DOE must propose its chosen method, and any underlying assumptions, to NRC for approval.

(1) The DOE may calculate the dimensions as a well-capture zone. If DOE uses this approach, it must assume that the:

(i) Water supply well(s) has (have) characteristics consistent with public water supply wells in the Town of Amargosa Valley, Nevada, for example, well-bore size and length of the screened intervals;

(ii) Screened interval(s) include(s) the highest concentration in the plume of contamination in the accessible environment; and

(iii) Pumping rates and the placement of the well(s) must be set to produce an annual withdrawal equal to the representative volume and to tap the highest concentration within the plume of contamination.

(2) The DOE may calculate the dimensions as a slice of the plume. If DOE uses this approach, it must:

(i) Propose to NRC, for its approval, where the location of the edge of the plume of contamination occurs. For example, the place where the concentration of radionuclides reaches 0.1% of the level of the highest concentration in the accessible environment;

(ii) Assume that the slice of the plume is perpendicular to the prevalent direction of flow of the aquifer; and

(iii) Assume that the volume of ground water contained within the slice of the plume equals the representative volume.

Additional Provisions

§ 197.35 What other projections must DOE make?

To complement the results of § 197.20, DOE must calculate the peak dose of the reasonably maximally exposed individual that would occur after 10,000 years following disposal but within the period of geologic stability. No regulatory standard applies to the results of this analysis; however, DOE must include the results and their bases in the environmental impact statement for Yucca Mountain as an indicator of long-term disposal system performance.

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

Yes. The DOE's performance assessments 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. The NRC shall exclude unlikely features, events, and processes, or sequences of events and processes from the assessments for the human intrusion and ground water protection standards. The specific probability of the unlikely features, events, and processes is to be specified by NRC. In addition, unless otherwise specified in 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.

§ 197.37 Can EPA amend this rule?

Yes. We can amend this rule by conducting another notice-and-comment rulemaking. Such a rulemaking must include a public comment period. Also, we may hold one or more public hearings, if we receive a written request to do so.

§ 197.38 Are The Individual Protection and Ground Water Protection Standards Severable?

Yes. The individual protection and ground water protection standards are severable.

[FR Doc. 01–14626 Filed 6–8–01; 2:05 pm]

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