will use water contaminated with radionuclides released from the disposal system. We believe this lifestyle is conservative but similar to that of most people living in Amargosa Valley today.

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

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

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

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

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

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

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

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

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

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

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

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

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

An important provision of our standards is the establishment of the principle of "reasonable expectation" to guide implementation of our standards and provide context for evaluating projections against the numerical compliance standards discussed above. It is a critical element in implementing our standards, but its importance might easily be overlooked or misunderstood. We use the concept of "reasonable expectation" in these standards to reflect our intent regarding the level of "proof" necessary for NRC to determine whether the projected performance of

the Yucca Mountain disposal system complies with the standards (see §§ 197.20, 197.25, and 197.30). In issuing our 2001 standards, we noted that this term is meant to convey our position that unequivocal numerical proof of compliance is neither necessary nor likely to be obtained for geologic disposal systems. We believe unequivocal proof is not possible because of the extremely long time periods involved and because disposal system performance assessments require extrapolations of conditions and the actions of processes that govern disposal system performance over those long time periods.

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

B. Legal Challenges to 40 CFR Part 197

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

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

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

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

2. Challenge by the Nuclear Energy Institute

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In today's action, we are not proposing to revise all of these standards, only those affected by the Court decision. Therefore, we are proposing to revise only the individual-protection and human-intrusion standards, along with certain supporting provisions related to the way DOE must consider features, events, and processes (FEPs) in its compliance analyses. In addition, we are proposing to adopt updated scientific factors for calculating doses to show compliance with the storage, individual-protection, and human-intrusion standards, as described in more detail in Section II.C.6. We are not proposing to change any aspect of the ground-water protection standards. We are providing notice and requesting public comment only on our proposed revisions to 40 CFR part 197. With the exception of the updated factors for calculating doses for the storage standard, we are not requesting and will not consider public comment on either the storage or ground-water protection standards. Furthermore, we are not requesting, nor will we consider, comments on those aspects of the individual-protection and

human-intrusion standards to which no changes are proposed.

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

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

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

1. Individual-Protection Standard

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

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

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

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

2. Human-Intrusion Standard

While the Court did not specifically address the human-intrusion standard, we believe it is logical and defensible to modify it to parallel the individual-protection standard. Like the individual-protection standard, our provisions for human intrusion envisioned some consideration of performance beyond 10,000 years. The 2001 standard required that DOE determine when an intrusion by drilling would be possible and assess the consequences. The resulting exposures

were then subject to the same compliance standard as the individual-protection standard (15 mrem/yr at 10,000 years or earlier and dose projections beyond 10,000 years to be compiled in the EIS). In proposing revisions to the human-intrusion standard to conform to changes we are proposing to make to the individual-protection provisions, we are adhering to the NAS recommendation that "EPA require that the estimated risk calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case" (NAS Report p. 12). In light of this recommendation, and the Court's interpretation of how closely we must align with the NAS recommendations to be deemed "based upon and consistent," we believe it is both prudent and reasonable to propose to revise the human-intrusion standards to incorporate peak dose compliance measures that conform to the proposed revisions for individual protection.

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

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

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

3. Ground-Water Protection Standards

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

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

NEI, 373 F.3d at 46–47.

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

4. Reasonable Expectation

"Reasonable expectation" is the compliance concept underlying our disposal standards. That is, we require that DOE show a "reasonable expectation" that the standards will be met. As discussed extensively in our 2001 Yucca Mountain rulemaking, "proof" of disposal system performance

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

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

5. Effects of Uncertainty

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

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

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

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

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

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

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

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

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

For example, the IAEA has stated that, for periods lasting from about 10,000 to 1 million years, "While it may be possible to make general predictions about geological conditions, the range of possible biospheric conditions and human behaviour is too wide to allow reliable modelling * * * Such calculations can therefore only be viewed as illustrative and the 'doses' as indicative" (IAEA–TECDOC–767, "Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," p. 19, 1994, Docket No. OAR–2005–0083–0044). Also, "[t]he utility of individual numerical indicators will vary greatly and, given the large uncertainties, considerable caution is needed to avoid any suggestion or expectation that any given indicator of disposal system performance can be an accurate estimate of future reality. Such an indicator typically provides only an estimate of what might happen under certain assumed conditions * * * The aim of the assessment is not to predict the actual performance of the disposal system * * * but rather to reach reasonable assurance that it will provide an adequate level of safety" (IAEA–TECDOC–975, "Regulatory Decision Making in the Presence of Uncertainty in the Context of the Disposal of Long Lived Radioactive Wastes," pp. 22, 24,

1997, Docket No. OAR–2005–0083–0045). Finally, "[c]are has to be exercised in applying the criteria for periods beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making" (IAEA Draft Safety Requirements DS154, "Geological Disposal of Radioactive Waste," Section A.7, p. 37, April 2005, Docket No. OAR–2005–0083–0051).

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

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

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

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

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

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

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

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

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

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

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

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

In Section II.D of this document ("How Will Today's Proposal Affect the Way DOE Conducts Performance Assessments?"), we propose to limit speculation over the long compliance period now being addressed by requiring compliance within a performance assessment that continues to emphasize the most significant features, events, and processes. The purpose is to provide a reasonable test of performance over a range of conditions. To do so, we propose to eliminate very unlikely features, events, and processes, and the scenarios

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

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

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

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

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

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

In balancing these goals, we have carefully examined the NAS recommendations and looked more broadly to international models and guidance on long-term radioactive waste disposal. We believe today's proposal satisfies these goals. We believe the first three are straightforward and our reasoning outlined in the next sections will clearly show how they influenced our proposal. The fourth point relates to an essential purpose of our action that can sometimes be overshadowed by emphasis on the NAS recommendations and the Court ruling. As NAS stated, "standards are only useful if it is possible to make meaningful assessments of future repository performance with which the standards can be compared" (NAS Report p. 34). Ultimately, NRC must be able to use our standards to judge whether DOE has provided sufficient evidence that the disposal system will be protective of public health and safety. While there are

significant scientific aspects to this decision, regulatory judgment must bridge the gap between what science can show and the unprecedented time frames involved. The licensing process must consider the confidence that can be placed in performance assessments used to represent disposal system evolution and the information necessary to make a decision. Our "reasonable expectation" standard is critical to making this judgment.

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

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

1. Multiple Dose Standards Applicable to Different Compliance Periods

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

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

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

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

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

First, we are retaining the standard promulgated in 2001 as § 197.20, which requires that DOE demonstrate a reasonable expectation that the RMEI will not incur annual exposures greater than 150 μSv (15 mrem) (expressed as a committed effective dose equivalent) from releases of radionuclides from the Yucca Mountain disposal system for 10,000 years after disposal. DOE will make this demonstration using the arithmetic mean of performance

assessment results (see Section II.C.5, "How Will NRC Judge Compliance?" for further discussion of the mean). We believe this is appropriate, protective, and will maintain consistency with our generic standards (now applied to the WIPP) and other precedents described earlier. Further, NAS stated that the "range [of 10^{-5} to 10^{-6} per year for risk] could therefore be used as a reasonable *starting point* for EPA's rulemaking" (NAS Report p. 49, emphasis in original). By maintaining the 15 mrem/yr standard for 10,000 years we clearly establish a "starting point" for assessing compliance that is consistent with both NAS and our overall risk management policies, and serves as a logical foundation for us to incorporate concerns regarding far future projections.

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

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

Examination of DOE's Total System Performance Assessments (TSPA) for the site shows that the time of peak dose occurs in the hundreds of thousands of years (FEIS, DOE/EIS–0250, Appendix I, Section 5.3, February 2002, Docket No. OAR–2005–0083–0086). The waste packages assessed in the TSPA are heavily engineered to provide corrosion resistance under the conditions expected in the repository, and are projected to remain essentially unbreached for periods well beyond 10,000 years. The scientific data that underlie these corrosion resistance projections are laboratory tests on the metals, under conditions intended to stress the metals and simulate their performance in the repository. These testing methods are typical "state-of-the-art" techniques for corrosion testing. However, it must be recognized that the extrapolation of laboratory test results in a predictive sense involves significant uncertainties, and our experience in verifying such projections is only for time frames of decades in the case of industrial applications ("Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments," Section 5, July 2005, Docket No. OAR–2005–0083–0085). While DOE projects, based upon the results of laboratory testing, that the waste containers will maintain their integrity for thousands to tens of thousands of years, it is not possible to claim unequivocally that no information will come to light that might cause a reassessment of the containers' behavior and its effect on disposal system performance. Although we believe that significant doses within 10,000 years are highly unlikely, we also believe it important to structure our regulations to preclude the chance that protection at Yucca Mountain would be less than that provided for WIPP or the Greater Confinement Disposal facility (GCD, which is a group of 120-feet deep boreholes, located within NTS, which contain disposed transuranic wastes). It would be inappropriate to apply a standard designed to accommodate the uncertainties in projections many tens to hundreds of thousands of years into the future to projections within 10,000 years, when uncertainties are much more manageable. The 15 mrem/yr dose limit is the measure against which compliance would be judged during the initial 10,000-year period.

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

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

Some readers may note that we rejected similar approaches offered in comments on our 1999 proposed rule. One commenter in particular suggested that the dose standard could be increased over time, i.e., 15 mrem/yr up to 10,000 years, 150 mrem/yr from 10,000 to 100,000 years, and 1.5 rem/yr from 100,000 to 1 million years (Docket A–95–12, Item IV–D–35). As stated in our Response to Comments document published in conjunction with the 2001 final rulemaking (p. 3–8, Docket No. OAR–2005–0083–0043), we considered that our approach accomplished the same goal as that offered by the commenter. While we did state that "no regulatory body that we are aware of considers doses of 150 mrem to be acceptable," we also stated that "the

uncertainties involved in very long-term assessments would make it more difficult to judge compliance with any numerical standard," which we still believe is true. It is clear that we struggled to reconcile the competing claims of confidence in projections and intergenerational equity. We sought an approach that would account for what we see as potentially unmanageable uncertainties, but did not depart from levels of risk that are considered protective today. Nevertheless, the Court's decision puts us in the position of establishing a quantitative standard at the time of peak dose. It is necessary for us to re-evaluate potential approaches to doing so, including whether and under what conditions a higher dose standard can be justified. We discuss an approach similar to that offered by the commenter in Section II.C.2.c ("Peak Dose Standard Varying Over Time").

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

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

2. What Other Options Did EPA Consider?

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

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

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

b. Dose Standard To Apply at Peak Dose Alone

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

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

c. Peak Dose Standard Varying Over Time

We also considered a variation on our proposed approach, in which the post-10,000-year dose level would rise incrementally as time and the effects of uncertainty increase. This approach would provide greater continuity with the 10,000-year standard and a gradual transition as the role of uncertainty increases. The difficulty in this approach is identifying criteria to define the timing and level of these transitions, which would have to incorporate some appraisal and comparison of the effects