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Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada (40 CFR Part 197)—Final Rule

Response to Comments Document

Docket No: A-95-12
V-C-1

RESPONSE TO COMMENTS

Public Health and Environmental Radiation
Protection Standards
for Yucca Mountain, Nevada
40 CFR Part 197

June, 2001

Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
Washington, D.C.

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Introduction

The Environmental Protection Agency (EPA) has promulgated public health and safety standards for radioactive material stored or disposed of in the potential repository at Yucca Mountain, Nevada. Section 801 of the Energy Policy Act of 1992 [(EnPA, Pub. L. 102-486, 42 U.S.C. § 10141 n. (1994)] directed EPA to develop these standards. Section 801 of the EnPA also required EPA to contract with the National Academy of Sciences (NAS) to conduct a study to provide findings and recommendations on reasonable standards for protection of the public health and safety. The health and safety standards promulgated by EPA are "based upon and consistent with" the findings and recommendations of NAS in its 1995 report titled: "Technical Bases for Yucca Mountain Standards"(NAS Report, Docket A-95-12, Item II-A-1).

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

What is Yucca Mountain?

Yucca Mountain is the site of DOE's potential geologic repository designed to dispose of spent nuclear fuel (SNF) and high-level radioactive waste (HLW). If approved, the site would be the nation's first geologic repository for disposal of this type of radioactive waste.

The potential Yucca Mountain repository is above a large, deep source of fresh water, currently used as agricultural and drinking water. This water feeds a larger ground water basin south of the site which has the potential to supply many more people in the surrounding areas.

The site is located in Nye County, Nevada, about 100 miles northwest of Las Vegas on federally owned land on the western edge of DOE's Nevada Test Site (NTS). The repository would be approximately1,000 feet below the top of the mountain and 1,000 feet above the ground water.

Background

The SNF and HLW have been produced since the 1940s, mainly as a result of commercial power production and defense activities. Since then, the proper disposal of these wastes has been the responsibility of the Federal Government. The Nuclear Waste Policy Act of 1982 (NWPA, Pub. L. 97-425) formalizes the current Federal program for the disposal of SNF and HLW by:

> (1) making DOE responsible for siting, building, and operating an underground geologic repository for the disposal of SNF and HLW;
>
> (2) directing EPA to set generally applicable environmental radiation protection standards

based upon authority established under other laws[1], and

(3) requiring the NRC to implement our standards by incorporating them into its licensing requirements for SNF and HLW repositories.

The EnPA, enacted in 1992, continues these general responsibilities. Thus, NRC will issue implementing regulations for this rule. The DOE will submit a license application to NRC. The NRC then will determine whether DOE has met the standards and whether to issue a license for Yucca Mountain. The NRC will require DOE to comply with all of the applicable provisions of 40 CFR part 197 before authorizing DOE to construct the repository and receive radioactive material on the Yucca Mountain site.

In 1985, EPA established generic standards for the management, storage, and disposal of SNF, HLW, and transuranic (TRU) radioactive waste (see 40 CFR part 191, 50 FR 38066, September 19, 1985), which apply to any facilities for the storage or disposal of these wastes, including Yucca Mountain. In 1987, the U.S. Court of Appeals for the First Circuit remanded the disposal standards in 40 CFR part 191 (*NRDC v. EPA, 824 F.2d 1258 (1st Cir. 1987)*). As discussed below, EPA later amended and reissued these standards to address issues that the court raised.

Also in 1987, the Nuclear Waste Policy Amendments Act (NWPAA, Pub. L. 100-203) amended the NWPA by, among other actions, selecting Yucca Mountain, Nevada, as the only potential site that DOE should characterize for a long-term geologic repository.

In October 1992, the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP LWA, Pub. L. 102-579) and the EnPA became law. These statutes changed EPA's obligations concerning radiation standards for the Yucca Mountain candidate repository. The WIPP LWA:

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

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

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

EPA issued the amended 40 CFR part 191 disposal standards, which addressed the judicial remand, on December 20, 1993 (58 FR 66398).

In August, 1999, we proposed public health and safety, radiation standards for Yucca Mountain, 40 CFR part 197. EPA has finalized the standards for Yucca Mountain based, in part, upon the consideration of the public comments included in this document.

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

Response to Comments

EPA held a 90-day public comment period for the proposed radiation protection standards for Yucca Mountain (August 27, 1999 through November 26, 1999). Sixty-nine (69) sets of written comments were submitted to EPA's Air Docket regarding the proposed standards, although some commenters submitted more than one set of written comments. In addition, the Agency received oral testimony on the proposed standards from 28 speakers during public hearings that were held in Washington, DC; Las Vegas, NV; Amargosa Valley, NV; and Kansas City, MO. Comments received on the proposal were categorized according to topics, which correspond generally to sections in the final rule. A list of the issues addressed in each section can be found at the beginning of each section. While EPA has cross-referenced related topics where possible, it has not done so in every instance. The entire document should be considered as a whole, for it collectively reflects EPA's consideration of public comments. In some cases, EPA has combined or paraphrased comments.

This document addresses comments received on the proposed radiation protection standards for Yucca Mountain by summarizing the views expressed by cementers and presenting EPA's response to the comments. All comments received during the public comment period and the public hearings have been fully considered. Some comments were received after the close of the public comment period on November 26, 1999. These comments were identified as late and placed in the docket. We reviewed these comments and have addressed any significant new issues that were raised in the late comments. We have addressed all significant comments, both written and oral. Responding to comments was difficult in some cases because certain comments did not articulate specific concerns, did not suggest concrete alternatives, or did not substantiate the position advocated.

Each comment is identified by a unique number in parentheses that follows the comment. Appendix A of this document correlates these identification numbers to the docket numbers and name(s) of the cementer. Appendix A also identifies the people who testified at the public hearings and the corresponding comment numbers. Copies of all comments submitted to EPA regarding the proposed certification decision can be found in Air Docket Number A-95-12 Categories IV-D and IV-F. A list of acronyms and the terms they represent are in Appendix B. To locate references used in response to comments or references that are cited in other EPA support documentation, see Docket: A-95-12, Item V-B-1.

The official docket, A-95-12, is located in Room 1500 (first floor in Waterside Mall near the Washington Information Center), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460 (open from 8:00 a.m. to 4:00 p.m. on weekdays). As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying docket materials. We also have placed an informational docket in the Lied Library at the University of Nevada-Las Vegas, Research and Information Desk, Government Publications Section (702-895-2200). Hours vary based upon the academic calendar, so we suggest that you call ahead to be certain that the library will be open at the time you wish to visit (for a recorded message, call 702-895-2255).

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

Section 1 General Comments[1]

[1] All acronyms are defined in Appendix B.

Issue A: EPA's standard unnecessarily duplicates NRC's implementation role.

1. [T]he duplication of the NRC role that EPA proposes in the implementation criteria in the draft standard is unnecessary and counter-productive. NRC can do a much better job of implementing any standard EPA prepares and promulgates if they are left to their own devices in

determining how to implement. (1)

2. Implementation of the standard is an NRC responsibility under the Nuclear Waste Policy Act. Provisions, such as those specifying the detailed parameters and conditions to be used in determining whether the standards are met and those specifying guidelines concerning the use of opinion in the licensing process, should be deleted. (219)

3. EPA should bear in mind that in setting its radiation standards, that the NRC will need some flexibility in implementing them as the Commission considers the license application that will be submitted by the DOE. (257)

4. TVA is concerned that the proposed rulemaking could result in having two federal agencies involved in determining compliance with radiation protection regulations and standards which could cause confusion for licensees and be potentially counterproductive to the interests of the general public. (299)

5. EPA should delete provisions that duplicate and conflict with the statutory authority of the Nuclear Regulatory Commission. (449)

6. It is not within the EPA's authority to specify whether or not the proposed repository meets applicable standards. This authority has been solely granted to the U.S. Nuclear Regulatory Commission. Examples of where the EPA standard attempts to impose methods for determining compliance include:

> (1) the use of the term "reasonable expectation" versus the U.S. NRC term "reasonable assurance;"
>
> (2) the requirement to apply the dose limit to the "reasonably maximally exposed individual" (RMEI), versus "average member of the critical group;" and
>
> (3) specifying details of how the repository must meet the standard in the area of human intrusion. (403)

7. Comments such as EPA expects the engineered barrier system to be "backfill in the spaces between the waste packages and adjacent rock" is better left for the NRC and others to contemplate. (346)

8. We do not support the establishment of qualitative requirements in this proposed rule. We consider such requirements to be duplicative of EPA's intent to promulgate radiation standards that are fully protective of public health and safety. An appropriate level of confidence in the Department of Energy's (DOE's) compliance can be achieved through NRC's implementation of a site radiation standard. (769)

Response to Issue A:

EPA believes that the provisions of the proposal are clearly within its authority and are central to the concept of a public health and safety protection standard. It is reasonable and appropriate for a public health and safety protection standard not only to set the level to which the public must be protected but also to define who the standard should be assessed against and at what location. Moreover, it would be unreasonable for EPA to establish a purported public health and safety standard that did not include such vital parameters as who the standard should be assessed against and where it should apply. Such parameters are common features of radiological protection standards. For example, IAEA Safety Series No. 99 provides that for releases from a repository due to gradual processes the dose upper bound should be less than an annual average dose value of 1 mSv/yr for prolonged exposures for individuals in a critical group. Similarly, disposal standards issued by countries such as Sweden, France, and the United Kingdom specify a dose limit and a general statement of to whom the limit applies (note that other countries are generally much less prescriptive in these regulations than is the United States). These disposal standards are analogous to EPA's generic 40 CFR part 191 in the sense that they could apply to a number of possible locations, so they are written in broader terms. It is not inappropriate for a site-specific standard to include site-specific details. By defining such parameters as who the standard should be assessed against, at what location compliance is to be determined, and what is the minimum level of expectation applicable to EPA's standard, EPA has not usurped any responsibilities properly belonging to NRC. NRC will be the sole agency to determine compliance with the EPA standard and its own licensing criteria. The EPA standard leaves NRC with sufficient flexibility to adapt to changing conditions at the Yucca Mountain repository (e.g., gathering of site characterization data, improved monitoring capabilities, improved performance assessment models, or development of new materials for constructing engineered barriers), or to apply more stringent criteria in licensing the repository. The EPA proposal requires DOE to demonstrate a "reasonable expectation" that the repository will meet the relevant standard(s). As described in the preamble, and as set forth in great detail in responses to specific comments on the reasonable expectation approach (Section 2 of this document), EPA believes that "reasonable expectation" is a more realistic measure to apply over very long time periods than "reasonable assurance", which NRC prefers; however, because EPA does not require that NRC use reasonable expectation in its licensing determination, but, rather, recommends that reasonable expectation be the minimum level of proof used, EPA does not intrude inappropriately into the NRC's implementation responsibilities for decision-making. There is nothing to prevent NRC from applying the "reasonable assurance" concept in its licensing process, as doing so should satisfy "reasonable expectation" as well. In the case of human intrusion, EPA adopted the recommendation on framing the scenario from the NAS Report. In instances where EPA did not directly adopt an NAS recommendation, the proposal discusses the reasons for the deviation. There were no compelling technical or policy reasons to justify excluding or significantly altering the human intrusion scenario.

On the subject of backfill, DOE's most recent statements indicate that it is reconsidering the need or desirability of backfilling the emplacement drifts. Given these statements, and other comments on the subject, EPA is modifying the definition of "disposal" in subpart B of the rule to eliminate

the reference to backfill (see Issue RR). Regarding the description of EPA's "expectation" for the engineered barrier system in the preamble to the proposal, this was simply a generic statement describing the most recent thinking on repository systems in general and DOE's plans for the Yucca Mountain repository in particular, and echoed statements in the NAS Report (p. 27).

Issue B: EPA should be commended for its independence and strength of standard.

1. I want to compliment you folks for making your standard as stringent as it was. (62)

2. I would like the record to show that we truly appreciate the independence that the EPA has shown. As rules have changed on this project so many times, EPA is the one agency out of three when you count DOE, the Nuclear Regulatory Commission and the EPA, that did not choose to change its rules, and in fact, tried not to make it a different rule for Yucca Mountain but was ordered to do so. We appreciate the fact that you've stayed very independent.(104)

3. I must say I am pleasantly surprised that this standard has been put out in its present form, and it includes a ground-water standard, and that the EPA's managed to stick to its guns under the extreme political pressure that I know it's been under these past several years. (134)

4. [I]t is of concern to us that EPA's authority to set radiation exposure limits for ground water and other exposure pathways could be undermined by legislative dictate of a health standard. (491)

Issue C: EPA's standard is based on a completely inappropriate concept.

1. Emission limits in the form of radiation dose limits to individuals and to populations are appropriate for manufacturing facilities because emissions of radionuclides are expected and are to be regulated. The Yucca Mountain Repository is not such a facility and it is a gross error to treat it as such. (413)

2. As there will be no emissions from the repository under expected conditions for the next 10,000 years, this fact should be reflected in proposed standards for normal operations of the YMR. EPA should not propose standards based on hypothetical, very low probability accident conditions - such a course has no precedent and is not a credible regulatory procedure. In summary, EPA is proposing standards appropriate only for accident conditions, which it should not do, but has failed to propose standards for routine operational conditions, which it is required to do. (417)

Issue D: EPA's standard is too weak.

1. The EPA has proposed stronger standards than the NRC, but even these standards are too weak. The EPA should strengthen its standards! (453)

2. EPA radiation experts were not sufficiently knowledgeable about the traditional and customary Tribal uses to properly incorporate them into the formula upon which the draft standards are based. The result is that the standards may not be based upon accurate assumptions. (791)

Issue E: EPA's standard is too stringent.

1. We are concerned that the radiation standards in the proposed rule may make siting a permanent repository at Yucca Mountain (or elsewhere) more difficult, if not impossible. Until a permanent repository or centralized interim storage facility is sited, utilities will be forced to store the waste at plant sites which were never intended for storing waste indefinitely.(492)

Issue F: EPA's standard will hinder implementation without increasing protection.

1. EPA's proposed radiation standard would cause unnecessary expense, delay, and inefficiencies in the construction, licensing, and operation and maintenance of the repository at Yucca Mountain without any comparable increase in the protection of public health and safety and/or the environment.(273)

Issue G: EPA is compromising its mission with lax standards to make Yucca Mountain pass.

1. We feel that the standard should be legitimate and if that were the case, that Yucca Mountain would be eliminated from consideration for the national repository. (9)

2. The proposed rule places the focus for the release standard on the estimated capability of the proposed repository, rather than on an acceptable amount of risk for humans and the environment. Instead of starting from a baseline of what would be safe for the environment and the public, the Proposed Rule's standard is based on what the repository can accomplish. (176)

3. EPA's job is to protect the environment and public health, not to lower standards so that an unsuitable site like Yucca Mountain might still qualify. (350)

4. To lower standards due to political and economic pressures so that a unsuitable site would still qualify would set a terrible precedent within EPA, across the nation, and even internationally. (427)

5. It now appears that the constraints of the Yucca Mountain site are the determining factor in EPA's standards, which are largely being negotiated through closed-door interagency meetings before being issued publicly. (436)

Response to Issues B through G:

The EnPA mandates that EPA promulgate public health and safety standards that apply specifically to the Yucca Mountain site. Developing such standards required EPA to assess existing population patterns, land and water usage, and the geologic and hydrogeologic characteristics of the Yucca Mountain region. It was also necessary to make some reasonable assumptions about how those factors might change in the near future, and how any releases of radioactivity from the Yucca Mountain repository might reach the exposed population. EPA believes that its assumptions in these areas are prudent and defensible. Regarding the traditional and customary Tribal uses of the area, EPA considers that its assumptions used to describe the RMEI are appropriate, as the traditional and customary uses do not lead to the continuing, year-round exposures assumed for the RMEI (although some of these uses may take place at locations closer to the repository).

EPA's standard represents the level of performance the Yucca Mountain repository would have to meet for the specified compliance period. EPA's promulgation of the standard does not mean that a final decision has been made as to the suitability of the site, nor is it a determination as to whether the repository could meet the standard under any circumstances. The final decision as to suitability has yet to be made through the NRC licensing process.

EPA disagrees with the comment that its analyses are inappropriate for the expected conditions at Yucca Mountain. While it is true that DOE's design is intended to fulfill the purpose of the repository by containing and isolating the waste, the long time periods involved in projecting facility performance introduce significant uncertainties that cannot be ignored. EPA cannot justify categorizing continuing natural processes that might reasonably be expected to affect repository performance as "accident conditions" (unlike less probable, more catastrophic events, the effects of which would typically be evaluated during the licensing process). However, for the purposes of the management standards in subpart A, Yucca Mountain is indeed an operating system, just as are other present-day facilities handling radioactive materials. Relative to the disposal standards in subpart B, the Yucca Mountain disposal system is a passive system and has not been confused with an operating system. For exactly this reason, EPA recommends that "reasonable expectation" be the minimum level of proof used, which allows the NRC to take into account the inherently large uncertainties that will accompany the performance assessments for Yucca Mountain. (The commenter should note that the subpart A standards are not written using "reasonable expectation", but as a standard for a typical currently active operating facility.) EPA's standard takes into account the known natural characteristics of the Yucca Mountain region that can be predicted to endure, possibly with some boundable variation. In addition, the dose standard represents a level that EPA believes is protective for lifetime exposures to the RMEI, and is consistent with its other actions related to radioactive waste management, including those covering more "routine" operations (such as air emissions under radionuclide NESHAPs). See the discussion of comments on the level of protection in Section 4 of this document.

The coordination process conducted by the OMB in accordance with Executive Order 12866 permits the President to monitor and ensure the consistency of agency actions throughout the

Executive Branch. This process has been recognized as necessary and vital to the administration of the Federal government, and has been upheld by numerous court decisions [see, e.g., *Sierra Club v. Costle*, 657 F.2d 298, 405-06 (D.C. Cir. 1981); *State of New Mexico v. EPA*, 114 F.3d 290, 295 (D.C. Cir. 1997)]. With respect to the Yucca Mountain public health and safety standard, records summarizing all meetings throughout the OMB review process, and any substantive changes to either the draft proposed or draft final rules, have been placed in the rulemaking docket, as required by Executive Order 12866.

Issue H: EPA is the appropriate Agency to set the radiation protection standards.

1. We feel that EPA is much better able to protect the public's health and the environment than the NRC. (3)

2. I want to offer a strong support to EPA in all of its standards settings endeavors. We really feel that this is the only organization that takes quite seriously its responsibility for protection not only of public health but also of the environment. (28)

3. Although there have been some debate of utilizing the NRC to set protection standards, we maintain that this will compromise the integrity of the process. This is EPA's responsibility, and they should continue to serve this function. (68)

4. I am very happy to have this group, protective of the public and environmental sense, sort of act as a salutary force on what some gung ho scientists may be projecting, including some of the professors who have advanced in academia to a point where they're out of touch, actually, with their students. (95)

5. It's my opinion that the EPA is the natural agency to establish exposure standards for the public, and that agency, through its vast experience and real time data, is the best organization to establish this important standard for this program. (96)

6. The EPA has the regulatory responsibility we feel to develop, implement and monitor environmental protection standards. Utilizing the NRC to set protection standards we feel would compromise the integrity of this process. This is the EPA's responsibility, and they should continue to serve this function. (116)

7. We do however support EPA's authority to set standards for Yucca Mountain and the requirement of a ground-water specific standard for use in designing and licensing the Yucca Mountain repository. (131)

8. It seems to me the impression is the Nuclear Regulatory Commission is looking for cost saving ways from the Department of Energy when we're going to have this massive material that's going to be radioactive for 100,000 years, and it's not a time to be in my opinion, or at least speaking on behalf of my elected officials, to be cutting corners on the standard. (140)

9. I support EPA as the standard setter for the proposed Yucca Mountain nuclear waste dump, as opposed to replacing EPA with the Nuclear Regulatory Commission (NRC). (185)

10. The EPA should set the standards for Yucca Mountain because it would better protect the health and safety of the public and the environment. (192)

11. The Mayor and the City Council of Las Vegas understand EPA's responsibility in establishing these standards and disagree strongly with the Congressional attempt to have the Nuclear Regulatory Commission establish a lesser standard which is inappropriate and will not provide the level of public health and safety that would be established under the EPA rule. (204)

12. In all the options offered, the proposed standards are very conservatively protective of public health and safety. (458)

13. EPA has probably made a reasonable compromise, given all the existing pressures. While the end result may still be standards that are excessively stringent, they are an improvement over some of the NAS proposals. (475)

14. This comment is to support the U.S. Environmental Protection Agency (EPA) as the standard setter for Yucca Mountain. (404)

15. We want the EPA to set standards for Yucca Mountain or for any nuclear waste repository. (408)

16. We much prefer EPA as the standard setter for Yucca Mountain than the U.S. Nuclear Regulatory Commission (NRC). (426)

17. We support EPA's proposed rule because the radiation standards are consistent with those already adopted and approved by EPA for other repositories, including the Waste Isolation Pilot Project in New Mexico. (528)

18. We agree with consistency in rulemaking and urge EPA to move forward with amending 40 CFR 190 and 191 to reference CEDE methodology. (761)

19. We support EPA's choice of a risk-based individual dose standard expressed as an annual CEDE limit. . . However, we do not agree with all aspects of EPA's specific implementation of the standard. (762)

20. We commend the EPA for stepping forward and proposing environmental radiation protection standards for Yucca Mountain and for directly soliciting input of affected Indian Tribes. (789)

Issue I: NRC is the appropriate agency to set the standard.

1. EPA has seen the comments on the proposed rule provided by the NRC and support the positions taken by the NRC. We have trust that the NRC has the expertise, experience, and charter to properly license a repository facility that will protect public health and safety and the environment. (253)

2. As the federal agency principally and historically responsible for radiation protection, we believe the NRC is qualified to determine adequate radiation standards for the repository. (493)

Response to Issues H through I:

Pursuant to Section 801 of the EnPA, EPA must promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at Yucca Mountain. The NRC must utilize the EPA standards in its licensing action for the Yucca Mountain repository.

Issue J: Sufficient notification of the public hearings was not given.

1. I'm saddened or a little disappointed, perhaps, that the notice of the extension of this session into this evening was, perhaps, not as widely disseminated as was possible. (76)

2. First, I would like to say that there's a real problem with people getting to the hearings. You may have noticed that. We have hearings going all over the country and all over the State of Nevada. . . There are county officials and representatives of other citizen groups who just had to make the choice and could not make it here, and they are being encouraged to submit written comments. (103)

Response to Issue J:

Because of the importance of public involvement in this issue, EPA makes every effort to inform the public of opportunities to obtain information or provide comment, and to provide adequate notice of upcoming events. EPA compiled an extensive mailing list of interested parties and provided up-to-date information through the EPA Web page and a telephone hotline. EPA requested that members of the public who wished to speak at the hearings register in advance, and very few people did so. There may be occasions in which a decision is made on short notice to extend a hearing, and it may not be possible to ensure that every interested person is informed. It’s unfortunate that the schedule is inconvenient for some people, but EPA is required to announce hearing dates well in advance.

Issue K: EPA is not protecting Nevadans at the same level as WIPP/Other Radiation Regulations. (430)

1. How can, or why would, Nevadans be less deserving than the New Mexicans for protection, and so why would there be a difference between the point of compliance between Yucca Mountain and WIPP? (12)

2. In many respects the alternative presented in the proposed rule would be less protective of human health and the environment than those applied to WIPP, and appear to be responsive to the uncertainties associated with the capabilities of the Yucca Mountain site to safely isolate high-level radioactive waste. (456)

3. I am even more perplexed as to why the EPA would want to lower some of its radiation standards in the case of Yucca Mountain, considering the controversy and risk now associated with natural geological disposal. Due to the potentially enormous gravity of a high level radioactive waste leak, it would seem to be the EPA's obligation to hold the Yucca Mountain repository to at least, if not more, stringent standards than it has used in the past to regulate radiation. (210)

4. Recognizing that this performance goal is probably unattainable at Yucca Mountain, it becomes even more important that the safety standards for this site be at a minimum as stringent as and consistent with, other applicable radiation protection standards. That would mean that the, standard for Yucca Mountain must be the same as that for the WIPP repository including a 15 mrem annual individual dose exposure from all sources. The standard should include a ground-water protection standard equivalent to the four mrem annual individual dose set by the Safe Drinking Water Act. The boundary for the controlled area applied under the WIPP standard should be no farther than five kilometers which would provide adequate protection to residents living in the Amargosa Valley, within 20 miles of Yucca Mountain. (424)

5. The standards for protection of the public and the environment otherwise required by DOE, NRC, and U.S. EPA are not being applied to Yucca Mountain. (760)

Response to Issue K:

The EnPA explicitly requires that EPA promulgate public health and safety standards that apply specifically to the Yucca Mountain repository. In doing so, EPA evaluated information describing local population patterns, land and water usage, and the geologic and hydrogeologic characteristics in the Yucca Mountain region. EPA's standard incorporates reasonable assumptions regarding the future development and behavior of Yucca Mountain. Based on these reasonable assumptions, EPA concluded that there are unlikely to be significant permanent populations or extensive water demand much closer to the repository than at present because of the difficult terrain and the fact that, as one moves closer to the repository, the ground water becomes much less accessible (see Chapters 7 and 8 and Appendix VI of the BID). EPA's proposed dose standard represents a level that it believes is protective for lifetime exposures to

members of the public and is consistent with its other actions related to radioactive waste management.

The WIPP, however, must comply with EPA's generally applicable standards in 40 CFR part 191. These standards are not site-specific and potentially apply to sites with a range of characteristics throughout the United States (see 40 C.F.R. §§ 191.01, 191.11, 191.21). The provisions of these standards (e.g., definition of controlled area, assurance requirements, release limits) are intended to protect future populations that might be able to locate fairly close to the repository, while ensuring, to the extent possible, that the site will perform adequately. These specific provisions may not be necessary at Yucca Mountain (e.g., the release limits in 40 CFR part 191 were included to protect populations, while the conditions at Yucca Mountain are such that the individual protection and ground-water standards are sufficient). Note that the WIPP site would be much more accessible for future settlements than Yucca Mountain (and, in fact, there are currently permanent residents at the boundary of the WIPP controlled area). The individual dose standard proposed for Yucca Mountain is identical to that applied to WIPP (15 mrem annual committed effective dose equivalent from "all potential pathways from the disposal system"), as are the ground-water standards.

Issue L: EPA's standard should consider the cumulative/additive impact of NTS and other existing sources of contamination. (564)

1. Yucca Mountain does not exist in a vacuum out there. The Nevada Test Site is right there. The low-level nuclear dump is right there. . . All of these multiple exposures should be considered in a connected way, and not in isolation from each other. (14)

2. [T]here is a concern about overall population dose that does not seem to have been given due consideration. The produce of the Amargosa Valley already ends up in the Los Angeles markets, and again, given the potential for climate change, for alterations of land use, that could become a more significant factor, particularly when we add in the anticipated additional doses from deregulated materials that may be recycled into consumer products over time, and many other sources of ionizing radiation, and alternatively, other contaminants. (36)

3. We have a certain amount of background exposure. It's higher than many parts of the country. And my initial question is, "Why make it worse? Why allow it to be worse?". . . It may not be statistically significant, but it's significant to us to create a certain amount of additional concern. (63)

4. Another major concern is that the Yucca Mountain program is being treated as an isolated project without considering that it should be evaluated along with other issues associated with the Nevada Test Site and contamination. (115)

5. [T]he county feels very strongly that all federal decision makers must take into account the cumulative impacts which the county and its residents have already experienced from fifty some years of weapons testing and nuclear waste disposal activities on the Nevada Test Site (NTS). . . the policy of Nye County is that no additional radiological burden should be imposed upon the public, now or in the future. (300)

6. [T]here can be no acceptable justification for the exclusion of pollutants found at the adjoining Nevada Test Site and Nellis Air Force Range from the calculations of doses relative to Yucca Mountain. (357)

7. Cumulative effects from multiple sources received over an individual lifetime of exposures must be taken into account in addition to annual doses. (359)

8. The individual protection standard can not solely consider contamination from Yucca Mountain, but, also must consider the cumulative affects of underground weapons testing. The individual protection standard should be applied to and must consider all potential contamination streams. (499)

Response to Issue L:

EPA recognizes that there are several potential sources of radionuclide contamination in the Yucca Mountain area besides the proposed repository and the concern this may cause among residents of Southern Nevada. The NTS has been subjected to both above and belowground testing of nuclear weapons, and DOE has also disposed of significant amounts of low-level and TRU waste at the site. The now-closed Beatty commercial low-level waste disposal site is located west of Yucca Mountain. The most likely transport path of contaminants from these sites would be through ground water. The available information suggests that the same ground water could provide transport for radionuclides from Yucca Mountain and affect the same population(s) (see Chapter 7 of the BID). There may also be significant potential for exposure to radioactivity from natural sources in the area.

DOE provides an estimate of the total effect of contamination at these locations in Section 8.3.2 of its DEIS. The greatest inventory of radionuclides is present in soil at NTS as a result of nuclear weapons testing. Using several conservative assumptions (total inventory available for transport, all transport along the same flow path serving Yucca Mountain, limited dilution), DOE estimates that the maximum potential dose over 10,000 years would be approximately 0.2 mrem/year. Since other activities at NTS and Beatty represent a much smaller radionuclide inventory, exposures from those sources would be a fraction of that from weapons-related radionuclides. DOE believes that a more rigorous analysis would result in even lower estimates.

EPA's mandate is to set standards that apply to activities at the Yucca Mountain repository, not to quantify potential exposures from these other already-existing sources. Moreover, the peak doses from these sources would not necessarily correlate with those from the repository. For example, exposures from low-level waste operations would be expected to peak after a few

hundred years, while the expected peak doses from Yucca Mountain are expected significantly later.

In addition, EPA's standard is consistent with existing international guidelines on radiation exposure, which recommend individual limits on non-occupational exposures from non-natural sources (excluding accidents and medical procedures). These guidelines recommend allocating a fraction of the overall limit to any particular activity precisely in order to account for multiple potential sources. On the question of population doses, EPA has used reasonable assumptions regarding the future population of the Yucca Mountain region and the resultant demand on ground water in characterizing the RMEI. Any member of a more distant population exposed solely through ingestion of produce would be expected to receive doses significantly smaller than the RMEI. In addition, as stated on page 46991 of the proposal, the limited potential for dilution of ground water at Yucca Mountain is one reason it is not necessary to include the type of population-protection requirement included in 40 CFR part 191. Part 191 used a model that included an aquifer emptying into a river and eventually reaching an ocean. Such a mechanism for exposing large populations to small amounts of radiation does not exist at Yucca Mountain.

Issue M: Transportation of SNF/HLW is not safe/must be better regulated than current.

1. God forbid DOT should do the transport after their horrible record with the chemical industry, two hundred and fifty thousand plant accidents and two hundred and sixty thousand on the roads from 1987 to 1996, and they are not indemnified, not even for five hundred and fifty million. So this is terrifying. (42)

2. Our nonexistent highways and railroad trains would be a hundred feet long by ten by twelve. It is absurd. The trucks -- eighty-two thousand pounds is allowed in Nevada. And these trucks are a hundred and twenty tons. The canister, from what I have seen, is a hundred and twenty-five thousand pounds. So they way exceed anything that you could possibly have. (48)

3. Now, how can you possibly have trucks going on any highways, fifteen thousand to thirty miles an hour or trains doing the same thing without an accident? And this is not talked about either. I think it's of major importance. (49)

4. When your containers are transported, your truck drivers have a little badge that says they're only allowed to be exposed to the load for a certain amount of time. That tells me you're transporting leaky containers. (64)

5. One glaring case in point, there is a map on -- I think it's page S-28. Please don't hold me to the particular page. There's a nice little transport route from Jean to up this direction. And it looks like a great route if you don't know the area. If you do know the area, you know that Pahrump is significantly missing from that map, and the route goes right through Pahrump. (66)

6. The risk from the transport of waste for the immediate future offers a greater potential risk for Nevada citizens. (72)

7. EPA and the NRC as regulatory agencies need to ensure that the public is protected from the potential large number of shipments of nuclear waste that will be transported throughout the nation should Yucca Mountain open as a repository. (123)

8. So as a Kansas Citizen, as a citizen, in general, of the country, I would be very concerned about that going on and I would have to support Ms. Drey in her suggestion that none of this stuff should be moved, especially through our cities and through populated areas along our interstate highways. (156)

9. Mineral County would like to have a separate standard for transporting the radioactive nuclear waste. (199)

10. I just sent to Senator Reid a proposition for emergency medicine for Nye County. . .We have no help here any which way, really, no facilities. (43)

11. There is no way anyone would feel comfortable living under the constant threat of getting cancer from extra radiation given off by the train or accidents. (505)

12. [T]he Shoshone-Paiute Tribes hereby demand that nuclear waste destined for the proposed Yucca Mountain Repository, not be transported through the Duck Valley Indian Reservation on Nevada State Highway 225 and Idaho State Highway 51. (781)

Response to Issue M:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. The EnPA does not separately provide EPA with authority to regulate transportation of SNF and HLW outside the Yucca Mountain site. Transportation of radioactive materials is generally regulated by NRC, DOE, and/or the DOT. DOE has prepared a DEIS that includes information related to transportation of SNF and HLW to Yucca Mountain.

Issue N: Yucca Mountain is not a safe site/cannot be made safe/cannot be corrected.

1. If you look at the Yucca Mountain project as it's described today in the Environmental Impact Statement and other documents, it becomes clear that it is designed to leak. The only question is when will the leaks begin? Another question is how fast will the leaks occur? Another question is how fast or how soon people in this valley begin to become exposed? That's not the people's conception of safety. (51)

2. If Yucca Mountain isn't safe, this is one problem we can't correct. If our water is polluted, we can't grow our crops and we can't raise our children and we don't have a future. And all of us here have worked hard for that future, and we want to make sure that everything is done properly and it's done safely.

And if there are minor problems which, in the future, might cause problems to our generations down the line, however minor they may be, I don't want to see the Yucca Mountain come in. (60)

3. [O]nce the project gets started, if there were found to be leaks that impacted this area, then, aside from having state limits, what would happen? (75)

4. I am opposed to shipping the irradiated fuel rods from over 100 nuclear reactors on the highways and railways of the United States out to one location, especially to a seismically-active site where in the past 20 years there have been over 600 earthquakes of greater magnitude 2.5 within a 50 mile radius. (147)

5. How can we keep 300 generations of our descendants away from these lethal wastes? (154)

6. [I]t is unlikely that the Yucca Mountain site will provide a safe repository for geologic nuclear waste isolation as required by the guidelines of the Nuclear Waste Policy Act. (423)

7. The selection of Yucca Mountain as a dumpsite for high-level radioactive waste is an egregious error that will threaten the coming generations for with impure air and water poisoned by radioactive waste. (450)

Response to Issue N:

The purpose of the EPA standard is to ensure that any potential releases from the Yucca Mountain repository do not result in unacceptably high exposures to affected populations. EPA's standard makes no judgment regarding the suitability of the Yucca Mountain site. The final decision on the suitability of the site has yet to be made.

Regarding the presumed safety of the site, it is standard practice in radioactive waste disposal to conduct a *performance assessment*. A performance assessment is an analysis intended to indicate how the disposal facility will perform over hundreds or thousands of years, the time that is necessary to isolate long-lived radionuclides. Parameters can be varied to see how the results change or how the facility would perform over a range of conditions. Facility designers use this information to predict whether the facility can meet the applicable environmental standards or whether some part of the facility needs to be improved. Given the long time frames involved, there can be areas of significant uncertainty, so performance assessments generally select parameters that are somewhat conservative (but not the absolute "worst case"). This includes assuming some release of radioactivity, so that the most probable routes of transport through the surrounding environment can be examined.

Issue O: Consider other alternatives to waste disposal/current proposed technologies.

1. The equipment is available to clean up these things. This whole thing can be stopped, and it can be reprocessed and transmuted. (44)

2. The other thing that the EPA, I think, needs to get into, is [that] this so-called waste is a really valuable resource if properly handled by standard technology. It'll generate seventy-two billion dollars worth of power at a very nominal cost. (91)

3. I believe this high level, lethally high level radioactive waste should be kept on site at the nuclear power plant at which it was generated until a safe technology has been developed to neutralize it, to make it not radioactive. (148)

4. I hope the EPA will have the opportunity to question the effectiveness of borosilicate glass; that is, the Nuclear Regulatory Commission's reliance on vitrification as a technology to solidify high level radioactive waste sludges and liquids. (152)

5. Consider sending nuclear waste into space! (454)

6. How can EPA get your organization to show the trillionaires who own the nuclear power plants how to make money? By helping this powerful group can EPA convince them that Y.M. 1 & 2 are not acceptable analogs? How can you assure this group that transmutation, recycling etc. will ensure their continued prosperity? (485)

7. All states should share the burden equally for storing nuclear waste because it will keep people tuned into the serious problems that the nuclear industries create. Only when people's personal lives are close to this deadly waste will the less toxic energy options be developed even though we are told they aren't economical. (506)

8. Keep this waste <u>above ground</u> in the state where each was created. Then each state should guard, monitor, and re-cask the waste forever. (540)

9. [W]e feel that an assessment of the risks of opening a Yucca Mountain repository always should be considered in the context of risks associated with other choices for disposal or storage of the waste. (553)

<u>Response to Issue O:</u>

Pursuant to the EnPA, EPA is authorized to promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. The EnPA does not authorize EPA to consider how the risks from the Yucca Mountain repository compare to other management options (or to pass judgment on the specific technologies employed at the repository). There may in fact be alternatives that are now or will in the future be generally preferred over disposal in a geologic repository, either because of technological advances or as a result of future public policy choices.

Issue P: EPA must implement the recommendations of the NAS into the standard.

1. Wherever NAS has made a definitive determination regarding the technical basis for the standard, EPA is bound to apply that decision in its rulemaking.

It is, however, apparent that there were a number of areas (such as the time of compliance) where NAS conceded that there might be policy reasons for not following its technical recommendations and, hence, was not definitive. It is therefore appropriate that, in such instances, EPA can deviate from the NAS recommendations provided there is a public health and safety policy reason for doing so. (239)

2. EPA's argument is strictly one of policy and exaggerates the impact of the NAS Report on its rulemaking authority and its duty to protect the public health and safety. Applying the NAS findings and recommendations, as required by statute, would not diminish or infringe upon the Agency's authority to promulgate rules governing radiation protection at Yucca Mountain, nor would it preclude meaningful public comment thereon. Contrary to the suggestion made by the EPA in the SOC for the proposed rule, the NAS has not attempted to assume the EPA's standard-setting responsibility, but rather has provided, as directed by Congress, the scientific basis that should bound that effort. Therefore, applying the dictates of the APA, the EPA's proposed rulemaking is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; exceeds the EPA's statutory jurisdiction, authority, or limitations; and is unsupported by reasoned decision making. (275)

3. IEER believes that the EPA must treat the TBYMS report as authoritative unless:

> (1) there was an internal disagreement on the panel, in which case the EPA must exercise its own well-considered scientific judgement;
>
> (2) there are clear scientific, environmental or health protection grounds to reject the TBYMS report's analysis or recommendations and adopt a different approach;
>
> (3) or the TBYMS report did not take into account certain health or environmental factors, thereby leaving open the door for the EPA to use its own scientific judgement. (280)

4. EPA's proposed standard is not consistent with the National Academy of Sciences' (NAS) findings and recommendations in this report, and the proposed separate ground-water standard is specifically not recommended by the NAS. (494)

Issue Q: EPA is not bound to implement the recommendations of the NAS into the standard.

1. EPA remains the agency that was directed by the Congress to promulgate these dose limits, and the limits must first and foremost be protective of public health and the environment,

consonant with but not overridden by findings and recommendations in the Congressionally mandated report of the National Academy of Sciences. (352)

2. [We] agree with the EPA's position that the NAS recommendations cannot be binding on the Agency's independent rulemaking authority. (455)

3. I think it is good that EPA is not letting NAS dictate outcomes, but is using their views as advisory. (542)

4. We endorse EPA's departure from NAS' findings and recommendations on the compliance period. (766)

Response to Issues P through Q:

As set forth in the preamble to the proposed rule, it is clear that the intent of the EnPA is that the NAS assume a special role in advising EPA on technical matters in this rulemaking (64 *FR* 46981-46983). Pursuant to that statutory mandate, EPA has given the NAS Report special weight in developing its standard; however, there is no basis for the conclusion that the EnPA intended to require that EPA adopt the NAS' findings or recommendations directly into the standard without question or consideration. In addition, another factor to consider is that more than four years elapsed between publication of the NAS Report and the proposed rule. A tremendous amount of data has been collected in that time, resulting in greater understanding of the site's characteristics and the capabilities of the disposal technology and computer models. Whether the NAS' broad conclusions would change is not clear; however, it does seem clear that there is additional information to incorporate into specific aspects of the standard.

Issue R: EPA should not issue guidelines on expert elicitation.

1. We generally agree with EPA's views on expert elicitation expressed on Page 46997. However, setting guidelines in this area is an implementation issue that should be left up to the NRC. (247)

2. Expert elicitation should not be used to estimate parameters using Delphi surveys or similar techniques. This restriction should be specified in the EPA standard because Delphi type of techniques can create more problems than they solve and, moreover, exclude the public from vital areas of debate. (290)

3. Any guidelines for the use of expert opinion should be set by the NRC, the only agency responsible for the conduct of the licensing process itself. (312)

4. Use of expert elicitation by NRC or DOE will be subject to the public process used in the licensing proceeding. A separate EPA guideline would be inappropriate. (329)

5. It is not appropriate for the EPA to set guidelines for use of expert elicitation in the licensing process. (347)

6. The NRC's NUREG-15G3, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive waste Program," provides an acceptable functional guide, if applied as intended. It would not be productive to reopen this issue for consideration when the basic principles and methods have already been explored and the existing guidance is seen as reasonable. (376)

7. It is unnecessary for EPA to set such guidelines in this standard, because of the fact that NRC has had such guidelines in place since 1996 (NUREG 1563) and the fact that DOE has used NRC's guidelines since that time to conduct several elicitations of expert opinion. (575)

8. It is unnecessary for the EPA to set guidelines for the use of expert opinion in its standards for Yucca Mountain. The NRC's licensing requirements and licensing process will govern the DOE's use of expert opinion in the development of its licensing case for a repository at Yucca Mountain. (606)

9. EPA should not include specific requirements for expert elicitation. (651)

10. We do not consider it appropriate for EPA to set guidelines for the use of expert opinion in this standard. We consider that the NRC will appropriately establish the use of expert opinion during the licensing process. (768)

Response to Issue R:

The comments EPA received were uniformly opposed to EPA's setting requirements to address expert opinion. There was general agreement among commenters that it would be more appropriate for NRC to use the licensing process to address any requirements relating to expert elicitation. Some commenters referred to NRC's existing NUREG-1563 ("Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program"), and to the fact that DOE has used it on several occasions. These comments reinforced our opinion that issuing requirements would be an implementation function better left to NRC.

Issue S: The Yucca Mountain site should not be used for SNF/HLW disposal.

1. [T]he Ely Shoshone Tribe hereby establishes and records its disfavor for the proposed Yucca Mountain Repository facilities for reasons as indicated in this resolution. The Tribe also believes that the overall negative environmental impacts must be minimized to the greatest extent possible. (315)

2. [T]he Elko Band Council recognized that our Tribal membership will be affected in all aspects of the Yucca Mountain Repository and strongly opposes the Yucca Mountain Repository for Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada

and is against any and all nuclear waste that may be transported through the Elko Indian Colonies in Elko, Nevada. (754)

3. [T]he Elko Band Council hereby establishes and records its disfavor for the Yucca Mountain facilities for reasons indicated in this resolution. This Council believes that the overall negative environmental impacts must be minimized to the greatest extent possible. (756)

4. [T]he Shoshone-Paiute Tribes hereby establish and record its disfavor for the Yucca Mountain facilities. The Tribes also believe that the overall negative environmental impacts must be minimized to the greatest extent possible. (782)

5. The fact the Washoe Tribe is submitting comments should in no way be construed to mean that the Washoe Tribe supports the placement of a nuclear waste repository at Yucca Mountain. (787)

Response to Issue S:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. EPA does not have authority to regulate transportation of SNF and HLW outside the Yucca Mountain site or evaluate the impacts of alternative management, nor will it make the final decision on the suitability of the Yucca Mountain site. The final decision has not yet been made, and will be made by other agencies.

Issue T: No release of radioactivity is acceptable - EPA's standard must reflect this.

1. The whole idea of a repository is to ISOLATE radionuclides from the environment for the required period of time. Simply DELAYING the off-site migration of radionuclides for an arbitrary period of time that is 90,000 to 1,000,000 YEARS too short smacks of the same dementia that is infecting Murkowski and the nuclear thugs at NRC. (406)

2. To preserve our own collective integrity during our time now on Earth and to be responsible to our children and posterity for untold thousands of generations, repository standards must require natural barriers to allow zero release of radioactivity. (407)

3. What we strongly urge is that you work toward total isolation of the nuclear waste from the environment for the totality of its hazardous radioactive life with NO release of radioactivity! (411)

4. Application – for purposes of repository design – of the EPA standard, or any standard that allows the repository to release *any* radioactive material from the facility, constitutes Federal and affected-agency acquiescence to the construction of a "leaky" repository. (487)

Response to Issue T:

EPA's dose standard represents a level that it believes is protective for members of the public, and is consistent with its other actions related to radioactive waste management. The standard is based on an appropriate level of public health protection in the Yucca Mountain region, not on the contents of the repository. EPA also has a responsibility to set a standard that can be implemented, and with which it can be determined if the facility complies. While an absolute certainty of zero release is an ideal goal, it is likely to be extraordinarily costly to meet, impossible to demonstrate with reasonable expectation, and may preclude society from addressing more threatening health conditions. Regarding the use of natural barriers, they do influence the suitability of a site. However, natural barriers are subject to the same long-term stresses as engineered barriers. Their effectiveness can be compromised by weathering, seismic activity, volcanic activity, or climatic changes.

Issue U: Geologic disposal of SNF and HLW is underground injection.

1. EPA's argument that geologic disposal of high-level radioactive wastes is not a form of underground injection is contrary to established case law. (443)

Issue V: Geologic disposal of SNF and HLW is not underground injection.

1. [E]mplacement of HLW and SNF in a geologic repository would not constitute "underground injection" and the UIC Class-IV ban does not apply to underground repositories. (639)

Response to Issues U through V:

EPA described at some length its reasoning in not classifying geologic disposal as underground injection (pp. 47004-47007 of the proposal). Without reproducing this extensive discussion, EPA's position is that disposal of SNF and HLW in the Yucca Mountain repository is not underground injection because: (1) the extensive series of engineered cavities at Yucca Mountain is not a "well;" (2) mechanical transport and ordered emplacement of waste packages within those cavities is not "injection;" and (3) containerized radioactive waste is not a "fluid" that "flows or moves." The commentor offers no compelling reason for EPA to change that interpretation. The case law referred to is *NRDC v. EPA*, 824 F.2d, in which the commentor states "the Court resolved this very issue [underground injection]." EPA disagrees that the issue was resolved (see p. 47004, col. 1 of the proposal).

Issue W: Spent nuclear fuel must be moved from its present locations as soon as possible.

1. We want the repository built in a safe, economic and expedient manner as required by the Nuclear Waste Policy Act, and whatever other laws and regulations will apply. We want the waste moved from its present locations as soon as possible. (17)

2. I distrust the Federal government to handle really important issues affecting my life. I distrust the motivations of the EPA in their management of this country's environmental issues. I distrust EVEN MORE motivated individuals and groups who could gain access to SNF and HLW from its current repositories around the country. These individuals and groups may use SNF and HLW to contaminate the world in which I and my family live. (158)

3. The NTS is already a "nuclear wasteland" which needs mitigation and security. The NTS is a better site for SNF and HLW than the populated and "wetter" regions of the east and south where these are currently "temporarily" stored. (159)

4. Our message is simple: the repository must be built in a safe, economic and expedient manner as required by the Nuclear Waste Policy Act and whatever other laws and regulations that apply. The waste must be moved from its present locations – which were never intended to store the material indefinitely – as soon as possible. (254)

5. Numerous stakeholders have proposed that allowing indefinite storage of spent nuclear fuel at operating and decommissioned facilities is an option. However, the HPS believes that such an option avoids, rather than offers a solution to the HLW disposal issue. In addition, it ignores the legal obligation of the federal government to take possession of, and provide for safely disposing of spent nuclear fuel, not only from nuclear power reactors, but also from our national defense program. (419)

6. Or should it [the base case against which Yucca health impacts would be assessed] be a case in which the waste is held in indefinite surface storage at many sites? Each of these waste-storage sites is much closer to a large population center and more vulnerable to human intrusion than any acceptable permanent geological repository would be. The reality is the latter, and perhaps the calculations and projections required for licensing a nuclear waste repository should reflect this reality. (474)

Response to Issue W:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. EPA does not have the authority, nor is it EPA's role, to resolve the significant differences of opinion regarding the appropriate location(s) for disposing spent nuclear fuel and high level radioactive wastes.

Issue X: It is unrealistic to rely on untested canisters for millions of years.

1. We are not going to have one repository, but two that cost fifty billion dollars. The canister is ten, eleven to twenty to twenty-two. Canisters will be a hundred and twenty billion dollars. Because these things cost three hundred and fifty to five hundred thousand apiece. Can you afford it? (47)

2. And in Yucca Mountain where you have waste that has a nine hundred million year half-life and we're looking at several billion years before that thing is safe to dig into or walk around and so forth, I think that having [a canister] that will split up in two to six months is probably not what we want. (87)

3. And is there a disposal container design capable of what you expect? I don't think so. Nobody knows. None has been built or tested at all, much less long-term. (537)

4. Has a drip shield ever been tested?....And what holds the casks? Will it be on a pedestal of ceramic – heavy metal? (538)

Response to Issue X:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. EPA is not authorized to design, construct, test, or approve the waste package. The package will be one component of an overall system that will have to meet EPA's standard, among other specifications. The DOE/VA has more information about the various materials and configurations under consideration for the waste package.

Issue Y: Current monitoring related to NTS is inadequate.

1. [M]onitoring is not being done properly, and you are not getting the right numbers. (46)

2. We have in Pahrump a monitor that's right next to the community center. I was talking to the guy that runs it, and he laughed and said, "It's a waste of time. Never found any radioactivity ever". . . all of our dirt around here has at least a half a picocurie of plutonium per gram in it. And while that may not be a problem, the instrument not being able to detect it is a problem. (89)

Response to Issue Y:

The type, location, and frequency of monitoring during the repository's operating period and after closure has yet to be determined.

Issue Z: How is EPA going to help the local community?

1. And all these things that they promised in the beginning has not resulted. . .we would like to know what kind of help you're going to give our communities to develop things. We have to lose a lot of things. . .We need roads. We need park systems. All these things, I know you guys can help develop these things. (61)

Response to Issue Z:

The concern over the impact the Yucca Mountain repository will have on such things as infrastructure and property values is understandable. It is also reasonable to expect that any promises made to local residents on behalf of the United States Government will be fulfilled. Unfortunately, these considerations are beyond the scope of EPA's standard-setting role. EPA is not in a position to give assurances to the communities in the Yucca Mountain region, and is not aware of assurances made by other government agencies.

Issue AA: The Yucca Mountain repository will contain hazardous waste in violation of RCRA

1. I'm particularly concerned about the chromium, molybdenum, nickel. And continue, in YMP and risk assessment environmental statement, they do not comply with EPA rule and regulation such as RCRA. You cannot show me. It's a violation of the law. (101)

Response to Issue AA:

EPA does not believe that there is any basis to conjecture that the repository at Yucca Mountain would operate in violation of the requirements applicable to RCRA hazardous wastes. Section 6001 of the Solid Waste Disposal Act requires that any Federal department or agency that is engaged in any activity that results or may result in the disposal or management of solid waste or hazardous waste is subject to, and must comply with, all Federal, State, Interstate, and Local requirements respecting the control and abatement of solid waste, or hazardous waste disposal and management [42 U.S.C. § 6961(a)]. EPA has no reason to believe that DOE will not comply with this express statutory obligation should solid or hazardous wastes be disposed of or managed in the Yucca Mountain repository.

Issue BB: There has been enough study - Yucca should be opened now.

1. After 20 years of investigation and deliberation the concept such as Yucca Mountain should be implemented without further delay. (157)

Response to Issue BB:

The final decision regarding the suitability of the Yucca Mountain site has not yet been made. The process leading up to that decision was established by Congress through the NWPA, the NWPAA, and the EnPA. Even if Yucca Mountain had received final approval, there is still significant construction work to be done on the repository and a license must be issued.

Issue CC: EPA has insufficient information on the waste to issue a standard.

1. You say "non-solid waste forms would not be allowed to be stored or disposed of in Yucca." That makes no sense, for that is certainly the result long-term. (533)

2. No low-level waste should be allowed. (534)

3. How on earth can you base any analysis for Yucca Mountain Radiation Standards when you know very little about what the radiation source will really be like when it arrives at the repository? (536)

Response to Issue CC:

The prohibition on liquids is one measure to reduce the stress on the waste package. If liquid waste were accepted, the liquid could come into direct contact and begin to corrode the package from the inside. Whether or not the vitrified waste can maintain its form for long periods and at high temperatures, it will delay any contact with the waste package. LLW would generally be considered to present a much lower hazard than SNF. If "Greater-than-Class C" LLW is to be accepted by the repository, appropriate packaging would have to be used (Greater-than-Class C waste is generally considered not appropriate for typical shallow land burial sites, and is generally recommended for disposal in a geologic repository such as the proposed Yucca Mountain facility). The commentor suggests that it is not wise to put LLW in the repository, as the overall volume of waste that can be disposed is limited; that decision does not rest with EPA. The proposed dose standard represents a level that EPA believes is protective for members of the public, and is consistent with its other actions related to radioactive waste management. The standard is based on an appropriate level of public health protection in the Yucca Mountain region, not on the contents of the repository. The repository system will have to be designed, constructed, and operated so that it meets the EPA standard and the requirements of the facility license.

Issue DD: The Yucca Mountain repository will violate Environmental Justice requirements.

1. Environmental justice will not prevail and that's obvious. (548)

Response to Issue DD:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. The EnPA does not authorize EPA to evaluate alternative sites, or to assess other impacts to local populations. DOE has prepared a DEIS under NEPA, which requires assessment of the cultural and archeological significance of affected sites, among other aspects. The final decision on the suitability of the Yucca Mountain site has not yet been made.

Issue EE: EPA should force DOE to clean up NTS.

1. And if the DOE is not responsible for handling that and the EPA doesn't step into it, how much trust do you think you're getting from the public that you can handle this Yucca Mountain problem, I think, is my point. (90)

Response to Issue EE:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. Whether DOE conducts remediation activities at the NTS is outside the scope of this rulemaking. Nonetheless, EPA notes that the DOE DEIS provides an estimate of the impact of contamination at NTS in its DEIS. Assuming that the entire inventory of radionuclides resulting from nuclear weapons testing is available for transport (excluding the short-lived tritium), that transport would follow the route analyzed for releases from Yucca Mountain, and using conservative dilution factors, DOE estimates that the maximum potential dose from NTS during the 10,000 year compliance period will be roughly 0.2 mrem per year (DEIS, Section 8.3.2). DOE further estimates that the impacts from the GCD and LLW disposal facilities at NTS would be only a fraction of the potential impact from the transport of weapons-related radionuclides.

Issue FF: EPA should apply 40 CFR part 191 subpart A to aboveground storage.

1. We agree with EPA that the EnPA does not provide for the development of such standards, and that application of subpart A of 40 CFR part 191 would not be inappropriate. (240)

Issue GG: EPA should issue a new standard for aboveground storage at Yucca Mountain.

1. A revision of Subpart A of Part 197 to make it the only standard applicable to storage aboveground and in the repository is appropriate because the EnPA directs EPA to develop Yucca Mountain site-specific standards. . . DOE, believes, however, that the dose from storage aboveground should be limited to 25 mrem/year, consistent with NRC's 10 CFR Part 72 and proposed 10 CFR Part 63. Also, revising Subpart A of Part 197 to be the only applicable standard would avoid the need to utilize the older dose methodology of 40 CFR §191.03(a). (647)

Issue HH: NRC's proposed standard is appropriate for the operating period of the repository, when exposures are more likely.

1. We would expect that the more likely risk of radiation exposure at Yucca Mountain is in the "pre-closure" phase of the repository performance. This period covers the 23 year period of emplacing waste packages and performance monitoring for as few as 50 years or as many as 300 years before the repository is sealed. The standards applicable to that period are to be set forth in 10 CFR Part 63 currently pending at the NRC using 25 mrem annual dose limit as the radiation standard. (255)

Response to Issues FF through HH:

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

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

Regarding the likelihood of exposure during the operating period, EPA has not studied whether the probability of an exposure of a member of the public is greater in the pre- or post-closure periods because it is irrelevant to our setting a standard. Our authority under the EnPA is to set public health and safety standards that apply to releases from radioactive material "stored or disposed of in the repository". We have done that by setting the level of protection for both the pre- and post-disposal periods, found in subparts A and B, respectively. The commenter is also correct in stating that NRC has proposed an annual dose limit of 25 mrem that would apply during the pre-closure period. However, under the EnPA, NRC must issue a final 10 CFR part 63 (or amend its final rule) that is consistent with our standards in 40 CFR part 197.

Issue II: The Yucca Mountain repository should remain open so that waste can be retrieved.

1. The only way to ensure that no significant amounts of radioactive material escape the repository is to leave the facility permanently open and perpetually monitored, retaining sufficient handling and clean up facilities on site to retrieve leaking or questionable waste containers, repackage the waste and clean up spills before material can migrate to ground water. (488)

2. The ability to monitor and retrieve the waste, which offers future generations the ability to revisit the licensing decision tens of hundreds of years in the future before a final closure decision is made, is an additional measure of safety that should be taken into account. (554)

Issue JJ: EPA's standard should not be used for design or licensing of the repository.

1. The proposed EPA standard should be applied to the region around Yucca Mountain to provide a level of protection from radiological contaminants similar to that provided to the rest of the nation, however, the Department of Energy and Nuclear Regulatory Commission should not be allowed to utilize the proposed EPA standard for purposes of designing and licensing the repository. (489)

Response to Issues II through JJ:

The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca Mountain. The EnPA does not authorize EPA to direct DOE's operation of the repository. As long as DOE meets the EPA standard applicable to storage of SNF and HLW (i.e., prior to final closure of the facility), there are no constraints from EPA's perspective on how long DOE may keep the repository open to allow waste retrievability. EPA also has no authority to forbid DOE and NRC from using its standard to guide design and licensing of the repository. In fact, it would be impractical to do so, as NRC must be satisfied that the repository will meet all applicable standards, including EPA's, prior to licensing.

There is, however, the consideration that leaving the repository open for long periods after all waste has been emplaced would present an undue burden on future generations. A fundamental tenet of radioactive waste management is that those responsible for generating the waste must bear the burden of managing it. Leaving it for future generations would put the onus on those who received no benefit from the processes that led to the waste being generated. This principle has been expressed by Congress ("...appropriate precautions must be taken to ensure that such waste and spent fuel do not adversely affect the public health and safety and the environment for this and future generations," NWPA, 1982) and by the IAEA ("Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations," Principles of Radioactive Waste Management, IAEA Safety Series No. 111-F, 1995, Docket A-95-12, Item V-A-10).

Issue KK: The status of water rights may not be as EPA stated.

1. While it is true, as stated in the first paragraph, that "the Yucca Mountain site is on several federally controlled areas of land," it is unclear that the "U.S. government is the senior appropriator," although it holds water rights. If this is true, why has the DOE had to seek and obtain water rights from the Nevada State Engineer through allocation hearings? (588)

Response to Issue KK:

Whether or not DOE is the "senior appropriator" of water rights makes no difference to EPA's standard. Nonetheless, the situation appears less clear-cut than characterized in the proposal.

Issue LL: Request for extension of the public comment period.

1. [T]he Federal Register notice for this public hearing only came out on October 1st, and I know that a number of organizations who would otherwise be here are very busy right now. . .an extension of the comment period would be helpful for all of our organizations to do the best job that we can. (11)

2. I think that most of the public has been unaware of, well, perhaps not of the issuance of the draft standard, but of your schedule for hearings and the deadline for comment, I would ask right now that EPA extend the comment period so that those throughout the nation, not just here in Washington, and Las Vegas, but also throughout the entire nation have an opportunity for comment. (27)

3. [W]e also request an extension of the time to submit comments which will ensure that the broad interests of the Western Shoshone Nation are included and considered. (112)

4. We note that submission of comments has been made more difficult due to inability to find a statement of the correct electronic mailing address in either 64 FR 46976 or 53304. We suggest that EPA should have and still should extend its deadline to account for this apparent omission of information. (351)

Response to Issue LL:

EPA's proposed standards for Yucca Mountain were published on August 27, 1999. This began 90-days of public comment on the proposed standard. Notification of the availability of the proposed standards and the opportunity to comment was published in the Federal Register, on the EPA's Yucca Mountain Home Page and on EPA's Yucca Mountain Information Line. EPA believes that the 90-day comment period was sufficient and sufficient notification of the opportunity to comment was given. EPA has received comments on the proposed standard after the close of the comment period on November 26, 1999. These comments were identified as "late" and placed in the official Yucca Mountain docket (Docket A-95-12). In this Response to Comments document, EPA has addressed all comments that were received during the comment period and has made every effort to also respond to any "late" comments.

In response to comment #351, the proposed standard stated that two copies of comments were to be sent to EPA's Central Air Docket (64 *FR* 46976). No electronic address was given for the submission of comments.

Issue MM: EPA should consider all comments equally.

1. And I hope that the public comment that you receive both in written and in oral testimony is weighed equally with any other testimony you may receive from government agencies, industry groups or OMB, NRC, whatever. I think this is a public project. It's public health and safety. It's public money. The public needs to be heard, and they need to have their concerns weighed in a

way that is equal to other comments that are received. (139)

Response to Issue MM:

EPA does consider all comments received on this proposed standard and other standards equally. All written comments and comments received during public hearings, regardless of who has said them, receive consideration. This Response to Comments document addresses all the comments that were received that are relevant to this rulemaking.

Issue NN: EPA needs to improve the quality of the supporting documentation for the proposed rule.

1. We find the 36 page discourse of Supplementary Information published with the Proposed Rule to be difficult for the layperson to comprehend. It does not surprise us to learn that there was very little attendance at the public hearings.(252)

2. EPA needs to do a much better job of describing the various dimensions of this rulemaking and how they relate to one another. Full transparency demands that EPA distinguish between, for example, simplifying assumptions required because certain data are not available, limits imposed by existing models, and decisions EPA is making as a matter of general policy. (437)

Response to Issue NN:

EPA has tried to make the materials for this standard as easy to understand to as many people as possible. For example, we have structured the standard into a question and answer format. We do realize, however, that many of the issues addressed in this standard are highly technical in nature. Any further simplification of these standards could result in unintended interpretations of the standards. For this reason, EPA has developed other documents that are aimed at providing an overview of the issues at Yucca Mountain, EPA's role and process and the role of other agencies.

EPA has also attempted to provide information on our work for Yucca Mountain through many different venues. EPA maintains a web page from which both technical and non-technical documents can be downloaded. We also maintain an information line from which the public can receive updates on the project and request additional information or assistance.

Issue OO: Communication about the proposed standard and the comment process was inadequate and inappropriate.

1. We are completely locked out. We have no internet. We have no e-mail. We have no Federal Register, as you well know, and I've been telling you for years. We are deprived, but we don't have to be deprived. (45)

2. The Newe people, Western Shoshone people, practice an ongoing oral tradition of communication. We have a sophisticated social communication process which do not respond well with US written hearing processes. This includes notification of meetings and proposed radiation standards. (107)

Response to Issue OO:

EPA has attempted to provide alternative methods for communication on work in setting radiation protection standards for Yucca Mountain. EPA recognizes the challenges to communication that may affect the communities surrounding Yucca Mountain. For this reason, EPA has tried to offer varying forms of communication. For example, in addition to the Federal Register and EPA's web site, we have established a toll-free information line. Through this number, a caller can receive updates on our activities and can request information or assistance. For activities like public hearings, EPA advertised in local newspapers and on local television and radio stations, in addition to the Federal Register and the information line.

Issue PP: What costs are associated with EPA standard?

1. Before finalizing this rule, EPA should evaluate the costs and benefits of a 15 mrem versus 25 mrem standard. Lincoln County and the City of Caliente are concerned that EPA will require a standard which carries with it extraordinary costs of compliance while affording little if any tangible public health benefits. (520)

2. Without a cost-benefit analysis this question cannot be answered. What additional public health benefit will result from a 15 mrem versus 25 mrem standard? How much will it cost to attain this incremental increase in public health protection? If the cost of compliance with a 15 mrem standard is high, could Nuclear Waste Funds be spent in other risk minimization activities resulting in greater public health benefit (i.e., reduction of transportation risk). (523)

3. The statement that, "These Agency programs have demonstrated that such protection is scientifically achievable," does not address the relevance of these programs to Yucca Mountain. What is the added level of protection [from a separate ground-water standard] and at what cost? Why would not an appropriate, single, all-pathways standard for Yucca Mountain achieve this goal? (584)

4. The August 1999 economic analysis [that accompanied the proposed rule] seems to be of limited value, because of the lack of cost information on the repository design, which is still evolving, as well as other factors that prevent EPA from providing detailed cost estimates related to the Proposed Rule. Instead, the analysis is qualitative. (796)

5. We believe there should be a clarification of the worst case impact described in page 14 [of the draft economic impact evaluation]. You indicate that if DOE is unable to meet the proposed radiation standards at Yucca Mountain that re-siting may be required and "the costs would be borne by the commercial generators of spent nuclear fuel and the Federal Government." With the

profound political difficulties siting the proposed repository in the site already selected as best suited for a repository, it is hard to imagine re-siting elsewhere at less suitable sites if Yucca Mountain fails to meet the standards. We agree that re-siting is unlikely, but costs for spent nuclear fuel storage and disposal may be paid to the Federal Government by the commercial generators, but those costs are ultimately borne - over $16 billion to date - by the Nation's electric ratepayers. The prospect of them being asked to "re-incur" over two billion dollars should a new site be required would be unfair. (797)

6. We agree that the benefit of eliminating regulatory uncertainty by issuing a standard is tangible, even if not presently measurable. The last sentence on page 13 [of the draft economic impact evaluation] recognizes that the costs of maintaining spent fuel at present reactor sites continues until a repository is built. Those costs include not just the expense of additional, unanticipated on-site storage capacity but the settlement of outstanding claims for damages by many, if not eventually all, of the commercial generators. Although no basis for the estimate of that liability was given, one of the Congressmen in the floor debate of S. 1287 estimated those damages could be $60-80 billion. Even if the settlement costs are one-tenth of that amount, it is a large cost that could have been avoided had the Federal Government fulfilled its legal and contractual obligation in 1998. (798)

Response to PP.1:

The incremental costs for the IPS contained within 40 CFR part 197 have been addressed by EPA as part of its EIA performed for this rulemaking. Briefly, there do not appear to be any incremental costs attributable to EPA's standard as a result of either a 15 or 25 mrem IPS. This assertion can be made on the basis of DOE's performance assessments of the Yucca Mountain disposal system, which show that it, as currently designed, is capable of meeting a 15-mrem level of a standard by a very large margin [see Chapters 3, 4, and 7 of the EIA for Yucca Mountain (Docket A-95-12, Item V-B-2) for a more detailed discussion of this Ano impact@ determination].

Response to PP.2:

A 15-mrem IPS provides a marginal increase in health protection for the RMEI. The protection of the RMEI is an indirect method of providing protection to the public at large. EPA's most recent analyses, embodied in the EIA for Yucca Mountain (Docket A-95-12, Item V-B-2), show that this incremental increase is attainable at no additional cost due to the performance of the Yucca Mountain disposal system, as it is currently designed. Therefore, no additional Nuclear Waste Funds are expended in providing this level of protection.

Response to PP.3:

As described in EPA's most recent analysis of the cost impact of 40 CFR part 197 on the Yucca Mountain disposal system, "Evaluation of Potential Economic Impacts of 40 CFR 197" (Docket A-95-12, Item V-B-2), the level of protection offered by the individual and ground-water standards does not result in an increase in the disposal system's development cost.

A single, all-pathways standard for Yucca Mountain does not achieve the same goal as separate individual and ground-water standards because EPA views the protection of the ground-water resource as a goal separate and apart from the protection of the individual. The protection of ground water is entwined with the issues of: (1) protection of resources for future generations; (2) pollution prevention; and (3) consistency with the SDWA. As such, protection of ground water calls for a separate standard to achieve these goals.

Response to PP.4 through PP.6:

EPA addressed the fact that our draft economic impact evaluation was constrained in its conclusions by both the methodology and available information, by extensively revising it for the final rule. Using information from the most recently available DOE performance assessments, coupled with a review of Yucca Mountain design history, these revisions allowed the case to be made that our 40 CFR part 197 standards (1) have had no influence on the current repository design and (2) have imposed no additional costs on the Yucca Mountain Program. Implicit in this analysis is the argument that our rulemaking will neither result in a re-siting of the repository nor delay waste acceptance (see the Final EIA for 40 CFR 197, Docket A-95-12, Item V-B-2).

In addition, we note that comment 797 misconstrues the current status of the SNF/HLW repository program. The Yucca Mountain site has not been "already selected as best suited for a repository." In fact, it will never be known whether Yucca Mountain is the “best” site from a technical standpoint, simply because other candidate sites were never studied as extensively. Therefore, any conclusions regarding Yucca Mountain’s suitability will be based on its ability to satisfy certain performance objectives, not on whether it is “better” than other sites. As a result, while DOE has determined that the Yucca Mountain site is a viable alternative for location of a SNF/HLW repository (Viability Assessment, Docket A-95-12, Item V-A-5), DOE has not yet determined that Yucca Mountain is well-suited, and will not make a final determination as to whether it is "best suited," as the location for such a repository. DOE is currently characterizing the Yucca Mountain site to determine if it should be recommended as the site for disposal of SNF/HLW. Such determination is expected in 2001.

Issue QQ: The goal of the repository should not be the delay of radionuclide releases: it should be the prevention of such releases.

1. The definition wrongly sets the goal of the geologic repository to be a delay of release of radionuclides rather than waste isolation, which should include a controlled rate of radionuclide release and transport beginning at some time in the future. (125, 126, 504)

2. The definitions of “disposal” and “barrier” inappropriately skew the basic notion of geologic disposal through the use of multiple barriers, not just the natural geology, to accommodate Yucca Mountain’s known inadequacy to isolate waste from the biosphere. This is a fundamental flaw in the proposal. (118, 124, 126, 144, 374)

3. Defining successful disposal by an arbitrary reasonableness standard is an effort to enable licensing of a dump, not a fulfillment of the goal of geologic isolation. (207)

Response to Issue QQ 1-2:

It may be impossible to locate and design a deep geologic repository that provides an absolute guarantee of complete and permanent isolation of the disposed wastes from the environment in perpetuity, solely on the basis of the geologic features of the repository. EPA's definition recognizes this fact, and provides for the maximum protection of public health and the environment. Similarly, our generally applicable regulations at 191.14(d) require utilization of engineered barriers and do not assume that the geologic (natural) barrier at a repository site must of necessity provide total containment of radionuclides for unlimited time periods. Thus, we believe that it is appropriate, under the circumstances present at Yucca Mountain, for our standard to neither encourage nor discourage DOE from relying in its repository design on both engineered and natural barriers. Moreover, we did not develop our standard based on DOE's design for the repository, just as DOE has not based its repository design on our standard. For these reasons, we see no reason to amend our definition to preclude DOE from taking advantage of the available engineered barriers, especially because DOE expects those barriers to provide waste containment beyond that which Yucca Mountain's natural barriers alone could provide. Moreover, precluding DOE from taking advantage of available engineered barriers would have the perverse effect of diminishing the protectiveness of the repository. This would not constitute good regulatory policy. We believe that the basic notion of geologic disposal is not skewed by the incorporation of engineered barriers into the disposal system, but rather that the combination of optimized engineered and natural barriers is a prudent and technically sound approach to the permanent disposal of these wastes.

EPA's definition of barrier is substantially similar to the definition of "barrier" in our generally applicable standards (see 40 CFR § 191.12). The minor differences between the definitions in the two regulations are the result of the regulations' different roles. Part 191 is a generally applicable standard that can be used at any site where disposal of these wastes occurs. Part 197, on the other hand, is site-specific: it applies solely to the planned repository at Yucca Mountain. Thus, the definition in 40 CFR part 197 incorporates additional elements to account for the specific characteristics of the Yucca Mountain site.

Response to Issue QQ.3

EPA disagrees that its standards that require DOE to meet a "reasonable expectation" for the repository's performance are "arbitrary." First, this standard already is present in our generally applicable standards for disposal of HLW, SNF, and TRU radioactive waste [40 CFR § 191.13(b)]. Thus, applying a "reasonable expectation" standard to Yucca Mountain maintains consistency with the standards applicable to the only other deep geologic repository in the United States for the disposal of these wastes. Second, "reasonable expectation" is a standard that is better able to account for the extreme uncertainties that exist at a facility such as Yucca Mountain. The NRC uses "reasonable assurance" in its licensing process for nuclear power

plants. These licenses have a typical duration of 40 years. "Reasonable assurance" requires a much higher burden of proof than does "reasonable expectation." Because of the "reasonable assurance" standard's high burden of proof and because of the extremely long compliance time frames at issue at Yucca Mountain, we believe that it would be extraordinarily difficult, if not impossible, for the NRC to implement successfully a "reasonable assurance" standard. On the other hand, a "reasonable expectation" appropriately accounts for the great uncertainties associated with the extremely long time periods involved in regulating a facility such as Yucca Mountain. We believe that the NRC would have significantly less difficulty in implementing such a standard at Yucca Mountain. See Section 2 of this document for more extensive discussion of this issue.

Issue RR: Eliminate "sealing" and/or "backfilling" from the definition of "disposal."

1. Requiring backfilling and sealing may or would actually impede, rather than enhance, the safe isolation of nuclear waste. (86, 310, 589)

2. The terminology in the definition suggests that disposal begins when the repository is sealed and backfilled. This situation may not occur entirely under different ventilated or "cool" repository designs. Use of backfill is not a certainty, but a decision to be made. (503, 585)

3. There has been no demonstration yet of the benefits (if any) of backfill in protecting public health and safety. (656)

4. Comments such as EPA expects the engineered barrier system to be "backfill in the spaces between the waste packages and adjacent rock" is better left for the NRC and others to contemplate. (346, 589)

Response to Issue RR:

Several commenters requested that EPA remove the requirement that disposal include backfilling the excavated drifts and tunnels in the repository. In response to these comments, we amended the definition of "disposal" in the final rule to eliminate the backfilling requirement. We recognize that specifying that DOE must backfill the repository, essentially would force DOE to adopt a particular subsystem design feature. The NAS, in its report, recommended that we avoid specifying subsystem design features.

EPA believes that it is necessary and appropriate, however, for DOE to seal the repository after it reaches its maximum waste capacity; therefore, we retained this requirement in the final rule. Sealing the repository will help minimize direct releases to the air. It also will help prevent human intrusion at the repository.

Issue SS: The definition of "aquifer" specifically should exclude perched water bodies. Perched water will be of little value to future residents because there is little, if any, perched water in the area and there is abundant water in the saturated zone that is easier and cheaper to access. (250)

Response to Issue SS:

EPA does not agree that the definition of aquifer should exclude perched water bodies. Should a body of perched water, of sufficient size to allow withdrawal of the yearly representative volume, exist at Yucca Mountain, it is appropriate and logical that the rule should cover this water. On the other hand, should a body of perched water at Yucca Mountain not meet the representative volume criteria, the regulatory language of Section 197.12 would de facto exclude it from coverage under the rule's provisions. These same comments apply to the commenter's suggestions that we make similar changes to the definition of "ground water" in the same section of 40 CFR part 197.

Issue TT: In the definition of "barrier:" use "site" rather than "repository" because if EPA uses "repository," then DOE cannot claim some geological features as barriers. (251)

Response to Comment TT:

EPA developed its environmental protection standards independently of DOE's repository design. Further, we believe that it is essential to minimize, to the extent practicable, the amount of land dedicated to use as natural barriers. Extending the definition of "barrier" to encompass the entire Yucca Mountain site goes beyond our understanding of geologic disposal; namely, that the repository itself, and the immediately surrounding area where necessary, should serve as the primary natural barrier(s). Again, we wish to minimize the area contaminated by releases from the repository. Limiting the use of natural barriers to the features of the repository itself, and not the surrounding site, will help accomplish this goal. DOE's current design for the repository envisions using both natural and engineered barriers to limit or prevent releases of radioactive material from the Yucca Mountain repository. We do not believe that it is appropriate for us to link this (or any) aspect of our standard to DOE's planned design for the repository. Thus, while we sympathize with and understand the commenter's concerns, we see no need to amend the definition as requested.

Issue UU: DOE supports NAS's recommendations regarding ALARA, and supports EPA's proposal not to incorporate ALARA into its standards. (653)

Response to Issue UU:

EPA's final position is not to include ALARA provisions in its final standards.

Issue VV: EPA should consult with Indian Tribes about their traditional and customary uses of lands in the Yucca Mountain area, and the RMEI characteristics should consider such Tribal uses.

1. Although the EPA has indicated that there are no Indian reservations located within the Yucca Mountain area or its immediate vicinity, the Paiute and Shoshone Tribes use the area for traditional and customary purposes including traditional gathering. It is the Tribes' contention that these traditional and customary Tribal uses need to be researched in cooperation with the Tribes and incorporated into the formula upon which the draft standards are based. For example, the location and the qualities of EPA's current RMEI, as discussed in the proposed rule, do not consider traditional and customary Tribal uses in the area. There may be traditional and customary uses of natural springs, wildlife, and vegetation, in certain locations, which would significantly impact the RMEI calculations. Additionally, in light of the potential for ground-water contamination and the movement of that ground water, the location of the RMEI may need to be expanded. (790)

2. EPA's radiation experts were not sufficiently knowledgeable about the traditional and customary Tribal uses of the areas resources to properly incorporate them into the formula upon which the draft standards are based. Thus, the proposed standards may not be based upon accurate assumptions. Certain Tribes contend that their lifestyle, including the types of plants and animals they consume, doesn't provide as much shielding and protection and has different exposure pathways than the models used by DOE in its offsite radiation exposure project studies leading to increased risk. Depending on the traditional and customary Tribal uses and the locations of those uses, the assumptions related to the RMEI may need to be totally revised. (791)

3. EPA has a duty to consult with those Tribes whose aboriginal homelands will be potentially impacted by the proposed Yucca Mountain repository when developing its risk assessment model, and identifying potential exposure pathways. (790)

4. The Tribes need to be provided an opportunity to play a direct role in preparing the risk assessment and identifying the exposure pathways. (794)

5. EPA should engage the potentially-affected Tribes directly to develop a Tribally-specific risk assessment model that can be compared directly with the current RMEI model in order to check its accuracy. (795)

6. Full government-to-government consultation between the Timbisha Shoshone Tribe and the U.S. EPA did not occur. (784)

Response to Issue VV:

Consistent with the Federal government's trust responsibility to Federally-recognized Indian Tribes, it is EPA's policy to operate within a government-to-government relationship with such Tribes and to consult with them regarding EPA actions that affect their interests. EPA agrees,

therefore, that it was appropriate for the Agency to consult with those Federally-recognized Tribes whose interests, including their traditional and customary uses of their aboriginal homelands, may be affected by EPA's development of its risk assessment model and identification of potential exposure pathways in establishing radiation protection standards for the proposed Yucca Mountain repository. Consistent with EPA's Indian policy, in 1999, following publication of the proposed rule, EPA began its process of consultation and outreach with potentially affected Tribes.

In mid-October 1999, EPA staff hosted a conference call with representatives of several Tribes located in and around Nevada. Two weeks later, on October 29, 1999, EPA met with the Nevada Indian Tribes in San Francisco. During this meeting EPA representatives led a discussion about EPA's role in the process, requested comments from the participants, and answered questions. Finally, EPA staff held a workshop at the Inter-Tribal Council of Nevada Annual Conference on November 22, 1999. EPA staff gave a detailed presentation on the Yucca Mountain Project and EPA's role in the process. Additional comments from the Tribes were requested at this time. Many potentially affected Tribes have submitted comments to the Agency, and some have passed resolutions in response to the proposed rule. The culmination of these activities has provided EPA with valuable information regarding the Tribes' perspective on the proposed radiation protection standard for Yucca Mountain. EPA has considered the Tribal comments provided to the Agency in the final rule and responses to comments from Tribes are contained in this preamble and in the Response to Comment document.

After considering the description of Tribal land uses in the area of Yucca Mountain, EPA has concluded that the rural-residential RMEI is fully protective of Tribal members and the resources they use for four reasons. First, the Tribal use of natural springs is apparently occurring in the vicinity of Ash Meadows. EPA is aware of no other area downgradient from Yucca Mountain where water discharges in natural springs, with the possible exception of springs in the more distant Death Valley. These natural springs are likely fed by the "carbonate" aquifer, which is beneath the "alluvial" aquifer being used in the town of Amargosa Valley (including at Lathrop Wells) now, and which will likely be used in the future. The question of whether the carbonate aquifer would be contaminated by releases from the Yucca Mountain disposal system has not been resolved by DOE. The available data indicate that although it is likely that the alluvial aquifer would be contaminated by releases from the potential Yucca Mountain repository, flow is generally upward from the carbonate aquifer into the overlying aquifers, suggesting that there is no potential for radionuclides to move downward into the carbonate system. If downward movement were to occur, however, radionuclide concentrations would be significantly diluted in the larger carbonate flow system. As a result, springs fed from the carbonate aquifer would have lower contamination levels than would wells at the Lathrop Wells location, which tap aquifers closer to, and more directly affected by, the source of potential contamination. Thus, Tribal users of natural springs fed by the carbonate aquifer would experience lower contamination levels than users of the alluvial aquifer at Lathrop Wells upon whom the RMEI was based. A more extensive discussion of the aquifer systems and geology in the Yucca Mountain area may be found in Chapters 7 and 8 of the BID.

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

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

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

Issue WW: EPA should lower the proposed standard to 5 millirems. This standard more accurately takes into consideration the affected Tribes' traditional and cultural lifestyles. (316, 757, 783)

Response to Issue WW:

EPA has discussed extensively in the preamble to the final rule and in Section 4 of this Response to Comments document its basis for adopting the standard of 15 millirems. As discussed in the response to comments above, this standard is protective of Tribal members, taking into consideration their traditional and cultural lifestyles and uses of lands in the Yucca Mountain area.

Issue XX: The effects of radiation on plant and animal life that are used by Tribal people have not been included.

1. Members of the Elko Band have in the past gathered and hunted, and presently gather and hunt, in areas directly affected by the proposed repository. The affects of radiation on this plant and animal life have not been included in the studies EPA relied upon in setting the proposed standard. (755)

Response to Issue XX:

As discussed above in response to separate comments, the Tribal use of wildlife and non-irrigated vegetation should not contribute significantly to total individual dose estimates. Gaseous releases from the repository are not a significant contributor to individual doses (NAS Report, p. 59) through inhalation or rainfall, and should contribute less to contamination of wildlife and non-irrigated vegetation than the use of contaminated well water for raising crops and animals for food consumption. We believe our requirement that DOE and NRC base food ingestion patterns on

current patterns for the agricultural area directly downgradient from the repository is a more conservative requirement.

Issue YY: The United States has no lawful trust responsibility.

1. There is no lawful authority for the United States to exercise a so-called trust responsibility on behalf of the Western Shoshone government. That role is reserved under the inherent sovereign authority of the Western Shoshone National Council. (108)

Response to Issue YY:

The Federal government has a trust responsibility to Federally-recognized Indian Tribes that arises from Indian treaties, statutes, executive orders, and the historical relations between the United States and Indian Tribes. Like other Federal agencies, EPA must act in accordance with the trust responsibility when taking actions that affect Tribes. EPA's actions in accordance with the trust responsibility in this matter do not deprive any Tribe of any inherent sovereign authority.

Issue ZZ: The Treaty of Ruby Valley takes precedence over United States law.

1. The Treaty of Ruby Valley, the Northwest Territorial Ordinance of 1787, the United States Constitution, Article VI, Paragraph II, the Treaty of Guadeloupe Hidalgo of 1848, and the Act of Congress Organizing the Territory of Nevada in 1861 provide certain protections for the Western Shoshone people which preempts the application of United States law regulating nuclear material transportation, use, storage, or disposal except as authorized under the Treaty of Ruby Valley. (110)

Response to Issue ZZ:

EPA believes that we have the authority to regulate radiation protection standards for Yucca Mountain, NV. Congress specifically authorized and directed EPA to develop such site-specific standards for Yucca Mountain in the EnPA. EPA respects the Tribes traditional interests in the area. However, EPA does not believe that the Tribes have regulatory authority to set radiation protection standards in the Yucca Mountain area.

Issue AAA: EPA has a duty to protect the heath, welfare, and the environment of the Western Shoshone people. (113)

Response to Issue AAA:

To the extent that this comment is referring to EPA's statutory obligation to protect the health, welfare, and the environment of the Western Shoshone people, EPA agrees. In addition, as discussed elsewhere, EPA must act in accordance with the Federal government's trust responsibility to Federally-recognized Indian Tribes and consult with such Tribes and consider their views regarding EPA actions that affect their interests. EPA's site-specific radiation

protection standards for Yucca Mountain protect public health and the environment from harmful exposure to the radioactive waste that would be stored and disposed in the proposed underground geologic repository. To ensure this protection, EPA's standards address all environmental pathways: air, ground water, food, and soil. The standards are protective of the closest residents to the repository to 15 millirem per year, or a risk of no greater than a 3 in 10,000 chance of contracting a fatal cancer. This level is within the Agency's acceptable risk range for environmental pollutants. The closest residents to the repository in the path of any potential releases are at Lathrop Wells, NV, which is 20 kilometers (about 12 miles) from the site. EPA's final standards require DOE to calculate doses incurred by the RMEI at a distance no farther than about 18 km from the repository. The potential risk for those at greater distances would be even less.

Issue BBB: EPA should investigate U.S. government trespassing and environmental justice infringements.

1. Racial discrimination is believed to play an important role in selecting Newe Sogobia for the proposed nuclear waste repository site from the nine originally proposed sites. The Tribe expects the U.S. EPA to investigate the processes by which the site selection and standards are proposed to uncover institutional racism which the Western Shoshone Nation Council believes results in trespassing by the DOE, the BLM, the U.S. Air Force, and the State of Nevada, and other foreigners who seek to impair, usurp or otherwise destroy the rights and authority of the Western Shoshone Nation. (111)

Response to Issue BBB:

The EPA was not involved in, and has no authority to oversee or investigate, the process to identify a potential repository site for SNF and other HLW. EPA's only regulatory authority for Yucca Mountain comes from the Energy Policy Act of 1992, which directs EPA to set radiation protection standards for Yucca Mountain. EPA has set these standards to protect human health and the environment, including members of the Western Shoshone Nation.

Section 2 Reasonable Expectation[1]

Issue A: Which approach to compliance demonstrations is more appropriate: "Reasonable Expectation" as proposed by the Agency, or "Reasonable Assurance" as used by the Nuclear Regulatory Commission?

1. A reasonable expectation standard is a very appropriate approach. (480) RE is the better choice for the high uncertainty areas of geologic disposal provided that the term is defined as the median value of the spectrum of probabilities estimated. Another alternative would be to use neither term and simply address the use of median values in remaining unquantified areas in the calculation of the expected annual dose. (326)

2. No other engineering project has had to meet such difficult long-term total system performance standards or such challenging "burden-of-proof"as the NRC license review process is likely to require. DOE has conducted studies and analyses of future dose levels which provide a basis for NRC to apply whatever licensing criteria are appropriate to ensuring a safe repository. (256)

3. The level of confidence adopted in the final standards must take into account the inherent uncertainties in assessing compliance for a long-term repository. DOE agrees with EPA that the appropriate level of confidence needed for compliance is less than absolute proof because absolute proof is impossible to obtain due to the uncertainty of projecting long-term performance. Whether the standard is reasonable expectation or reasonable assurance, it should reflect inherent uncertainties. (655)

4. NRC's reasonable assurance is more tested in traditional licensing experience (judicially approved since 1961) and understood by all parties to a licensing proceeding, whereas reasonable expectation is a "new", "unfamiliar" term of "dubious legal authority", and may be less conservative in that it may require a lesser level of "proof" (as EPA states it is "less stringent") and would therefore have no place in these or any other standards. NRC has congressional authority to use the reasonable assurance standard and it is well understood and judicially approved. (309) Reasonable assurance is presently being used (a "tried and true" approach) whereas reasonable expectation may be subject to debate. (348) Introduction of a new untried standard of judgement for a repository... is not necessary or appropriate...it may imply that the determination requires less rigorous "proof" than that associated with the NRC's "reasonable

[1] All acronyms are defined in Appendix B.

assurance" approach, which has a long history of implementation.(375)

5. Reasonable expectation introduces an untried and untested standard of judgement which is based on expected outcomes rather than assurances that the repository will perform to the regulatory standard. Expectation implies that some degree of uncertainty is inherent...any standard which uses expectations must be capable of quantifying uncertainty into a range of expected outcomes similar to a confidence interval. The current individual protection standard does not do that. Based upon Section 197.14(b) the reasonable expectation standard is less stringent than the reasonable assurance concept that NRC uses to license nuclear power plants... to suggest a less stringent standard for a facility which has a greater degree of uncertainty in terms of construction and operation (performance) appears to fly in the face of common sense. (501)

6. It is NRC's responsibility to judge the adequacy of compliance arguments by DOE and NRC objects to EPA's establishing "minimum requirements for implementation" and intruding into implementation. Reasonable expectation is a new term, whereas NRC has used reasonable assurance in a number of licensing activities and it is derived from NRC's AEA responsibility and approved by the Supreme Court. Reasonable assurance allows necessary flexibility to judge quantitative data with large uncertainties and has been incorporated into 10 CFR Part 63. NRC believes that EPA has no authority for implementation and licensing decisions which are the sole responsibility of the NRC. (600)

7. The EPA wrongly asserts that use of "reasonable assurance" as a basis for judging compliance would force the NRC to focus on extreme values (i.e., "tails of distributions") for representing the performance of a Yucca Mountain repository. . . The NRC has made it clear in its policy statement on probabilistic risk assessment, its proposed implementing regulation for Yucca Mountain, and its draft technical position on performance assessment for low-level waste disposal, that it does <u>not</u> focus on extreme values but rather is evaluating expected doses. The EPA should remove language that incorrectly portrays the NRC's use of reasonable assurance. (603)

<u>Response to Issue A:</u>

In the proposal, EPA described its preferred approach to implementation relative to the expectations for "proof" of repository performance considered possible for deep geologic disposal. We provided descriptions of our "reasonable expectation" approach to provide a necessary context for understanding the intent of the standard so that the actual implementation through the NRC licensing process could be developed with our intention clearly in mind. In licensing the disposal facility, NRC may choose to adopt another approach. The term "reasonable expectation" conveys EPA's position that unequivocal numerical proof of compliance is neither necessary nor likely to be obtainable in the context of long-term deep geologic disposal of radioactive wastes. EPA believes that for very long-term projections, involving the interaction of natural systems with the engineered system and the uncertainties associated with the long time periods involved, reasonable expectation is the appropriate standard of proof to be met during the licensing process. Discussion of the broad concept of reasonable expectation is given here and in

the preamble to the standards.

The NRC has used a similar test, "reasonable assurance," for many years in its regulations. The NRC, as a matter of implementation discretion, may elect to impose a "reasonable assurance" approach in its licensing decision - rather than reasonable expectation. EPA believes, however, that reasonable expectation is appropriate to assess projections of repository performance and the regulatory decisions that make use of these assessments, and we prefer it over reasonable assurance, for the reasons described below. The standard, as established by today's rule, however, does not prevent NRC from applying the reasonable assurance approach, and we expect that doing so would also include the principles of reasonable expectation described in the standard.

Comments on the application of EPA's "reasonable expectation" approach in the standard were both for and against the concept and its application to the Yucca Mountain effort. Supporters commented that the approach is reasonable in light of the inherent uncertainties in making projections of geologic conditions and estimates of repository performance over long time frames (comments 480, 655, 326). Comments opposed to the reasonable expectation concept stated repeatedly that the "reasonable assurance" approach, which is transferred from nuclear power reactor licensing experience, is more well-established and tested within a regulatory framework. These comments referred to the reasonable expectation concept in terms such as "new", "unfamiliar", and "of dubious legal authority", essentially claiming that the concept is something new being introduced into the repository effort, and an approach that in some ways would encourage less defensible or rigorous science to be used in characterizing the repository system or projecting its performance (comments 309, 348, 375). Some comments also expressed concern that the reasonable expectation approach required a lesser level of "proof" than the reasonable assurance approach and, therefore, is not appropriate for the repository situation where uncertainties can be significant (501), and that NRC does not focus on extreme values in applying the reasonable assurance approach (comments 600, 603). Two consistent themes in the comments that favor the use of reasonable assurance over reasonable expectation are that the reasonable expectation approach is untried in the licensing process and that it in some way encourages a less rigorous application of science to the repository effort.

With respect to the legal authority and use of the reasonable expectation concept in the regulatory process (comments 309, 348, 375), EPA believes that the reasonable expectation concept is well established in both the regulatory language in standards, as well as in actual application to deep geologic disposal of radioactive wastes, and has been judicially tested. We developed the "reasonable expectation" approach in the context of developing 40 CFR part 191, the generic standard for any geologic repository, and the concept has been applied successfully in the EPA certification of the WIPP, a deep geologic repository for TRU radioactive wastes [EPA 520/1-85-024-1, Response to Comments for the Final Rule (40 CFR part 191); Environmental Standards for the Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes, 52 *FR* 38066, 38071 (Sept. 19, 1985); EPA 402-R-96-002, BID for 40 CFR part 194, Docket A-95-12, Item V-A-23]. The WIPP repository is, to date, the only deep geologic repository for radioactive wastes in the United States that has been approved for operation

through a regulatory approval process. In fact, the use of reasonable expectation for the application to geologic disposal has been upheld in court [Natural Resources Defense Council, vs. U.S. E.P.A., 824 F.2d 1258, 1293 (1st Cir. 1987)]. Therefore, we believe that the reasonable expectation concept is neither "new" nor "untried", nor of "dubious legal authority", in the geologic repository regulatory experience. The question of dealing with the uncertainties of projecting repository performance over time frames in the thousands to tens of thousands of years is a concern for any deep geologic repository and not a concern that can be neglected for any specific repository setting. Uncertainties in predicting site characteristics over long time periods and consequent implications for performance projections are very real for the Yucca Mountain site (Chapter 7 of the BID) and should be a fundamental consideration in decision making.

In contrast, the reasonable assurance concept was developed and applied many times in the context of reactor licensing - not in the context of deep geologic disposal efforts - and has not been used in a regulatory review and approval process for a deep geologic repository. The judicial decisions cited in one comment (comment 309) refer to the use of reasonable assurance in the context of reactor licensing, not in the context of deep geologic disposal. EPA acknowledges NRC's statements that it will apply reasonable assurance appropriately at Yucca Mountain; however, the fact remains that, while the reasonable assurance concept has an established record of successful application and judicial approval in reactor licensing, it is in fact largely untried in the arena of geologic disposal. For these reasons, we disagree with comments that contend that the reasonable expectation concept is new, untried, or of dubious legal authority (comments 309, 348, 375) in the area of deep geologic disposal. We believe the reasonable assurance approach is the more untried approach in application to geologic disposal.

NRC points out in its comment (603) about the reasonable expectation concept that its reactor-based reasonable assurance approach is being re-examined to adapt the approach to the unique aspects of repository performance, noting particularly the preference in its technical position statements for probabilistic risk assessment techniques in projecting performance. EPA has reviewed these NRC documents and agrees that the assessment approaches are useful for assessing expected repository performance and welcomes their use. Except in the case of the IPS, for which we require performance assessment that incorporates probabilistic considerations, we have made no statements mandating the use of probabilistic or deterministic methods in making performance projections, since we believe both mathematical approaches have a place in the effort to establish technical consensus on repository performance. Nor have we made any requirements for the relative weighting of analyses produced by these approaches because we feel that question is firmly in the realm of implementation that should be handled by NRC in the context of the actual licensing process. Our statements on reasonable expectation are focused on broad concepts to be applied in making performance projections, as described in more detail below, rather than the specifics of particular calculation methods that are strictly implementation decisions. While NRC is making an effort to adapt the reactor based approach of reasonable assurance to deep geologic disposal, the application is still in fact new and untried in the regulatory arena for this application.

There was some comment that suggests that EPA's approach would allow the use of less rigorous

science for the assessment of repository performance in licensing (comments 375, 309, 501). This perception may have arisen from our choice of wording in the proposal where we stated that NRC may elect to use a more "stringent" approach. Such an interpretation was not our intent. The full text of our statement in the proposal is that NRC may impose requirements that are "more stringent" than the "minimum requirements for implementation" that our rule establishes; in addition, we clearly state that reasonable expectation "is less stringent than the reasonable assurance concept that NRC uses *to license nuclear power plants*" [proposed § 197.14(b), emphasis added]. However, we will clarify our meaning here and in the final rule and preamble. Performance projections for deep geologic disposal require the extrapolation of parameter values (site characteristics related to performance) and performance calculations (projections of radionuclide releases and transport from the repository) over unprecedented time frames that make these projections fundamentally not confirmable, in contrast to the situation of reactor licensing where projections of performance are only made for a period of decades and confirmation of these projections is possible through continuing observation. In this sense, a reasonable expectation approach to repository licensing would be necessarily "less stringent" (predictions not subject to confirmation) than an approach to reactor licensing (where predictions are possible to confirm with later observation). In fact, we expect that an appropriate application of reasonable assurance to repository licensing would also be "less stringent" than it is for reactor licensing. We encourage NRC's efforts to address the significant differences between repositories and reactors in its Yucca Mountain licensing process, as it indicates it will. We, therefore, must disagree (as further explained below) with these comments that reasonable expectation requires less rigorous proof than NRC's reasonable assurance approach.

EPA does not believe that the reasonable expectation approach either encourages or permits the use of less than scientifically rigorous science in developing assessments of repository performance for use in regulatory decision-making. As stated in the preamble to the proposed rule, the reasonable expectation approach takes into account the inherent uncertainties involved in projecting repository performance. It requires that the uncertainties in site characteristics over long time frames and the long-term projections of expected performance for the repository are fully understood before regulatory decisions are made. For example, the use of bounding assessments is a common tool for performance projections when significant uncertainties exist in data or in understanding precisely how measurements of system performance relate to individual system components. Without an adequate understanding of the waste isolation and containment system, attempts at "bounding" assessments may not be bounding at all if the uncertainties in the system are not adequately understood. Under the reasonable expectation approach, a cautious approach to the use of bounding analyses would be encouraged and efforts would be directed toward understanding the interactions between relevant processes and events before bounding assumptions could be made about the larger scale repository system. As other examples, parameters important to performance would not be omitted from performance assessments, or assumed to be at their most unfavorable values, simply because their actual distribution of values is not easily quantified with high accuracy. Elicited values for relevant data should not be substituted for actual field and laboratory studies when they can be reasonably performed, simply to conserve resources or satisfy scheduling demands at the expense of gathering information that would allow a more credible understanding of the uncertainties in the long-term performance of

the repository.

Some comment expressed the opinion that EPA's use of the reasonable expectation approach intrudes inappropriately into the area of implementation, which is the province of NRC (comments 256, 600). We do not believe that is the case because NRC is not required by this rule to implement the reasonable expectation approach in making its licensing determination. The NRC, as a matter of implementation discretion, may elect not to use the reasonable expectation approach in the licensing determination. We have included the concept of reasonable expectation in the Yucca Mountain standard to provide a necessary context for understanding the standard and as context for the implementation of the licensing process NRC will perform. Because we are establishing a numerical standard for compliance, we believe that it is an appropriate exercise of our authority to discuss the context that we believe is appropriate to understand the intent of that numerical standard. The reasonable expectation concept is recommended in the Yucca Mountain standard because we believe that unequivocal numerical proof of compliance is neither necessary nor likely to be obtainable for deep geologic disposal over the time frames involved. Projecting repository performance involves the extrapolation of physical conditions and the interaction of natural processes with the wastes for unprecedented time frames in human experience, i.e., many thousands to tens of thousands of years. In this sense, the projections of the repository's long-term performance cannot be confirmed. Not only is the projected performance of the repository system not subject to confirmation, the natural conditions in and around the repository site will vary over time and these changes are also not subject to confirmation, making their use in performance assessments equally problematical over the long-term (see Chapter 7 of the BID). In light of these fundamental limitations on assessing the repository's long-term performance, we believe that the approach used to evaluate repository performance must take into account the fundamental limitations involved (including the basic guidance given in § 197.14), and not hold out the prospect the anticipation of a greater degree of "proof" (confirmable predictions, as in the application to reactor licensing) than in reality can be obtained. We are not requiring that the "reasonable expectation" approach must be adopted to the exclusion of any other approach, in fact our descriptions of the approach are broad in nature and intended as guiding principles for the actual development of a specific implementation approach for licensing the Yucca Mountain repository.

In contrast to the unconfirmable nature of repository projections, NRC has traditionally applied reasonable assurance to the licensing of highly engineered systems, i.e., power reactors, that operate over relatively short time spans, i.e., decades. Performance projections for these systems can be tested and verified during the license period for the facility. For example, the performance of containment vessels, piping, fuel rods and other man-made materials are estimated from laboratory testing, but the in-service performance is monitored and deficiencies can be corrected during the in-service time of the facility. For the case of reactor licensing, seismic hazard evaluations are the only area where the effects of potentially adverse natural processes are extrapolated in time, but in this case the extrapolation is only for a period of decades and the projection is confirmable over the licensing period for the facility. In contrast, for the geologic disposal situation, processes that affect performance take many hundreds to many thousands of years to manifest a measurable effect on performance. Most, if not all, aspects of projecting

performance of components of the repository/natural barrier system involve the extrapolation of conditions and performance over extremely long time periods, well beyond the time frames where active monitoring can be assured. Because of this dramatic difference between reactor licensing and geologic disposal, EPA believes that reasonable expectation is the more appropriate approach because it more explicitly recognizes the unconfirmable nature of repository performance projections. With that recognition, licensing decisions would, of necessity, have to explicitly recognize the uncertainties in making performance projections and the regulatory decisions based on them. We believe that compliance decisions should be made with a full understanding of the inherent uncertainties and limitations involved in projecting repository performance over long time frames, and not with an expectation that these uncertainties are lessened by applying an approach that derives from a very different situation, (i.e., the reactor licensing experience, where performance projections are much more subject to verification over the facility's operation period). In taking this position, we disagree with the comment that contends it "flies in the face of common sense" (comment 501) to apply a "less definitive" standard to a repository, which "has a greater degree of uncertainty in terms of construction and operation" than a nuclear power plant. Recognizing that a geologic repository has an inherently higher level of uncertainty in performance projections than a reactor, we believe the approach to evaluating performance should, of necessity, take these uncertainties explicitly into consideration in reaching regulatory decisions. Again, while NRC, as a matter of implementation discretion, may elect not to use the reasonable expectation approach in considering the licensing case put forth by DOE, we believe that applying the principles of reasonable expectation is a more appropriate and realistic way to assess projections of repository performance and the regulatory decisions that make use of these projections and that whatever approach NRC adopts for implementation would at least incorporate the principles described for our reasonable expectation approach. The NRC's comments (600, 603) on our proposal indicate that it recognizes the importance of avoiding "unnecessary conservatism" in probabilistic analyses, which is consistent with our principles for reasonable expectation, if not defined in detail. As explained in the text below, excess conservatism can arise from two sources, unrealistic assumptions in framing performance scenarios, and the selection of parameter values for calculations. Probabilistic approaches can effectively put parameter value selection into a proper context by providing a means to weight individual performance calculations. The more basic framing of the performance scenarios is not as easily or directly addressed by probabilistic techniques (see discussion of the example below).

Moreover, because EPA is not requiring that NRC use reasonable expectation in its licensing determination, but, rather, is recommending that reasonable expectation be the minimum level of proof used, EPA does not intrude inappropriately into NRC's implementation responsibilities for decision making. The primary task for the regulatory authority is to examine the performance case put forward by DOE to determine "how much is enough" in terms of the information and analyses presented, (i.e., how will the regulatory authority determine when the performance case has been demonstrated with an acceptable level of confidence?). We have proposed no specific measures in our standard for that judgement, as one comment suggested we must to justify our approach (comment 501). We have not specified any confidence measures for such judgements or numerical analyses, nor prescribed analytical methods that must be used for performance assessments, quality assurance measures that must be applied, statistical measures that define the

number or complexity of analyses that should be performed, nor have we proposed any assurance measures in addition to the numerical limits in the standard. We have specified only that the mean of the dose assessments must meet the exposure limit, without specifying any statistical measures for the level of confidence necessary for compliance. We believe that measure is a minimal level for compliance determination consistent with the application of the individual protection requirement we applied for the WIPP certification [40 CFR 194.55(f)]. For the WIPP certification, EPA is also the implementing agency and in 40 CFR Part 194 we also included implementation requirements, including statistical confidence measures for the assessments and analytical approaches [Sections 194.55(b), (d), (f)] along with quality assurance requirements (Section 194.22), other assurance requirements (Section 194.41), requirements for modeling techniques and assumptions (Sections 194.23 and 25), use of peer review and expert judgement (Sections 194.26 and 27). We have not incorporated a similar level of detail in the Yucca Mountain standard because we believe we must specify only what is necessary to provide the context for implementation. We believe that our discussion of the reasonable expectation approach provides a necessary context for understanding the intent of the standard and for its implementation. We have provided guidance statements in the standard (Section 197.14) relative to the approach we believe appropriately addresses the inherent uncertainties in projecting the performance of deep geologic repositories. The implementing agency is responsible for developing and executing the implementation process and is free to adopt an approach it believes is appropriate to the site-specific situation at Yucca Mountain, but we believe that whatever approach is implemented should be consistent with the aspects of reasonable expectation we have described in the standard and amplified upon in these responses to comments.

Along these lines, one comment (comment 326) urged that EPA specify that the mean value of the spectrum of dose assessments weighted according to their probabilities be defined as the compliance measure. We basically agree with the thrust of the comment, that the repository dose assessments should consider the relative probabilities of expected processes and events and that biasing the performance projections by an overemphasis on low probability but high dose consequence scenarios should be avoided. We note that dose assessments for the Yucca Mountain site performed by DOE have adopted a probabilistic approach (DOE/VA, DOE/RW-0508, vol. 3, and Draft EIS, DOE/EIS-0250D, Docket A-95-12, Items V-A-5 and V-A-4). We also note that the NRC draft standard incorporates requirements that imply a probabilistic approach to the dose assessments [10 CFR 63.114(b) and (d)], and that NRC in its comment on the proposed standard noted its efforts to incorporate probabilistic risk assessment approaches into its licensing approach. We believe that the probabilistic approach is well established in the geologic disposal field and that it is not necessary for us to require a probabilistic approach to dose assessments in our standard. We believe the probabilistic approach will be implemented by DOE and NRC. We also implicitly incorporated a probabilistic approach in § 197.12 of our proposal, where we stated that performance assessments must consider the probabilities of occurrence of processes and events that might affect the Yucca Mountain disposal system. In keeping with our intention to avoid imposing unnecessary requirements that might constrain implementation flexibility, we were concerned that specifying in our standard that probabilistic approaches be used, may imply that deterministic assessments cannot play a role in the compliance case. We believe the relative role of deterministic versus probabilistic assessments in building and

evaluating the compliance case should be left to the judgement of the applicant and regulatory approval authority. However, we have adopted wording along the lines suggested by the commenter to be more explicit as to our intent. Our final rule requires that the IPS demonstrate compliance through performance assessment. The definition of performance assessment explicitly states that dose estimates are to be weighted by the probability of their occurrence. We do not require that DOE use performance assessments to demonstrate compliance with the human intrusion and ground-water standards, which leaves DOE and NRC the flexibility to consider deterministic analyses for that purpose. However, if performance assessments are used, they would incorporate probabilistic aspects similar to those used for the IPS.

One comment suggested that the Yucca Mountain performance assessment will have to quantify judgments "in far more detail than in past NRC compliance proceedings" (comment 256). This comment appears to support the use of "reasonable expectation"; however, the comment also expresses support for NRC's positions on the standard, which call for the reasonable assurance approach. EPA agrees with the comment's assertion that the time frame for the performance projections is unprecedented in engineering efforts. We believe that our reasonable expectation approach, as described previously, responds appropriately to the understanding and treatment of the inherent uncertainties involved in these long-term assessments of repository performance, and therefore, we believe our approach is consistent with the intent of this comment.

Another comment (comment 603) stated that NRC does not focus on extreme values in repository performance assessments and that EPA's description of reasonable expectation and reasonable assurance in the preamble to the proposed rule could be potentially misleading in this respect. The NRC cited several documents in its defense. Though the statements referenced by NRC are not as detailed as we would like in outlining the level of proof demanded under reasonable assurance to make a compliance determination, we recognize that NRC's assessments of repository performance will give consideration to the full range of values for relevant performance parameters. Our phrasing in the preamble for the proposed rule was not as clear as it should have been to convey the intent of our statements. In particular, we intended to warn generally against focusing on tail-ends of parameter distributions, and our statement in the standard itself does not say that reasonable assurance typically does so or that the application of reasonable assurance to the geologic repository application will or must do so; again, we are not the implementing authority and therefore we cannot assume how reasonable assurance will be applied to the Yucca Mountain site. We will take the opportunity here to explain the intent of our statements more fully to explain how excessively conservative assumptions can result in performance projections that essentially focus on the "tails" of distributions of otherwise more realistic assessments.

There are two fundamental components to be established in setting up and analyzing repository performance scenarios. First, the scenario itself 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 scenario is developed from an understanding of the natural processes, the engineered barrier design, and its interactions with the repository environment. The range of expected parameter values for the analyses is based on the results of site

characterization studies and laboratory testing. For both of these components, unrealistic and perhaps extreme choices can be made that would in effect give false expectations of repository performance, or hide important uncertainties that would in reality have important consequences on the performance projections. If extreme assumptions are made in defining the scenario, a "worst-case" scenario is developed at the outset and analyses using the expected range of site 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 extremes of the probability distributions for the dose assessments if a realistic approach were taken in defining the performance scenarios. On the other hand, if the scenario were defined more realistically and the same distribution of site 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 the full range of realistic 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 scenarios which can then easily be mistaken as expected case analyses. Under the reasonable expectation approach, expected case versus conservative and worst-case assessments would be more explicitly identified and the uncertainties presented more directly so that regulatory decisions can be more easily made and defended.

As a specific example, the DOE/VA report (DOE/RW-0508) presents results of performance assessments for the repository which are in fact extreme, rather than expected, performance. In these assessments, all ground water that seeps into the waste emplacement drifts is assumed to contact the waste packages, whereas the diameter of the waste packages is in reality only one-third that of the emplacement drift. This results in an over-estimate of the water available to contact the waste packages by at least a factor of three. The range of water seepage rates is determined by the hydrologic and climate variation data for the site, but this overly conservative assumption biases all the calculations to extreme values. Overestimating the water inflow leads to earlier failure of the waste packages than would otherwise be expected, increased transport of radionuclides out of breached waste packages, and consequently higher resultant doses than would be realistically expected. While it would be impossible to quantify the exact amount of water contacting the waste package, making a worst-case assumption for the scenario at the outset generates overly conservative results. Since these assessments did not consider some other uncertainties in the performance, the dose assessments can be easily interpreted as unrealistically non-conservative - if one assumes that these additional untreated uncertainties would result in further adverse performance. Until these additional uncertainties are analyzed, it is equally possible that the excessively conservative (unrealistic) assumptions built into the basic performance scenario could easily compensate for the untreated uncertainties. By having unrealistically severe assumptions for the analyzed performance scenario, it becomes very difficult to weigh the importance of all the uncertainties and come to a defensible picture of the actual variation in the expected performance of the repository and the inherent uncertainties. To further illustrate this point, for this particular example assumptions were made about premature failures of waste packages from manufacturing defects. One premature failure was assumed during the 10,000 year period for the assessment. With the overestimate of ground water contacting the

waste packages, seventeen additional waste packages were breached by corrosion processes and released radionuclides. With more realistic assumptions about available water, fewer waste packages would be projected to fail by corrosion during the regulatory time period, and the relative importance of the premature package failures to repository releases becomes more apparent, thereby allowing this inherent uncertainty to be identified and addressed in design efforts, as well as more visibly in performance assessments.

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Section 3 Regulatory Time Frame[1]

Comment Issues Page #

Issue A: EPA should establish the compliance period at an appropriate time beyond 10,000 years. For a variety of reasons, the proposed compliance period of 10,000 years is too short.

1. Numerous models have shown that the peak dose will occur well after the proposed 10,000 year compliance period. The proposed 10,000 year compliance period is arbitrary and should be extended to at least the time of peak dose. (4, 23, 94, 138, 173, 180, 206, 281, 334, 353, 369, 384, 425, 438, 457, 471, 482, 500)

2. Numerous alternative specific compliance periods beyond 10,000 years were suggested to ensure that peak doses are covered, including 50,000, 100,000, 200,000, 300,000, 500,000, and one million years. A few suggested that the standard should apply for all time. (23, 177, 184, 186, 196, 353, 409, 452, 482, 759)

3. The compliance period for the standard should be comparable to the hazardous lifetime of the materials to be emplaced in the Yucca Mountain repository. The repository will contain significant amounts of radioactivity for hundreds of thousands to millions of years. (52, 119, 167, 191, 206, 341, 353)

4. The predicted radioactive content in Yucca Mountain after 10,000 years of radioactive decay will [be] greater than the total amount of radioactivity placed in WIPP before any radioactive decay happens. Thus if WIPP is to be used to justify a time limit for compliance at Yucca Mountain, the compliance time should be (defined in total Ci) as that necessary for the waste [at] Yucca Mountain to decay to the same level WIPP will reach at 10,000 years. Then and only then, will it be possible to claim that YM will be as safe as WIPP. (220)

5. DOE has projected that peak doses will occur at 100,000 years and after, and would be orders of magnitude higher than EPA's proposed standard. (186)

[1] All acronyms are defined in Appendix B.

6. Given that the peak dose may occur beyond 10,000 years and exceed the proposed dose limits, future generations should not be subjected to unacceptable levels of radiation. They deserve the same level of protection as that provided in the proposed 10,000 year standard. (128, 143, 409, 425, 429, 457)

7. A 10,000 year compliance period may be pragmatic but with peak risk (or dose) occurring after 10,000 years, the licensing process may become more difficult. (466)

8. The NAS Panel recommended that adequacy of health protection be assessed for the time of greatest calculated dose, rather than by applying arbitrary cutoffs at earlier times, as this proposal would do. (398)

9. The quantity of long-lived radionuclides is far greater and the specific mix of radionuclides at Yucca Mountain is different from that in the WIPP, where 40 CFR 191 is the governing rule...EPA has not provided sufficient grounds to reject the NAS report's conclusion that estimates could be made for up to one million years. Its rejection of the NAS report's recommendation regarding compliance at the time of peak dose is scientifically and environmentally inappropriate. (281)

10. The EPA suggests that rather than setting the regulatory period to extend to the time of peak dose, DOE should consider this matter of extraordinary peak dose rates in its EIS. This evasion of regulatory responsibility is unacceptable despite the EPA's argument that beyond 10,000 years uncertainties in performance assessments become overwhelming. (127)

11. With regard to the EPA's choice of a 10,000 year compliance period, this was apparently based, in part, on the assumption that generic sites could be chosen that would assure long groundwater travel times, that is, for at least the thousand years that it would take for the water to migrate. (153)

12. In response to the regulatory dilemma posed in the commentary for the Proposed Rule, if the projected peak dose, at whatever time it might occur, is accompanied by an uncertainty range of 5 orders of magnitude around the standard, there should be no compliance dilemma at all. The repository license application should be rejected. (385)

13. The period of compliance must be greater than only 10,000 years...The way to prevent DOE falling into the optimism trap or even hiding the truth during licensing, is to set a standard that gradually relaxes the dose for compliance as time increases. (412)

Response To Issue A.1 through A.11:

EPA is aware that numerous estimates project that doses from the proposed Yucca Mountain repository may reach their peak sometime after the proposed 10,000 year compliance period. Further, the 1995 NAS report on Yucca Mountain ("Technical Bases for Yucca Mountain Standards,"August 1, 1995, National Academy Press, Washington, D.C., or, more simply, "the NAS Report") recommended that the compliance period should be "the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment." (NAS Report, p. 7). This period of long-term geologic stability could extend to one million years, according to the NAS Report (p. 6). The NAS based its recommendation upon technical, not policy considerations. Specifically in regard to the time period when the standard should apply, the NAS noted "...although the selection of a time period of applicability has scientific elements, it also has policy aspects that we have not addressed" (NAS Report, p. 56). As discussed below, the NAS Report explicitly recognized that policy considerations might also factor into the determination of the appropriate compliance period. EPA has carefully considered this issue and we conclude that the selection of the compliance period involves both technical and policy considerations. EPA's goal is to establish health and safety standards that protect the public from releases of radioactive materials from Yucca Mountain. An important consideration in this regard is whether the standard is practical to implement. Furthermore, DOE's calculation of peak dose after the period of compliance as a part of the environmental impact review process allows for public comment to contribute constructive suggestions that may impact how the repository is ultimately designed, operated, and closed. For a variety of reasons, we believe that a 10,000 year compliance period, along with the requirement for the EIS to include a calculation of peak dose beyond 10,000 years but within the period of geologic stability, is meaningful, protective, and practical to implement and, further, will encourage a robust repository that will provide long term protection of the public health and the environment.

First, while the NAS suggested a compliance period that would extend to the time of peak risk, within the period of geologic stability for Yucca Mountain (which might be up to one million years), the panel also recognized that such a decision has policy aspects not addressed by the NAS (NAS Report, p. 56). It suggested, for example, that "EPA might choose to establish consistent policies for managing risks from disposal of both long-lived hazardous nonradioactive materials and radioactive materials." With respect to the compliance period, EPA has used a 10,000 year limit in programs related to hazardous wastes. Waste subject to the land disposal restrictions requirements of the RCRA must meet a variety of requirements before land disposal is authorized (see 40 CFR part 268). Facilities may seek an exemption from these requirements by demonstrating that there will be no migration of hazardous constituents from the disposal unit for as long as the waste remains hazardous (40 CFR 268.6). With respect to the WIPP no-migration petition, 10,000 years was judged the longest practical timeframe for evaluating this petition (55 *FR* 13068, 13073, April 6, 1990). With respect to underground injection wells under the purview of the SDWA, we have specifically required a demonstration that the injected fluid will not

migrate within 10,000 years [40 CFR 148.20(a)]. More recently, modeling conducted in support of our HWIR has been carried out for 10,000 years to assess human health and ecological impacts (64 *FR* 63381, November 19, 1999). It is apparent that a compliance period of 10,000 years is the longest timeframe that has proved practical in our regulation of a variety of hazardous wastes.

Second, EPA has concerns related to uncertainty in projecting human exposure over extremely long time periods (up to a million years), such as those advocated by the NAS report and the commenters. One commenter (281) states that we have not provided sufficient reason not to adopt the NAS recommendation to evaluate peak dose for the period of geologic stability, and that our stated reasoning is inconsistent and not sound. We disagree with this commenter. Over such long time periods, we do agree that it is possible to calculate the performance of the Yucca Mountain disposal system within certain bounds. Indeed, numerous commenters (128, 186, 143, 409, 425, 429, 457, 466) expressed concern that the peak dose beyond 10,000 years may exceed the dose limits in the final standards. Such a calculation, however, entails two aspects of uncertainty that may call into question the meaning of any projections of human health impact over such times and consequently the value of such projections in a licensing process. One aspect of uncertainty relates to the **impact of long-term natural changes**. For extremely long time periods, major changes in the global climate could occur (see, for example, Chapter 7, BID). While the climate likely will remain, in general, similar to present day conditions over the next 10,000 years, over longer time frames comparable to the NAS suggested time of geologic stability, geologic evidence suggests that the global climate regime will likely pass through several glacial-interglacial cycles, with the majority of time spent in the glacial state (NAS Report, p. 91). These longer time periods would require the specification of exposure scenarios that would not be based upon current knowledge but rather upon potentially arbitrary assumptions. The NAS indicated that it knew of no scientific basis for identifying such scenarios (NAS Report, p. 96). As noted by the IAEA, beyond 10,000 years it may be possible to make general predictions about geological conditions but the range of possible biospheric conditions and human behavior is too wide to allow “reliable modeling” (IAEA TECDOC-767, 1994, p. 19, Docket A-95-12, Item II-A-5).

The second aspect of uncertainty associated with extremely long time periods relates to the **possible biosphere conditions and human behavior**. Even for periods as “short” as 10,000 years, it is necessary to make certain assumptions. This time period is twice as long as recorded human history and represents a very long compliance period for current-day assessments. For periods on the order of one million years, even natural human evolutionary changes become a consideration, disregarding the recent advances in genetic engineering. Thus, reliable modeling of human exposure may be untenable and regulation to the time to peak dose, as suggested by the NAS Report and at least one commenter (281), is likely to become arbitrary.

Third, EPA considered this issue and comprehensively evaluated the appropriate regulatory compliance period promulgated in the generally applicable environmental standards for the land disposal of SNF, HLW, and TRU wastes at 40 CFR part 191. The individual-protection requirements and ground-water protection standards (58 *FR* 66398, 66414, 66415, December 20, 1993), as well as the containment requirements (50 *FR* 38086, September 19, 1985), in 40 CFR part 191 require a compliance period of 10,000 years. One comment (153) suggested that this compliance period was based on the assumption that generic sites would be chosen that would exhibit long ground water travel times. Rather, the 10,000-year compliance period in 40 CFR part 191 was chosen for a variety of reasons, without relying on specific assumptions about ground water travel times. It allows well-designed, well-sited repositories to be distinguished from poorly sited and/or poorly engineered repositories. At the same time, major geologic changes are unlikely and repository performance can be reasonably projected over a 10,000-year period. (50 *FR* 38070-38071, September 19, 1985) EPA is also implementing a 10,000 year regulatory time period in the application of 40 CFR part 191 to the WIPP TRU waste repository in New Mexico (63 *FR* 27354, May 18, 1998). Notably, these 40 CFR part 191 standards apply to the same types of waste and type of disposal system (deep geologic repository) as proposed for Yucca Mountain. The WIPP LWA (Public Law No. 102-579, as amended by Public Law No. 104-201), however, exempted Yucca Mountain from the 40 CFR part 191 standards and Congress established a separate standards setting process detailed in the EnPA (Public Law 102-498), the authority for this rulemaking. Adopting a 10,000 year compliance period for Yucca Mountain would provide a consistent regulatory period for the land disposal of all SNF, HLW, and TRU waste in this country.

On this point, one commenter (220) argues that EPA is inappropriately using its WIPP experience to justify a 10,000 year compliance period for the Yucca Mountain repository. The commenter correctly points out that the radioactivity of the waste at Yucca Mountain will far exceed the expected inventory at the WIPP, and suggests that the appropriate compliance period for Yucca Mountain would be the time that it takes for radioactivity at the repository to decay to the same levels expected at the WIPP after 10,000 years. We disagree with this position, and believe that the commenter has too narrowly focused on the application of the 40 CFR part 191 standards to a single facility, the WIPP. Part 191 also applies to SNF and HLW, and would have applied to the Yucca Mountain repository had Congress not directed EPA to set site-specific Yucca Mountain standards.

At the time 40 CFR part 191 was developed, the bulk of the technical analyses supporting the rulemaking were aimed at evaluating SNF disposal (see EPA's 1985 BID, EPA 520/1-85-023, Docket R-82-3). Nevertheless, the limits of 40 CFR part 191 apply to the land disposal of radionuclides whether they originate from any combination of SNF, HLW, or TRU waste. EPA focused on SNF because of the excellent quality and amount of information available regarding the characteristics and volume projections for spent fuel. SNF also represented the highest inventory of wastes to be disposed and included many of the same radionuclides found in both

HLW and TRU waste. By contrast, DOE had characterized HLW and TRU waste but this data contained considerable variability and uncertainty. As pointed out by commenters (220, 281), the inventory of radionuclides in SNF proposed for Yucca Mountain is much greater, and the radionuclide composition is different, than that in the TRU waste destined for WIPP. That being the case, there is no simple correlation between inventory and the risk to the public. The dose to an offsite individual or group is ultimately determined by a whole host of factors. In addition to inventory, the isolation capabilities of the natural geology, the engineered barriers included in the repository design, and site hydrogeology and climatology, among other factors, all may strongly affect the ability of the repository to isolate radioactive wastes for extended periods. These factors will be part of the full record presented to NRC as it makes its licensing decision. It will be important to evaluate projections of repository performance in light of the greater uncertainties associated with such long-term assessments, while not excluding important parameters from assessments simply because they are difficult to quantify.

Fourth, numerous international repository programs already invoke a 10,000 year compliance period. Canada, France, Germany, and Sweden have established 10,000 year compliance periods but have also committed to perform some kind of evaluation of the disposal system for time periods beyond 10,000 years [see NAS Report, Table 2-3, at 43, and GAO/RCED-94-172, "Nuclear Waste, Foreign Countries' Approaches to High Level Waste Storage and Disposal," August 1994 (Docket A-95-12, Item V-A-7)].

Fifth, a compliance period beyond 10,000 years would be unprecedented. Neither any of our national disposal programs nor international programs have implemented a compliance period approaching that suggested by the NAS panel (times approaching one million years). Given the unmanageable uncertainties associated with extremely long compliance periods on the order of one million years, a more complicated licensing process would undoubtedly result with no additional discernible benefits. Focusing upon a 10,000-year compliance period forces more emphasis on those factors over which our present society can exert some degree of control, such as repository design features and engineered barriers. By focusing upon an analysis of the features that society can influence or dictate at the site, it becomes more likely that the magnitude of the peak dose can be minimized even for periods beyond 10,000 years.

In a similar vein, another commenter (184) raised DOE's modeling capability as justification for EPA to set an unlimited compliance period. The commenter states that if DOE cannot demonstrate compliance with the standard in the short term (10,000 years), that will indicate either that the site is unsuitable or that knowledge is insufficient to site the repository. If DOE cannot demonstrate compliance with the standard over much longer periods, it shows that DOE has "a total lack of real understanding" of the processes at work in the repository and a "lack of justifiable predictive capability". It is noted that if DOE is unable to demonstrate compliance within the 10,000-year compliance period in the final rule, NRC would be unable to approve a license for Yucca Mountain. Over longer time periods, our rule requires calculation of peak dose

but we realize the modeling supporting quantitative assessments becomes much more tenuous, as discussed previously. If the post-10,000 year modeling results exceed the limits in our standard, the commenter argues, the repository also should not be sited at Yucca Mountain. In fact, one commenter (127) accused EPA of evading its regulatory responsibility for not requiring compliance until the time of peak dose. We strongly disagree that we have evaded our regulatory reponsibility. We have established a protective final standard that applies for 10,000 years, the longest practical, meaningful, implementable time period achievable, and in light of some of the unmanageable uncertainties discussed above, we still require a calculation of peak dose beyond the 10,000-year compliance period. We believe this approach achieves a proper balance between meaningful assessments over a hard 10,000-year compliance period and less reliable assessments clouded by the considerable and different uncertainties that emerge beyond 10,000 years. We do believe, however, that a post-10,000 year assessment would make more complete information available and offer opportunities to enhance long-term (>10,000 years) performance. We refer to our above discussion of uncertainty considerations, particularly those associated with long-term (>10,000 years) projections. Uncertainty is but one of the many factors that will enter into a compliance determination by the NRC.

For the reasons cited above, EPA believes that a 10,000-year compliance period is meaningful, practical to implement, and will result in a robust repository protective for time periods beyond 10,000 years. Imposing a 10,000-year compliance period on Yucca Mountain means that the health and safety standards promulgated in this rule to protect the public from releases of radioactive materials from Yucca Mountain will have force and effect for 10,000 years. Moreover, imposing a compliance period beyond 10,000 years would introduce significant and unmanageable uncertainties in the licensing process, and would likely complicate the licensing process so as to dilute the meaning of any associated licensing determinations. Also, a compliance period beyond 10,000 years would be unprecedented both nationally and internationally. A 10,000-year compliance period for Yucca Mountain, in conjunction with the requirements of our generally applicable standard (40 CFR part 191), ensures that all SNF, HLW, and TRU wastes disposed anywhere in the United States will be held accountable to a 10,000-year compliance period. A 10,000-year compliance period also is the longest timeframe that has proved practical in our regulation of a variety of hazardous wastes. At the same time, consideration of the impacts beyond 10,000 years as a part of the environmental impact review process allows the public and decision makers to consider alternatives for enhancing long-term repository performance. We believe this is the appropriate balance that allows for meaningful consideration of the issues related to both “short” term (up to 10,000 years) and “long” term (10,000 years to one million years) aspects of repository development.

Response to Comment A.12:

Regarding uncertainty within the regulatory period, it was suggested that the license application should be denied if modeling results showed an uncertainty range of five orders of magnitude around EPA’s dose standard. What is required, however, is a “reasonable expectation” that the standard will be met. As indicated in our proposal, calculation of doses to the RMEI involves projecting doses that are within a reasonably expected range rather than projecting the most

extreme case. This is in concert with the NAS recommendation to use "cautious, but reasonable" assumptions in defining who is to be protected (NAS Report, pp. 5, 6). Modeling results, and their associated uncertainties, are but a part of the full record upon which NRC will determine compliance with this rule.

Response to Comment A.13:

This commenter suggested that it would be possible to prevent overly optimistic projections for very long time periods by gradually relaxing the standard as time progresses. This would allow DOE to demonstrate "graceful degradation" of the repository system and avoid "big surprises" created by errors in the performance assessment. Under this scenario, the standard would increase to 150 mrem from 10,000-100,000 years, and to 1.5 rem from 100,000-1,000,000 years. Curiously, the commenter offers this approach as a way to counter DOE's "horrendous track record in protecting health and safety", which shows the "political and technical credibility and competence of the DOE". EPA finds this proposal to be flawed for several reasons. First, no regulatory body that we are aware of considers doses of 150 mrem to be acceptable, much less 1.5 rem, for members of the general public. Such exposures may be experienced by radiation workers but they are not members of the public (see 10 CFR 20.1201, for example). Second, while our standard requires compliance for 10,000 years, we also require that DOE project performance beyond 10,000 years and place these projections in its final EIS. We do not require that NRC use those projections to determine compliance with our standard, nor do we preclude NRC from doing so if it believes that they provide insight into the long-term performance of the disposal system (e.g., the "big surprises" envisioned by the commenter). In any case, projections beyond 10,000 years will provide a more complete evaluation of disposal system performance. Third, we do not see why a relaxed standard such as that proposed by the commenter would provide any additional confidence in DOE's ability to assess performance for the first 10,000 years. Finally, the uncertainties involved in very long-term assessments would make it more difficult to judge compliance with any numerical standard, as discussed in the response to Issues A.1 through A.11 above. For a period of 10,000 years, it may be more effective to focus on features over which repository designers can exercise some control, which should positively influence disposal system performance beyond 10,000 years.

Issue B: The proposed 10,000 year compliance period, coupled with DOE's calculation of peak dose after 10,000 years in the Yucca Mountain environmental impact statement, is appropriate/reasonable.

1. A 10,000 year compliance period is reasonable. Just because it is feasible to calculate the performance of engineered and geologic barriers, as well as radiation doses to human beings, beyond 10,000 years does not imply that such results will be meaningful or realistic. (79, 228, 234, 271, 327, 476, 514, 551, 557, 566, 615)

2. Given the greater uncertainties associated with projections of repository performance beyond 10,000 years, there is no guarantee of greater public health benefit for projections beyond 10,000 years. (228, 526)

3. Requiring a compliance period beyond 10,000 years would unnecessarily complicate the licensing process because of the extreme uncertainty accompanying any such dose calculations. (216, 265, 776)

4. Requiring a compliance period longer than 10,000 years would be unprecedented. (216)

5. Given that there will likely be impacts beyond 10,000 years, DOE should calculate the peak dose, within the period of geologic stability, and display these doses in the Yucca Mountain EIS so that the public and all decision makers are fully informed. (80, 234, 303, 327, 779)

6. Given that the proposed EPA standard requires that the performance of the disposal system be examined after 10,000 years if the peak dose is calculated to occur then, there may be little practical difference between the TYMS report's recommendations and the proposed EPA standards. The major issue is that EPA provides no guidance on how analyses should be done for the period of geologic stability beyond 10,000 years and gives no indication of how the results should be use in judging acceptability. (398)

7. The time of peak dose within 10,000 years after disposal is preferable for use in determining compliance with the IPS, as opposed to use of time to peak dose beyond 10,000 years, given the large differences in uncertainty of both...Further, it is questionable that requiring DOE to include in the EIS results from calculations to peak dose beyond 10,000 years would be an "indicator of the future performance of the disposal system" ...A better approach would be to test results from performance assessment calculations periodically with better data sets and simpler more understandable analyses that would serve both reality checks and confidence builders. (557)

Response To Issue B.1 through B.5:

For a variety of reasons, EPA agrees that a 10,000 year compliance period is meaningful, protective, practical to implement, and will encourage a robust repository that will provide long-term protection. Furthermore, DOE's calculation of peak dose after 10,000 years as a part of the environmental impact review process will make more complete information available in the public record, which we believe will have a positive effect on the Yucca Mountain repository program. We believe that the selection of a meaningful compliance period requires consideration of both technical and policy issues. We are aware that numerous estimates of projected doses from the proposed Yucca Mountain repository may reach their peak sometime after 10,000 years. We are sensitive to the recommendation of the NAS panel that, on the basis of technical considerations, the compliance period should be the time when the greatest risk occurs, within the limits of the long-term stability of the geologic environment. For Yucca Mountain, this could extend up to one million years.

While NAS suggested a compliance period that would extend to the time of peak risk, the panel also recognized that such a decision also has policy aspects not addressed by the NAS (NAS Report, p. 56). It suggested, for example, that "EPA might choose to establish consistent policies for managing risks from disposal of both long-lived hazardous nonradioactive materials and

radioactive materials." With respect to the compliance period, EPA has used a 10,000-year limit in programs related to hazardous wastes. Waste subject to the land disposal restrictions requirements of the RCRA must meet a variety of requirements before land disposal is authorized. Facilities may seek an exemption from these requirements by demonstrating that there will be no migration of hazardous constituents from the disposal unit for as long as the waste remains hazardous (40 CFR 268.6). With respect to underground injection wells under the purview of the SDWA, we have specifically required a demonstration that the injected fluid will not migrate within 10,000 years [40 CFR 148.20(a)]. Finally, with respect to the WIPP no-migration petition, 10,000 years was judged the longest practical timeframe for evaluating this petition (55 *FR* 13068, 13073, April 6, 1990). More recently, modeling conducted in support of our HWIR has been carried out for 10,000 years (64 *FR* 63381, November 19, 1999). It is apparent that a compliance period of 10,000 years is the longest timeframe that has proved practical in our regulation of a variety of hazardous wastes.

EPA also evaluated the compliance period promulgated in EPA's generally applicable environmental standards for the land disposal of SNF, HLW, and TRU wastes. The individual-protection and ground-water protection standards in 40 CFR part 191 (58 *FR* 66398, 66414, 66415, December 20, 1993) require a compliance period of 10,000 years. EPA is implementing this regulatory time period in the continuing certification process applicable to the WIPP in New Mexico (63 *FR* 27354, May 18, 1998). Notably, these 40 CFR part 191 standards apply to the same types of waste and type of disposal system (deep geologic repository) as proposed for Yucca Mountain. However, the WIPP LWA (Public Law 102-579) exempted Yucca Mountain from the 40 CFR part 191 standards and established a separate standards setting process detailed in the EnPA (Public Law 102-498), the authority for today's rulemaking. Adopting a 10,000 year compliance period for Yucca Mountain would provide a consistent regulatory period for the land disposal of all SNF, HLWl, and TRU waste in this country.

For extremely long time periods (up to a million years), EPA has significant concerns related to uncertainty in projecting human exposure. Over such long periods, we agree that it is possible to calculate the performance of the Yucca Mountain disposal system within certain bounds. Such a calculation, however, entails two aspects of uncertainty that may call into question the meaning of any projections of human health impact. One aspect of uncertainty relates to the **impact of long-term natural changes**. For extremely long time periods, major changes in the global climate could occur (see, for example, Chapter 7 of the BID). While the climate will remain, in general, similar to present day conditions over the next 10,000 years, over longer time frames comparable to the NAS suggested time of geologic stability, the global climate regime is virtually certain to pass through several glacial-interglacial cylces, with the majority of time spent in the glacial state (NAS Report, p. 91). These longer time periods would require the specification of exposure scenarios that would not be based upon current knowledge or cautious, but reasonable, assumptions, but rather upon potentially arbitrary assumptions. The NAS indicated that it knew of no scientific basis for identifying such scenarios (NAS Report, p. 96). As noted by the IAEA, beyond 10,000 years it may be possible to make general predictions about geological conditions but the range of possible biospheric conditions and human behavior is too wide to allow "reliable modeling" (IAEA TECDOC-767, 1994, Docket A-95-12, Item II-A-5).

The second aspect of uncertainty associated with extremely long time periods relates to the **possible biosphere conditions and human behavior**. Even for periods as "short" as 10,000 years, it is necessary to make certain assumptions. This time period is twice as long as recorded human history and represents a very long compliance period for current-day assessments. For periods on the order of one million years, even natural human evolutionary changes become a consideration, disregarding the recent advances in genetic engineering. Thus, reliable modeling of human exposure may be untenable and regulation to the time to peak dose, as suggested by the NAS, could become arbitrary.

For perspective, EPA looked at international repository programs. Many already invoke a 10,000 year compliance period. Canada, France, Germany, and Sweden have established 10,000 year compliance periods but have also committed to perform some kind of evaluation of the disposal system for time periods beyond 10,000 years (see the NAS Report, Table 2-3, p. 43, and GAO/RCED-94-172, "Nuclear Waste, Foreign Countries' Approaches to High Level Waste Storage and Disposal," August 1994, Docket A-95-12, Items II-A-1 and V-A-7).

Finally, a compliance period beyond 10,000 years would be unprecedented. Neither any of EPA's national disposal programs nor international programs have implemented a compliance period approaching that suggested by the NAS panel (times approaching one million years). Given the unmanageable uncertainties associated with extreme compliance periods on the order of one million years, a more complicated licensing process would result with no additional discernable benefits. Focusing upon a 10,000-year compliance period forces more emphasis on those factors over which society can exert some degree of control, such as repository design features and engineered barriers. Over longer time frames, engineered barriers are more likely to have failed and protection of the environment depends more and more on the geological retardation in the movement of radionuclides away from the repository. By focusing upon an analysis of the features that society can influence or dictate at the site, it becomes more likely that the magnitude of the peak dose can be minimized even for periods beyond 10,000 years.

For the reasons cited above, EPA believes a 10,000 year compliance period is meaningful, practical to implement, and will result in a robust repository protective for time periods beyond 10,000 years. We have regulated hazardous wastes for as long as 10,000 years. Having a 10,000-year compliance period for Yucca Mountain ensures that SNF, HLW, and TRU wastes disposed anywhere in the United States will be held accountable to a 10,000 year compliance period. Imposing a compliance period beyond 10,000 years would be unprecedented both nationally and internationally and would carry with it significant and unmanageable uncertainties. This would likely complicate the licensing process so as to dilute the meaning of any associated licensing determinations. At the same time, making more complete information available on the impacts beyond 10,000 years as a part of the environmental impact review process provides an avenue for enhancing long-term repository performance. We believe this is the appropriate balance that allows for meaningful consideration of the issues related to both short term and long term aspects of repository development.

Response to Comment B.6:

The commenter is correct that EPA has not provided guidance on how the post-10,000 year modeling should be done. Although we have not specified detailed modeling approaches or modeling parameters for DOE to use, we have specified that the modeling should evaluate the peak dose to the RMEI (§ 197.35). As indicated in the DOE/VA (p. S-20, Docket A-95-12, Item V-A-5), the repository design is evolving, and will likely continue to do so during the licensing phase. We therefore thought it would be premature to specify how such modeling is to be done or how it is to be interpreted. Essentially, we expect DOE will model the same scenario it applies in assessing compliance with the IPS. The results will be published in the Yucca Mountain EIS and become part of the public record. As a result, more complete information will be available regarding the disposal system's projected performance in the post-10,000 year period. The NRC will determine how to evaluate the results of this long-term performance modeling as it relates to licensing. We do not intend NRC to use this modeling in assessing compliance with our standard; however, NRC is not prevented from doing so if it believes that modeling results beyond 10,000 years might provide insights to enhancements of the disposal system that would positively affect repository performance during or after the compliance period.

Response to Comment B.7:

This commenter suggests that requiring periodic updates of the performance assessment using more recent data would be more useful than modeling through the period of geologic stability, when uncertainties would render results "essentially meaningless." This approach is somewhat similar to that taken for WIPP, where the WIPP LWA requires DOE to demonstrate compliance every five years. The EnPA, however, had no such mandate. EPA also supports the idea that alternative lines of reasoning, such as simpler and more understandable analyses, may be used to support the safety case for repository licensing. Whether these analyses would suffice for the licensing process is a matter for NRC to decide. It is noted that NRC's proposed 10 CFR part 63 does require a performance confirmation program to be carried out until permanent closure [proposed 10 CFR 63.102(m)]. This program would verify the assumptions, data, and analyses that support the performance assessment used to demonstrate compliance.

Section 4 Individual Protection[1]

[1] All acronyms are defined in Appendix B.

Issue A: EPA's proposed dose limit of 15 mrem CEDE/yr (committed effective dose equivalent per year) is appropriate.

1. The 15 mrem/yr level is justified and consistent with other domestic radiation standards. (69, 155, 161, 193, 339, 377, 424, 496, 528)

2. A zero-release standard would be much preferable, but 15 mrem/yr is implementable and better than many alternatives. (77, 78, 117, 302)

Issue B: The individual-protection dose limit of 15 mrem/yr CEDE is not at the appropriate level. (20, 35, 55, 57, 105, 146, 190, 202, 213, 222, 260, 287, 301, 316, 319, 335, 361, 363, 401, 414, 415, 421, 434, 472, 490, 495, 531, 552, 555, 602, 620, 623, 757, 763, 778, 783, 786)

Issue C: The individual-protection dose limit should be higher.

1. The 25 mrem/yr level proposed by NRC and DOE is adequately protective and more appropriate. (20, 190, 213, 222, 401, 472, 495, 531, 602, 623, 763, 778) (One commenter (20) stated 25 mrem would be appropriate "unless NRC finds that another standard is more appropriate")

2. A level of protection of 25 mrem/yr is sufficiently conservative and is consistent with international standards, and recommendations of scientific advisory organizations. (202, 260, 421, 552, 620)

3. Given the long time frame, limited evidence of harmful effects from small doses, and the location and importance of the project, 70 mrem/yr would be adequately protective. (319)

Issue D: The individual-protection dose limit should be lower. (146, 287, 335, 361)

1. Release and dose limits should be zero. (35, 55, 57, 105, 301, 363, 414, 415, 490, 786)

2. A 5 mrem/yr standard would be more protective and take into account the lifestyle of Native Americans in the Yucca Mountain region. (316, 757, 783)

Issue E: The 25 mrem/yr level supported by NRC and DOE is definitely too high. (174, 314, 755, 780, 785)

Response to Issues A through E:

Pursuant to Section 801(a)(1) of the EnPA, the IPS established by this rule is to "prescribe the maximum annual effective dose equivalent to individual members of the public from releases of radioactive materials." EPA believes that the development of the IPS requires evaluation of several factors, including, the level of protection, who the standards should protect, and the applicable time period. As stated in the preamble to the NPRM, we believe that the determination of the appropriate dose level is ultimately a question of both science and public policy (64 *FR* 46984). This is consistent with the conclusion of the NAS, which stated: "The level of protection established by a standard is a statement of the level of the risk that is acceptable to society. Whether posed as 'How safe is safe enough?' or as 'What is an acceptable level?', the question is not solvable by science" (NAS Report, p. 49).

In developing the proposed IPS, EPA considered the following in its evaluation process: (1) the recommendations of the NAS; (2) established EPA standards and guidance; (3) other Federal agencies' actions for both radiation and non-radiation-related actions; (4) other countries' regulations; and (5) guidance on dose limits provided by National and International, non-governmental, advisory groups of radiation experts.

The NAS recommended starting from a range of risk levels representing an annual risk of fatal cancers from 1 chance in 100,000 (1×10^{-5}) to 1 chance in 1,000,000 (1×10^{-6}) (NAS Report, p. 5). The range of risk levels recommended as a starting point by NAS corresponds to a range of dose levels of 20 to 2 mrem CEDE/yr. Dose limits imposed by EPA and other Federal agencies range from 4 mrem/yr for certain radionuclides in underground sources of drinking water (under the SDWA); 10 mrem CEDE/yr for radionuclides releases into ambient air (under the CAA); 15 mrem CEDE/yr for disposal of SNF, HLW, and TRU waste (under the AEA); 25 mrem/yr for management and storage of SNF, HLW, and TRU waste (under the AEA); and 25 mrem/yr for LLW and 25 mrem TEDE/yr for termination of a license by the NRC (under the AEA). The NAS cited other countries' regulations ranging from 5 to 30 mrem/yr (NAS Report, p. 41). Other guidance was cited by NAS regarding apportionment of a dose limit upon all radiation exposure except for background radiation and medical procedures (this is discussed further in Section III.B.2 in the preamble to the final rule). Based upon its consideration and evaluation of these standards, other guidelines developed by National and International groups, and the regulations of other countries, EPA proposed a dose limit of 15 mrem CEDE/yr (which corresponds

approximately to an annual risk of 8.5 chances in 1,000,000 (8.5×10^{-6}) using our value of 5.75×10^{-2} fatal cancers per Sv (see Chapter 6.3 of the BID) or 5.75×10^{-4} per rem.

EPA received numerous comments upon this issue. Many comments supported our proposed 15 mrem CEDE/yr standard. Many other comments objected that our proposed standard was not appropriate - some argued that the standard should be higher, e.g., 25 mrem; while others argued that it should be lower, e.g., 5 mrem or even 0 mrem.

After carefully evaluating and considering the numerous comments received on this issue, EPA continues to believe that 15 mrem CEDE/yr is the appropriate level for protecting the RMEI. Our determination is based upon the following: (1) the EnPA instructed us to write standards "based upon and consistent with" the findings and recommendations of the NAS. The annual risk basis of the 15 mrem limit, 8.5×10^{-6}, is within the range of annual risk levels which NAS suggested, i.e., 10^{-5} to 10^{-6} (NAS Report, p. 5); (2) this level of risk is the same as we used in our generic IPS for SNF and HLW, 40 CFR part 191; (3) 15 mrem CEDE per year is within the range of most international standards, which range from 5 to 30 mrem CEDE per year; and (4) for non-radioactive waste activities, EPA generally regulates in a range of 10^{-6} to 10^{-4} lifetime risk – the proposed dose level falls above this level, but only slightly (i.e., it corresponds to 3×10^{-4} lifetime risk).

A number of commenters supported a 25 mrem CEDE/yr standard because it is consistent with other NRC, DOE, and international recommendations. EPA disagrees that the standard should be set at 25 mrem CEDE/yr. Applying the reasoning given above, we see that a 25 mrem CEDE/yr standard would be: (1) higher than that recommended by the NAS (an annual dose of 25 mrem, using the NAS dose conversion factor on p. 47 of the NAS Report, is equivalent to a probability of fatal cancer of 1.25×10^{-5} – above the upper limit recommended by NAS, 1×10^{-5}); (2) inconsistent with our generic disposal standards in 40 CFR part 191 (the individual-protection limit in 40 CFR part 191 is 15 mrem CED per year); and (3) even farther outside the preferred EPA lifetime risk range. In general, the Agency does not regulate above a risk 1×10^{-4} chance -- the estimated risk, using the NAS dose-to-risk conversion factor of 5×10^{-4} per rem (NAS Report, p. 47), would be about 4×10^{-4} as compared with about 3×10^{-4} associated with our level. Therefore, we see no compelling reason to increase the standard.

EPA disagrees particularly strongly with the commenter who recommended a 70 mrem standard as adequately protective. The risk level associated with 70 mrem (about 4×10^{-5}) is about five times as high as the risk level associated with the individual-protection limit. This is well above the NAS-recommended level and unprecedented in the current regulations of this and other nations for this activity. It also is significantly inconsistent with the individual-protection limit of 15 mrem CEDE/yr in our generic standards (40 CFR part 191). This would result in a risk level at Yucca Mountain that is significantly higher than that at any facility that falls under 40 CFR part 191, such as WIPP and future radioactive waste disposal facilities. In addition, we believe that 70 mrem from one source is too high a proportion of the annual 100 mrem recommended by NCRP and ICRP (excluding background, occupational, accidental, and medical sources). The apportionment of the total dose limit among different sources of radiation is used to ensure that

the sum, or total, of all included exposures is less than 1 mSv (100 mrem) CED/yr. Thus, ICRP recommends that National authorities apportion or allocate a fraction of the 1 mSv (100 mrem)-CED/yr limit to establish an exposure limit for SNF and HLW disposal facilities (see the discussion in Section III.B.2 in the preamble to the final standards).

A number of commenters argued that there should be zero releases from the repository and the individual protection standard should be zero mrem/yr. Given the extremely long times involved, and using current knowledge and technology assumptions, as recommended by NAS (NAS Report, p. 122), it may not be possible to provide absolute certainty that there will be no releases from the disposal system over 10,000 years. Therefore, EPA believes that such a standard would be technically indefensible.

Another commenter encouraged EPA to set a zero dose level as a "design standard" consistent with the stated intent of the repository. The commenter argues that, since DOE is designing the repository to isolate the waste and prevent releases, the EPA standard should be based upon this goal. Using current knowledge and technology assumptions, as recommended by NAS (NAS Report, p. 122), the Agency does not believe that it can be shown, with reasonable expectation, that there will be no releases from the disposal system within 10,000 years. The state of current knowledge and technology inevitably leaves uncertainties in projecting the performance of the elements of the disposal system. The Agency agrees that zero release is the goal, however, we also recognize the current status of knowledge and technology and believe that the 15 mrem CEDE/yr limit is reasonable given the current capabilities of science and technology.

Issue F: If the basis of a 15 mrem standard is one in a million risk of fatal cancer, why does DOE say that one in 10,000 is acceptable? And why does EPA back them?

1. [A]s I understand it, . . .the 15 millirem limit. . . will only cause one latent cancer death per million people. And that, at best, it's an extrapolation. . . In other words, the one latent cancer death per million is not set in concrete. It's a wild guess. And probably the only thing we know for sure about it is that it's wrong. But even so, that's what we're using and pretty well worldwide, I think. (92)

2. Now, what I wanted to know is are the ingested radioactive standards based on the same one latent cancer death per million population? And I noticed that drinking water standards are much lower than just the exposure standards. So I don't know about the air standards. . . And if it is one latent cancer death per million people, if that's the standard that all this is based on, why is the DOE, then, proposing that Yucca Mountain, that they cause one in ten thousand latent cancer deaths? Why are they saying that's acceptable? (93)

Response to Issue F:

Comment 92 reflects the potential confusion in differentiating annual risks from lifetime risks. The level of protection in the IPS is based upon a fatal cancer risk factor of 5.75×10^{-7} per mrem. This means that the *annual* chance of an individual developing a fatal cancer from a dose of 15

mrem is about 8.5 in a million. The lifetime risk would then be the annual risk multiplied by the number of years of exposure (EPA assumes a 30-year exposure period). Regarding the commenter's statement that DOE has said that a 1 in 10,000 chance is acceptable, NRC will use our standard in its licensing regulations and DOE will have to demonstrate with a reasonable expectation that the performance of the Yucca Mountain disposal system will meet our standard. Therefore, any other statements about acceptable risk or dose levels are irrelevant.

The commenter also expressed some skepticism about the accuracy of the risk values. They represent the best understanding that EPA has today, but EPA acknowledges that science is continually evolving to improve that understanding. It is also noted that the risk value associated with the dose is an overall average risk derived from people of all ages and both genders, and most radionuclides, i.e., it is not a radionuclide-specific risk from a specific pathway. Some radionuclides would present a greater risk and some a lower risk, which would likewise alter the estimated risk if that radionuclide were the only one to which a person was exposed during his/her lifetime. This commenter also questioned the difference between the ground-water standard (based on drinking water MCLs) and the IPS. The IPS is based on an acceptable level of risk to a person from all exposure pathways. The ground-water standard, while it may also serve indirectly to protect public health, is being applied to Yucca Mountain to ensure that the ground water resource is protected for future generations to the same level of protection that we use today for other waste disposal projects.

Issue G: I would hope that you would consider adding detailed charts to your proposed standards that would list the calculated, maximum contaminant levels in air, water and soil permitted for each of the predominant fission, corrosion, and activation radionuclides. The charts would translate the maximum permissible dose into actual amounts in picocuries per liter or gram of each nuclide as encountered in the real world. (149)

Response to Issue G:

The commenter suggests that it would help local residents to understand the relationship between radionuclide concentrations in environmental media and the dose standard. While EPA certainly agrees that such a tool would be useful, it would not be appropriate for EPA to include a chart of radionuclide concentrations corresponding to 15 mrem for air and soil. Concentrations in soil, air, or water translate into dose by applying certain assumptions about movement of radionuclides, location and lifestyle of individuals, and the potential exposure pathways. For example, the dose incurred by an individual is affected by such things as the amount of time spent outdoors, the amount and type of locally grown produce eaten, and the uses of ground water other than for drinking. While we have included some basic requirements in defining the RMEI (i.e., the location, diet, and a ground-water drinking rate of 2 liters/day), specifying conditions in more detail would essentially preclude DOE from refining its modeling and reduce NRC's flexibility in assessing compliance and licensing the site. The existing drinking water MCLs (which have already been translated into concentrations) will be applied to the aquifer at the selected point of compliance. The addition of a nuclide-specific chart of MCLs in drinking water would be duplicative of the table showing the water concentrations equivalent to 4 mrem/yr that EPA has

previously published. The table, Table IV-2A, is in Appendix B of the "National Interim Primary Drinking Water Regulations" (EPA-570/9-76-003, Docket A-95-12, Item V-A-8).

Issue H: EPA has inappropriately focused on fatal cancer as the primary indicator of health effects (as has the NAS). The standard needs to consider non-cancer risks. (13, 32, 151, 283, 337, 360, 418, 446)

Response to Issue H:

EPA has historically used fatal cancer as the measure of health risk in setting its radiation protection standards, e.g., 40 CFR parts 190 and 191 (42 *FR* 2859 and 50 *FR* 38073, respectively). Also, fatal cancer is the endpoint used in the latest Federal guidance, Federal Guidance Report No. 13 (EPA 402-R-99-001, September 1999, Docket A-95-12, Item V-A-20). In addition, in its report on Yucca Mountain, the NAS observed that there are about five cancers for every severe hereditary disorder and that of those cancers, there are more nonfatal cancers than fatal cancers. However, the NAS went on to cite a report from the ICRP (NAS Report, pp. 37-39, cited by NAS as "Radiation Protection, 1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication 60), which judged that non-fatal cancers have an overall impact that was less than fatal cancers "because of their lesser severity in the affected individuals" despite that fact that nonfatal cancers occur five times more frequently than fatal cancers. As mentioned previously, this is consistent with our generic standards in 40 CFR parts 190 and 191 and, therefore, we have followed the NAS recommendation and have maintained the risk of fatal cancer as the basis of the standards. One commenter stated that the organ-weighting factors used in calculating the CEDE may be unrealistic compared to actual exposures to particularly vulnerable people (e.g., pregnant woman and fetus, elderly, or infirm). As noted in a previous response, the risk value is an overall average risk and includes all exposure pathways, both genders, and all ages. Further, we recognize that further research may reveal other effects from radiation exposure, or cause certain parameter values to be revised. This is to be expected as science and understanding evolve, but we must work with the best knowledge available today. The commenter did not offer specific criticisms or cite additional studies that would support the comment.

One commenter protests that EPA has not given appropriate consideration to non-cancer risks and failed to sufficiently consider the limitations in the 1990 NAS BEIR V (the fifth report in a series of reports on the biological effects of ionizing radiation) report. Other non-cancer outcomes are discussed in Chapter 6 of the BID accompanying this rulemaking (EPA-402-R-01-008, Docket A-95-12, Item V-B-1). The magnitudes of these effects (which are generally believed to be upper estimates) are not considered to be a dominant concern in the overall risk assessment of the possible exposures to radionuclides – including carbon-14 – from the Yucca Mountain site. Regarding the mention of EPA's failure to sufficiently consider the limitations of BEIR V, EPA notes that BEIR was not a major factor in the EPA's conclusions. It is referenced in the BID as a basis of comparison, not as a basis of the conclusions. As a result, any "limitations" (which were not specified by the commenter) would not change the conclusions reached by EPA.

Issue I: Clarify what the scientific/risk bases of the individual-protection standards are. (394, 460)

Response to Issue I:

The level of the IPS is, in the end, a decision influenced by both science and policy considerations. As the NAS stated in its Report: "The level of protection established by a standard is a statement of the level of the risk that is acceptable to society. Whether posed as 'How safe is safe enough?' or as 'What is an acceptable level?', the question is not solvable by science" (NAS Report, p. 49). The scientific and technical factors that EPA considered in establishing the IPS include, the NAS' findings and recommendations, previously established EPA standards and guidance for both radiation and non-radiation-related actions, other Federal agencies' actions, and other countries' regulations. In addition, we evaluated guidance on dose limits provided by National and International, non-governmental, advisory groups of radiation experts, for example, the ICRP.

The NAS recommended a range of annual risk level for the development of fatal cancer to use as a reasonable starting point for this rulemaking (NAS Report, p. 5). That range was 1 chance in 100,000 (1×10^{-5}) to 1 chance in 1,000,000 (1×10^{-6}) (this corresponds to a range of 20 to 2 mrem CEDE/yr). The NAS based its recommendation upon its review and evaluation of EPA's actions, other Federal actions, guidelines developed by National and International groups, and regulations of other countries. For these standards, we have established a limit of 150 μSv (15 mrem) CEDE/yr. This limit corresponds approximately to an annual risk of 8.5 chances in 1,000,000 (8.5×10^{-6}) – within the range that NAS recommended as a starting point for consideration (based upon information in Section 6.3 of the BID accompanying this rulemaking).

For further information, see Table 1 in the preamble to the proposed rule. In that table is a list of dose limits of other current EPA and NRC regulations (adapted from NAS Report, p. 50). EPA's proposed standard of 150 μSv (15 mrem) CEDE/yr is within the range of these established standards. Finally, the level is consistent with the IPS at 40 CFR 191.15 in our generic disposal standards which limits the annual CEDE to 150 μSv (15 mrem)/yr.

Issue J: The greatest impact in different dose levels is not in radiological risk to the public, which is roughly the same, but the cost of constructing the repository. (22)

Response to Issue J:

The difference among the various potential dose levels is only the radiological risk involved. For the Yucca Mountain site, in Section 5.4 (beginning on p. 5-25), the DOE's Draft EIS (DOE/EIS-0250D, Docket A-95-12, Item V-A-4) states and shows that compliance can be achieved for both the proposed MCLs and the individual-dose level, and that the EPA standard is not driving the design of the repository. Therefore, in this case, cost is not a significant issue in choosing dose levels (although cost could be more strongly correlated with regulatory dose levels in other instances). There is more discussion of this issue in the EIA that accompanies this rulemaking (Docket A-95-12, Item V-B-2).

Issue K: EPA's standards should also protect non-human parts of the ecosystem. (16, 33, 431)

Response to Issue K:

Pursuant to Section 801 of the EnPA, EPA must promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at Yucca Mountain. The EnPA does not authorize EPA to establish standards to protect non-human parts of the ecosystem at Yucca Mountain. Moreover, our policy on this issue is that by protecting human beings to an acceptable level, we are protecting the rest of the biosphere (41 *FR* 28409). However, the Agency is also cognizant of ongoing research in this area, particularly in Ukraine around the area of Chernobyl. The Agency will maintain its interest in this area and, once sufficient data has been gathered, will re-examine its policy.

Issue L: Further clarify how 25 mrem under the "old" dose system is essentially equivalent to 15 mrem under the currently proposed system. (19, 340)

Response to Issue L:

The issue of dose systems and risk can be confusing, as two factors are at work here. The first factor is that the dose system, or the way of calculating the dose, has changed. Its use does not affect the particular dose levels that are being established in 40 CFR part 197. The current method merely updates the methodology that was used in 1985 in EPA's generic standard for management of SNF and HLW in 40 CFR part 191, "Environmental Standards for the Management and Disposal of SNF, High-Level and Transuranic Radioactive Wastes" to the methodology being used in the Federal government today.

The 40 CFR part 191 standards provide a good example. Currently, the standard for storage in subpart A of part 191 (issued in 1985) is expressed as 25 mrem to the whole body, 75 mrem to the thyroid, and 25 mrem to any other critical organ. By contrast, the standard for disposal in subpart B of part 191 (issued in 1993) is expressed as 15 mrem CEDE. The difference in the way the dose is expressed is clear, (i.e., dose limits for specific organs versus one overall dose limit). This is the result of the different systems. The older method attempted to control cancer risk by limiting doses to every organ. However, each organ has a different sensitivity to radiation exposure. The research supporting the older system was insufficient to support a finer distinction among those organ sensitivities. In fact, as can be seen, the only distinction was that the thyroid could receive more radiation than other organs. The newer system is supported by much more research, which allows a system in which the risk imparted by a dose received by particular organs is recognized by the relative sensitivity of those organs. This then allows the various levels of risk to be summed to arrive at the total risk level for the entire body. This dose level can then be limited through a single value as EPA has done in 40 CFR part 197 (for more information, see Chapter 6 of the BID accompanying this rulemaking).

As the commenter points out, EPA maintains that the risk level for subparts A and B of 40 CFR part 191 are essentially the same. This seems to imply that the two dose levels, accounting for the difference in the calculational system, are also equivalent. Risk is the underlying basis for selecting particular dose levels. However, where the risk equivalence is concerned, it is not that the system has changed, but rather that research since 1985 has shown that it takes less radiation to result in the same level of risk than was previously believed. This is the second factor that must be considered when comparing standards issued under the two dose systems. The general risk level which we have tried to maintain from the standards in 40 CFR part 191 is about 3×10^{-4} lifetime (about a 30-year exposure period) risk (i.e., a chance of about 3 in 10,000 of developing a fatal cancer from a dose of radiation). In 1985, it was thought that a dose of 25 mrem/yr would result in that risk. However, EPA now believes that it takes only 15 mrem/yr to result in that risk. Therefore, to maintain the same risk level as was used in 1985, and again in 1993 when 40 CFR part 191 was amended, we are setting 15 mrem CEDE/yr as the storage and IPS (for more information, see Chapter 6 of the BID accompanying this rulemaking).

Issue M: What is the appropriate means of calculating compliance with the standard?

1. How will compliance be demonstrated? (18)

2. The NRC proposal (the Expected Annual Dose - the sum of the performance assessment calculations spectrum weighted by their individual probabilities) is more appropriate than the use of the median or mean in the EPA standard (the EPA method will be skewed by high consequence-low probability events). (320)

Response to Issue M:

Compliance will be demonstrated by comparing the results of computational models against the appropriate standard. The models will include certain assumptions regarding how well the repository barriers will keep water away from the waste packages, how long it would take the waste packages to fail, how quickly the radionuclides would then escape from the waste packages, how long it would take for the radionuclides to reach a person, and how much exposure that person could expect to receive. By varying the assumptions, a range of conditions can be modeled. Performance assessments covering very long time periods typically use assumptions that are conservative, but not the absolute worst case (we frequently refer to "cautious, but reasonable" assumptions). This increases the confidence that the system being modeled can perform to the appropriate level.

The comment on the proposed statistical measures to be used to determine if performance assessments demonstrate compliance with the IPS asserts that EPA's choice of the higher of the mean or median values of the projected dose range would overly bias the decision by emphasizing high-consequence, low probability events. Note that while we proposed using the higher of the mean or median, in our final rule we specify that the mean be used (see Section 7 of this document for a full discussion of our decision on this point). In the standard we have not specified all the details of how the estimated range of exposures calculated by various

performance scenarios would be aggregated to develop the final distribution of possible doses. Rather, the standard provides substantial flexibility for implementation decisions. The standard includes sufficient specificity, however, to preclude the conclusion that the extremes of the estimated doses should be the focus of decision making. We certainly recognize that projecting repository performance involves analyzing processes and events with different probabilities and that these probabilities could vary widely. We have stated that DOE need not consider events with a probability of occurrence less than 1 in 10,000 over 10,000 years, and NRC may exclude higher-probability events if they do not significantly influence performance assessment results. Similarly, in our final rule we have specified (in the definition of "performance assessment") that dose results must be weighted by the probability of their occurrence. This concept of weighting, taking relative probability into consideration, has been historically a basic part of the assessment strategies developed for geologic repositories, and such weighting was used in the WIPP certification process. After careful consideration, we considered it appropriate to specify that such methods also be applied in the Yucca Mountain performance assessments. The NRC will make the specific decisions on how this is done. To assure that the choice of biosphere parameters used to make dose assessments results in exposures to a RMEI, we require that the RMEI has a diet and living style representative of people currently residing in the town of Amargosa Valley. To differentiate this RMEI from the MEI we have specified high-end values for two parameters – 2 liters/day of drinking water from the aquifer and the location of the RMEI, but let NRC use average values for other biosphere-related parameters (rather than their maximum values) except the RMEI's diet and living style. We require the diet and living style of the RMEI be determined based upon surveys of the current residents of the town of Amargosa Valley, but leave it to NRC to determine the values to be used from those surveys. The standard also contains provisions for the use of "reasonable expectation" in presenting a case for compliance. The EIA for the Yucca Mountain rule contains more detail on how this approach could be applied to the Yucca Mountain performance assessments, and the reader is directed there for more discussion (Docket A-95-12, Item V-B-2) (see also the discussion of the "reasonable expectation" approach to compliance calculations given in Section 2, and the discussion of performance assessment issues in Section 7, of this document).

Issue N: The EPA standard should be stated as a dose limit.

1. I appreciate the EPA's decision to base the Yucca Mountain radiation standards on dose rather than risk. I would hope that you would consider adding detailed charts to your proposed standards that would list the calculated, maximum contaminant levels in air, water and soil permitted for each of the predominant fission, corrosion, and activation radionuclides. The charts would translate the maximum permissible dose into actual amounts in picocuries per liter or gram of each nuclide as encountered in the real world. (149)

2. People are more familiar with the "dose-calculated effect". It is tangible, measurable, one can make comparisons with it and when the projected dose has been reached, the process of transporting the nuclear waste can be stopped. A "risk-based standard" would be limited in time and uses hypothetical situations; thus, one is taking a guess at what might happen. (195)

3. We agree with the NAS recommendation on basing the individual protection standard on risk and believe the NRC's approach in applying dose as a proxy for risk as explained in their proposed 10 CFR 63 rulemaking meets the NAS recommendation. (201)

4. An individual dose standard based upon risk is an appropriate implementation of the NAS recommendation that a limit on risk to individuals should be established. Although this approach stops short of expressing the limit in terms of the probability of an adverse health effect, as recommended by NAS, there exist sound and established public policy reasons for applying dose as a proxy for risk. Furthermore, NAS itself noted the currently accepted direct link between individual dose and health risk in their report to EPA. (221)

5. We support the position expressed by NRC. [That is, support for expressing the standard in terms of dose.] (259)

6. [S]etting a dose limit is a reasonable way for the EPA to incorporate cancer risk into the regulation. (283)

7. We agree with the EPA and the NRC that an individual dose limit is more easily understood by the public and easier to implement and is therefore appropriate in this case. (318)

8. Although "philosophically" a risk-based standard may be preferable to a dose-based one, it would be almost impossible to interpret today in view of the on-going (and maybe evolving) debates over the LNT [linear, no-threshold, dose response] assumption. (478)

9. [T]he EPA proposal to use a standard expressed in terms of dose seems reasonable as far as it is supplemented by some appreciation of the probability or the likelihood of occurrence of the situations giving rise to the exposure. (507)

10. A risk-based approach or a dose-based approach each have potential merits. However, given the current statutory framework for establishment of Yucca Mountain site standards, EPA should adopt an individual protection standard that prescribes a maximum annual effective dose equivalent. (622)

Issue O: The EPA standard should be stated as a risk limit. (459, 518)

1. By proposing a standard dose as a proxy for risk, EPA is precluding the public from easily comparing the proposed IPSs for Yucca Mountain with standards for regulating other kinds of hazardous materials. Furthermore, the use of dose as a proxy standard also makes it difficult for the public to compare the proposed IPS, which is now expressed by EPA in units of microsieverts per year and millirems per year, directly with EPA's proposed ground-water standard, which is expressed by EPA in terms of both millirems per year and picocuries per liter. (391)

2. [T]he TYMS report's recommendation that the *form* of the IPS be based on *risk* does not preclude EPA from expressing the *numeric value* of the standard in units of risk and in derivative

units of dose, so long as the risk value is clearly understood as the underlying basis for the proposed dose standard. (392)

Issue P: Use of risk or dose depends upon the purpose of the standard.

1. Yes [dose is appropriate], if the standard is only used to evaluate a license application. No, if the standard will be applied for purposes of performance confirmation and regulatory compliance. In this latter case, the use of a dose-based standard versus a risk-based standard may result in needless exposure at levels in excess of the standard before non-compliance with the standard is known. Use of a risk-based standard would serve to minimize risk of exposure and thereby exposures themselves. (522)

Response to Issues N through P:

Whether to issue the standard in terms of dose or risk was the only issue where EPA faced conflicting direction from Congress and a recommendation from NAS. In Section 801(a)(1) of the EnPA, Congress explicitly directed that EPA's standards "shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository...." At the same time, the EnPA required EPA to issue the standards "based upon and consistent with" the findings and recommendations of NAS. Notwithstanding the statutory provisions in the EnPA, NAS explicitly recommended a standard expressed as risk rather than the dose (NAS Report, p. 3).

As discussed in the preamble to 40 CFR part 197, EPA examined the merits of both methods and decided to issue the standards expressed in dose for the following reasons.

First, both National and International radiation protection experts generally have recommended that radiation standards be established in terms of dose. Also, National and International radiation standards, including the individual-protection requirements in 40 CFR part 191, are established almost solely in terms of dose or radionuclide concentration, not risk. Therefore, a risk standard will not allow a convenient comparison with the numerous existing radiation guidelines and standards that are stated in terms of dose.

Second, EPA calculated the level of the proposed dose standard based upon the risk of developing a fatal cancer as a result of that level of exposure based upon a linear, non-threshold, dose-response relationship. We would establish a risk-based standard in the same manner. Dose and risk are closely related; one can be converted to the other simply by using the appropriate factor. Therefore, whether the standard is stated in terms of dose or risk, it is based upon scientific assumptions that could change and no matter how it is expressed, risk is the underlying basis of the standard. We were interested in public comment on whether the standard should explicitly set a dose level or a risk level for compliance. One commenter (comment 391), who favors a risk standard, states that EPA is wrong to suggest that risk and dose are equally subject to change, because selecting a risk level is a public policy decision, while selecting a dose to correlate with that risk is a matter of improving scientific understanding. While we do not

disagree that public policy is an important aspect of determining the acceptable level of risks, we believe that we have been straightforward in correlating the selected level of risk with the dose level in the IPS and that this information would be readily available to members of the public, and therefore, has satisfied the intent of the NAS recommendation. The same commenter (comment 392) was concerned that the public would have difficulty in comparing the individual-dose standard expressed in units of dose with ground-water protection standards, which are expressed in units of both dose and concentration. The commenter is correct; however, the concentration limits in which the MCLs have been established were done so as a result of previous Agency actions. We have decided that to change them just for this rulemaking is inappropriate. The appropriate forum would be a public rulemaking in which those MCLs would be the main focus of the rulemaking rather than just a part of a much larger rulemaking. We have, in fact, recently completed such a rulemaking (65 *FR* 76708-76753, December 7, 2000), in which we reaffirm the existing radionuclide MCLs.

Third, as mentioned earlier, Section 801(a)(1) of the EnPA specifically calls for a dose-based standard. As noted above, EPA believes that in many respects a risk standard and a dose standard are interchangeable. Nevertheless, since the statute directs us to set a dose standard, the Agency has followed that directive rather than the conflicting NAS recommendation. Nonetheless, we believe that by fully explaining the risk basis of the dose standard, we have met the intent of the NAS recommendation.

Finally, most commenters on the NAS Report asked for a standard stated in terms of dose rather than a standard stated in terms of risk.

Response to Issue N:

EPA has chosen the IPS to be in the form of a dose. This decision was made based upon the reasons given in the general “Response to Issues N Through P” above and is in concert with the tenor of the comments in Issue N.

In response to the comment that stated that use of "dose seems reasonable as far as it is supplemented by some appreciation of the probability or likelihood of occurrence of the situations giving rise to the exposure," EPA refers to the use of performance assessment requirement in § 197.20:

> § 197.20 -- What standard must DOE meet?
>
> The DOE must demonstrate, using **performance assessment** [emphasis added], that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed individual receives no more than an annual committed effective dose equivalent of 150 microsieverts (15 millirems) from releases from the undisturbed Yucca Mountain disposal system.

The definition of "performance assessment" is found in § 197.12.

> "Performance assessment" means an analysis that:
>
> (1) Identifies the features, events, processes, (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;
>
> (2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and
>
> (3) Estimates the annual committed effective dose equivalent incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

In subparagraph (1), there is the requirement that part of the performance assessment is the identification of the probabilities of the occurrence of features, events, processes, and sequences of events and processes. Similarly, subparagraph (3) refers to dose estimates as incorporating these probabilities of occurrence (language we added in our final rule). Therefore, there is a recognition in the IPS of the "probability of likelihood of occurrence of the situations giving rise to the exposure" as the commenter had requested.

Response to Issue O:

There are two comments in Issue O. One prefers the use of a risk limit in the IPS. The other would like to have the limit stated in terms of both dose and risk.

As explained in the general "Response to Issues N Through P" above, EPA did not agree with the commenter who supported stating the limit as a risk and have, instead, stated it as a dose. In response to the other comment, we believe that stating the standard in terms of both risk and dose could be a source of unnecessary difficulty during implementation of the standards, akin to setting two standards for the same activity. Rather, we have chosen to state the standards only in terms of dose (which also meets the statutory requirement) and accompany it with a full explanation of the risk basis of the dose limit (we estimate an annual risk of fatal cancer of about 8.5×10^{-6}, which equates to a lifetime risk, based upon a 30-year exposure period, of 3×10^{-4}). We believe that by including this full explanation of the risk basis of the dose standard, we have met the intent of the NAS recommendation.

Response to Issue P:

Regarding the purpose of the IPS, it will be a fundamental basis of NRC's licensing of the repository, as the license will be contingent upon DOE's demonstration that the repository will comply with it. This appears to be consistent with the comment since it will be used to "evaluate

the license application." It will be NRC's prerogative as to how it enforces the IPS, based upon what it believes is necessary and appropriate. Should NRC find it necessary to enforce the standards in an operational setting, (i.e., through field measurements), that is within its authority. EPA disagrees with the commenter's suggestion that risk would be a more appropriate benchmark for performance confirmation or regulatory compliance evaluations, for two reasons. First, the term "performance confirmation" implies that there could be a situation in which exposures may exceed those allowed by the standard for a period of time before measurements are taken. We do not want to rely upon active institutional controls for determining compliance with a standard whose duration is 10,000 years; however, if the standard is used in that manner, the suggested situation is just as likely to occur with a standard expressed in terms of risk. Second, some type of physical measurements will need to be taken. Again, we do not want to rely upon active institutional controls; however, if the standard is used for an operational standard, this would be the case whether the standard is expressed in terms of dose, or risk. In addition, most of today's instrumentation is set to measure exposure or dose, not risk.

Issue Q: Should EPA's individual-protection standard be stated as committed effective dose equivalent (CEDE). (160)

1. We agree with the NAS recommendation on basing the individual protection standard on risk and believe the NRC's approach in applying dose as a proxy for risk as explained in their proposed 10 CFR 63 rulemaking meets the NAS recommendation. However, we believe that the standard should be based on 25mrem/year TEDE and not annual CEDE. (201)

2. Further, we challenge the use of dose equivalent, effective dose equivalent, and committed effective dose equivalent in the formulation of a standard for the Yucca Mountain repository. This methodology of "pencil-whipping" or "book-keeping" radiation doses is yet one more example of an attempt to progressively relax permissible radiation exposure levels. (433)

3. The IPS should be specified in terms of an annual CEDE limit. The use of an "effective" dose limit correctly accounts for the variation in risk levels associated with different organs. Not using an effective dose provides widely varying degrees of protection depending on the organ and radionuclides used in the exposure scenario. (608)

4. DOE would support the expression of dose limits in Total Effective Dose Equivalent (TEDE) instead of Committed Effective Dose Equivalent (CEDE). . . It is important for the EPA standard and the implementing NRC regulations to use similar units. (624)

Response to Issue Q:

Comments 201, 608, and 624 raise an issue that appears to be one of terminology rather than substantive difference. EPA believes that its use of the term "CEDE" and NRC's use of the term "TEDE" are intended to accomplish the same sort of analysis of the effective dose equivalent over the committed period.

In Federal Guidance Report 11 (EPA 520/1-88-020, September 1988, Docket A-95-12, Item II-B-5) and the amendments to 40 CFR part 191 (58 *FR* 66397, December 10, 1993), EPA used the term "committed effective dose equivalent (CEDE)." The reason for using that term is to emphasize that this is a committed dose, that is, the dose received from radionuclides which stay in the body for long periods are included in the calculation. The term "annual" was added for two purposes. First, to make it clear that the CEDE was to be calculated for the intake over each year and, second, to indicate that the annual dose received from contamination in the environment was to be included in the calculation. In other words, if an individual was assumed to eat or drink contaminated food or water for 50 years, each of those 50 years would have its own value for the committed dose (the associated risk is based on the assumption that the individual receives the maximum allowable committed dose for each of the 50 years). None of those committed doses is allowed to exceed the standard.

The NRC proposed its term TEDE in its proposed rule for Yucca Mountain, 10 CFR part 63 (64 *FR* 8639, February 22, 1999). In that proposed rule, NRC refers to its definition in 10 CFR 20.1003, which states that the TEDE is equal to the sum of the dose from external exposures plus the CEDE (for internal exposures). There does not appear to be a functional difference between the terms, but EPA prefers the descriptive nature of its term and is in keeping with Federal Guidance, which was developed with the consensus of all Federal agencies for the purpose of standardizing radiation protection terms and methodologies within the Federal Government.

In response to comment 433 and its allegation that the use of terminology used to describe the magnitude of radiation doses is “an attempt to progressively relax permissible radiation exposure levels,” EPA disagrees. The basis of the level of protection is the risk of developing a fatal cancer as the result of a person absorbing a specific amount of radiation. The terminology used to describe the magnitude of the dose corresponding to that risk does not change the underlying risk basis and, therefore, has no role in either tightening or relaxing permissible radiation exposure levels. See, for example, the response to Issue L above.

Issue R: Negligible Incremental Dose/Risk

1. We support the NAS approach to negligible incremental dose. (264)

2. EPA should be more firm and explicit that it is rejecting the concepts of “negligible incremental dose” and “negligible incremental risk.” (285)

3. It is not acceptable for EPA to ignore low-level radiation or incremental doses for either individual recipients or for total populations, nor to derive that latter from such a limited approach to the former. (368)

4. It would be better to use a collective dose standard, IF AND ONLY IF, it was coupled to a NIR [negligible incremental risk] criterion set at some reasonable level. (479)

5. ICRP has not introduced in its recommendations for solid waste disposal the concept of exclusion from consideration of some extremely low incremental levels of dose to individuals. It was left to the appreciation of the decision-maker to decide whether [or] not to take into account some scenarios. (513)

Response to Issue R:

In response to comment 264, EPA has adopted neither the NID nor NIR concept. After considering those concepts, we do not believe that they should be used for Yucca Mountain for several reasons which are discussed in the preamble to the proposed rule (64 *FR* 46990-46992), and in Section III.B.1.e of the preamble to the final rule.

In addition, NAS stated (NAS Report, p. 7), "We conclude that an individual-risk standard would protect public health, given the particular characteristics of the site, provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk." We are not prepared to accept "that very low radiation doses pose a negligibly small risk." For example, one of the reasons is that we do not believe that it is appropriate to apply the NID/NIR concept to consideration of population dose. The NAS referred to NCRP Report No. 116 in discussing its concept. However, a later NCRP report, No. 121, questions the application of the NID concept to consideration of population doses: “A concept such as the NID (Negligible Incremental Dose) provides a legitimate lower limit below which action to further reduce individual dose is unwarranted, but it is not necessarily a legitimate cut-off dose level for the calculation of collective dose. Collective dose addresses societal risk while the NID and related concepts address individual risk.” Based upon this, we think it would be inappropriate to use the NID/NIR concept to evaluate whether an IPS adequately protects the general population.

In response to comments 285 and 368, EPA thought its proposed position when, on p. 46991 of the preamble to the proposed rule, EPA stated, "We are not proposing to adopt either an NID or NIR level." The final position and reasoning are the same as the proposed position and reasoning, as found in the preamble sections referred to in the first paragraph of this response.

In response to comment 479, from the preceding discussion, it is clear that EPA has not adopted an NID/NIR level. As discussed elsewhere in this document and in the preamble to the final standards, neither have we adopted a collective dose standard. Therefore, the outcome is not what the commenter stated.

In response to comment 513, EPA agrees with the approach that the commenter has pointed out is used by another organization. We have not adopted an NID/NIR because we do not believe that it is appropriate to do so for regulating either an individual or a population [see the discussion in the preamble to the proposed rule (64 *FR* 46990-46992)]. We recommended in our proposal that population doses be projected and placed into the Yucca Mountain EIS for consideration by the public and decisionmakers; however, upon further consideration, we have decided not to make such a recommendation in our final action (see the preamble to the final rule for a discussion of our reasoning).

Issue S: The general public will be protected by the individual protection standard. (465, 602, 609, 614, 645)

Response to Issue S:

This is the final position taken by EPA. We believe that the unique characteristics of the area downgradient from Yucca Mountain make this approach possible. The full reasoning is found in the preamble to the proposed standards on 64 *FR* 46990-46992, but basically it is the unique site-specific characteristics around Yucca Mountain that support this determination. When there are releases, the releases will be almost solely into the ground water, first. As we understand it, this ground water stays underground until it is pumped to the surface or it discharges into a playa where the water evaporates very quickly and, therefore, there is no surface water made up of water from the tuff (upper) aquifer in Amargosa Valley. Therefore, there is no transport mechanism, such as surface water, that would transport radioactive contamination to a large number of people. Therefore, we believe that protecting an individual (the RMEI) using cautious, but reasonable assumptions will also protect the general public.

Issue T: It is reasonable to address, but not require compliance with, collective doses. (227, 775)

Response to Issue T:

These comments are consistent with the proposed position taken by EPA. However, we have determined that it is not necessary for us to make such a recommendation in our final action, primarily because we believe that the IPS will adequately protect the general population (see the response to Issue S, above). In Section III.B.1.e of the preamble to the final rule, this is discussed in more detail (see also the preamble to the proposed rule).

Issue U: There should be a limit on dose to the population.

1. There should be a limit on the dose to the population and to the individual and it should be based on prevention of exposure and minimization of risk. (591)

Response to Issue U:

EPA chose not to adopt a separate limit on radiation releases for the purpose of protecting the general population because EPA believes that the IPS will adequately protect the general population, given the conditions at Yucca Mountain. Instead, we recommended in our proposal that DOE estimate and consider collective dose in its analyses. We proposed this based upon several factors, which are described in the preamble to the proposed rule. However, we have determined that it is unnecessary for us to make such a recommendation in our final action, primarily because we believe that the IPS will adequately protect the general population (see the response to Issue S, above).

Issue V: Emission limits in the form of radiation dose limits to individuals and to populations are appropriate for manufacturing facilities because emissions of radionuclides are expected and are to be regulated. The YMR [Yucca Mountain Repository] is not such a facility and it is gross error to treat it as such. (413)

Response to Issue V:

Prior to closure of the Yucca Mountain repository (during the time that subpart A applies), EPA considers the facility and its related surface facilities to be an operating system just as other present-day facilities handling radioactive materials are. Relative to the disposal standards in subpart B, NAS recommended using an annual risk limit, the Agency has chosen to use the equivalent dose limit instead. Both organizations clearly understand that the Yucca Mountain disposal system is a passive system. We have neither confused it with, nor treated as, an operating system. If the commenter is inferring that a dose limit is tantamount to an emission limit where emissions are expected, the commenter is in some respects correct since there would have to be releases to cause the exposure. However, since the commenter offers no alternative, we must conclude that the commenter is suggesting that the Agency should allow no releases.

There are several reasons that EPA does not believe that such an approach is reasonable: (1) the EnPA instructed EPA to write standards "based upon and consistent with" the findings and recommendations of NAS. As is described in the preamble to the proposed rule, the NAS recommended using a risk limit within the range of annual risk levels which NAS suggested, [i.e., 10^{-5} to 10^{-6} (NAS Report, p. 5)] – clearly not intended to be a zero release limit; (2) there are many international standards and sets of guidance of which EPA is aware, but none of them sets a zero limit – this is recognition by the international community that a zero release limit is unreasonable; (3) given the extremely long times involved, and using current knowledge and technology assumptions, as recommended by NAS (NAS Report, p. 122), it may not be possible to provide absolute certainty that there will be no releases from the disposal system over 10,000 years. The state of current knowledge and technology inevitably leaves uncertainties in projecting the performance of the elements of the disposal system.

Overall, EPA agrees that zero release is the goal, however, EPA also recognizes the current status of knowledge and technology and believes that the 15 mrem CEDE/yr limit is a reasonable compromise between zero release and the current capabilities of science and technology.

Issue W: EPA's collective dose requirement is inconsistent with the NAS and EPA's own conclusions.

1. EPA's requirement that the collective dose be "estimated and considered" is inconsistent with both the TYMS report and with the EPA's own conclusion (in the preamble to its proposed rule) that additional standards are not needed to protect the general public. Moreover, EPA has provided no guidance to either the licensee or the regulator on what they are to do with these collective dose estimates.

Further, EPA's urging of DOE to seek design alternatives to reduce potential risks to the general public from carbon-14 releases, even when individual-dose limits have been satisfied, is also without a firm scientific basis and will add little, if any, additional protection to the general public. . .

EPA is making policy judgements with respect to collective dose estimation and design alternatives to reduce carbon-14 releases but has not explained clearly its reasoning for these judgements. (395)

Response to Issue W:

In the responses to Issues R through U above, EPA explained that it has not established a requirement for collective dose. We did recommend in our proposal that DOE estimate collective dose, without truncation of any factors, because we believed that it would give decision-makers and the public more information (see the preamble to the proposed rule for more discussion of our reasoning). However, we are not including such a recommendation in our final action, primarily because we believe that the IPS will adequately protect the general population (see the response to Issue S, above).

Issue X: Background Radiation

1. My only other concern is that average exposure rates may permit persons living in this area, which has a very low natural background, to receive a larger dose and still remain within the exposure limit. (97)

2. A "health assessment" should be done now of all the affected communities. This assessment would reflect what is out there now. By showing the present health situations now, a case may be made for not adding to a potential number of latent cancer fatalities. (198)

Response to Issue X:

EPA is unaware of any significant source of radiation exposure other than that from natural sources in the downgradient direction from Yucca Mountain. Therefore, EPA assumes that the fatal cancer rate is based upon the exposure from natural background radiation. We are aware of the general level of background radiation in that area and, therefore, no new assessments need to be done.

In addition, EPA does not generally regulate background radiation (one exception is that the ground-water protection standards do include some naturally occurring alpha-emitting radionuclides). That is also true in these Yucca Mountain standards, which are intended to limit the potential impacts of releases from the Yucca Mountain disposal system rather than the impact from all sources of radiation since that is, in general, not implementable by NRC nor is it within our authority under the EnPA.

Issue Y: EPA's use of the RMEI is appropriate, but with reservations.

1. The RMEI dose fails because it is not possible to model the potential concentration of contamination in the CG groundwater hosting an un-mitigated contaminant plume. BUT...RMEI is better than the more generalized CG model. (162)

2. Most of the ANS group preferred the RMEI approach rather than the CG approach for selecting the appropriate receptor population. However, we wish to make clear that our preference is not based at all on the need to use Monte Carlo sampling to identify a critical group or any other population. Unconstrained Monte Carlo and LHS (where appropriate) are the preferred methods for including uncertainty in repository performance assessment. We recommend that EPA and NRC recognize this methodological preference in any implementation guidance. (322)

3. The EPA concept of RMEI is a conservative means of assessing compliance and would be more protective of human health and safety than the critical group employed by the NCRP and the ICRP. Considering those individuals are greater risk would add a further layer of conservatism and credibility to the standard. (344)

4. I do not see how an RMEI standard and a small critical group standard will differ much in impact and an RMEI standard may be easier to define and explain. It would be better to use a collective dose standard, if and only if, it was coupled to a NIR criterion set at some reasonable level. (479)

5. DOE believes that a probabilistic critical group approach is appropriate for the Yucca Mountain site. However, DOE does not object to the use of a RMEI, provided that the RMEI scenarios, assumptions, and parameters are reasonable. (625)

Response to Issue Y:

Since the late 1970s, EPA has been involved with the modeling of radionuclide movement from repositories through ground water. We have also reviewed and discussed such models with many agencies and organizations. As a result of these activities, we believe that reasonable projections of future contamination can be made. Therefore, we disagree that "it is not possible to model the potential concentration of contamination in the CG ground water hosting an un-mitigated contaminant plume." As a result of meetings among EPA, NRC, DOE, and the White House OSTP, it was agreed that modeling can be performed, using the specified representative volume of ground water, accurately enough to serve as a basis for decisionmaking (Memo to docket from Frank Marcinowski, EPA, Docket A-95-12, Item II-E-10).

Comment 322 expressed a recommendation that "EPA and NRC" recognize a methodological preference for unconstrained Monte Carlo and Latin Hypercube Sampling (where appropriate) for including uncertainty in repository performance assessment. The IPS, 40 CFR 197.20, specifies that a "performance assessment" be used in calculating the potential doses and that "performance

assessment" is defined in the rule, in 40 CFR 197.12, so as to require the consideration of probabilities of processes and events occurring over 10,000 years. The actual implementation of the standards will be the responsibility of NRC, as the licensing authority. The NRC proposed criteria for the Yucca Mountain licensing process in 64 *FR* 8640 (Feb. 22, 1999). In proposed 10 CFR 63.113(b), NRC requires that the Yucca Mountain engineered barrier system be designed such that, in concert with natural barriers, the expected annual dose to the average member of the CG does not exceed 25 mrem TEDE at any time during the first 10,000 years after permanent closure. [Pursuant to Section 801(b)(1) of the EnPA, NRC must revise its proposed criteria to incorporate the appropriate parameters from EPA's standard, including, for example, the annual IPS of 150 μSv (15 mrem) CEDE for the RMEI.] Section 63.114 of NRC's proposed rule requires that DOE demonstrate compliance with Section 63.113(b) using a performance assessment, which NRC defines as a "probabilistic analysis that identifies significant features, events and processes; examines the effects of such features, events and processes, and estimates the expected annual dose to the [RMEI] as a result of releases from the repository." We believe that a probabilistic approach is the best way, although not the only way, to assess the performance, and the uncertainties therein, of the engineered barriers, the behavior of the geologic barriers, ground-water flow, and the future climate.

Comment 344 agrees that the RMEI is a conservative means of assessing compliance and (1) asserts that it would be more protective of human health and safety than the CG employed by the NCRP and the ICRP and (2) recommends that EPA consider the RMEI to be at greater risk to add a further layer of conservatism and credibility to the standard. As discussed in detail in Section III.B.1.d of the preamble to the final rule, we do not believe that the RMEI approach is necessarily more protective in all situations than the CG approach, notwithstanding that, given the averaging that could occur using a CG approach, it is possible for the RMEI to be more protective, depending upon how the particular CG approach is implemented. We do not believe, however, that it is necessary or would necessarily be useful to consider the RMEI to be at greater risk than it would be under our standard. The purpose of the RMEI approach is to determine the level of potential future doses incurred by individuals. The projected doses will be nearly the highest doses to be received by any individual downgradient, but not the highest theoretical potential dose. In other words, the projected dose is the reasonably expected highest dose.

Comment 479 suggested that it would be better to use a collective dose standard, if and only if, it was coupled to a NIR criterion set at some reasonable level. EPA has declined to set an NIR level. We agree with the NAS conclusion that "...an individual risk standard will protect the public health, given the particular characteristics of the site...." (NAS Report, p. 7). We do not, however, accept the remainder of that same statement, "...provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk." We base our decision solely upon the basis of the site-specific characteristics of Yucca Mountain and the levels of individual risk which have been used previously in the Agency. The full discussion of our reasoning is in the preamble to the proposed rule beginning on 64 *FR* 46991, and is summarized here.

The NAS based its recommendations upon guidance from the NCRP that proposed a dose level of 1 mrem/yr, below which would be considered "negligible" for any source or practice. The IAEA has made similar recommendations to define an "exempt practice." It is not clear to EPA, however, that an exemption for whole sources or practices, such as waste disposal in general, should be applied to such specific situations as gaseous releases from a particular repository. In addition, we believe that it is inappropriate to not calculate a radiation dose merely because it is small on an individual basis. And, finally, we are not sure that it is appropriate to apply the NIR concept to population doses. In its Report No. 121, NCRP stated: "A concept such as the NID provides a legitimate lower limit below which action to further reduce individual dose is unwarranted, but it is not necessarily a legitimate cut-off dose level for the calculation of collective dose. Collective dose addresses societal risk while the NID and related concepts address individual risk."

Despite our belief that it is inappropriate to set an NID level, EPA acknowledges that the extremely low levels of individual risk from the doses that NAS estimated in its report (p. 59), (i.e., 0.0003 millirem/yr, for airborne releases) are well below those that EPA has used before. In addition, we do not foresee the potential for large-scale dilution in the Yucca Mountain area. The standards in 40 CFR part 191 provided both release limits, which acted as a form of collective dose protection, and an individual limit. The release limits acted to restrict the potential of dilution being used by disposal system designers to meet the individual-protection limit. However, the potential for large-scale dilution of radionuclides, through ground water and into surface water, does not exist at Yucca Mountain.

Comment 625 states that DOE believes that a probabilistic-CG approach is appropriate for the Yucca Mountain site, but that DOE does not object to the use of a RMEI, provided that the RMEI scenarios, assumptions, and parameters are reasonable. EPA agrees that the CG approach could be used in the Yucca Mountain performance assessments. As explained in the preamble to the final rule, however, we have not chosen to use it in these site-specific standards for several reasons. We relied upon many factors in making the decision to use the RMEI concept. First, this approach is consistent with widespread practice, current and historical, of estimating dose and risk incurred by individuals even when it is impossible to specify or calculate accurately the exposure habits of future members of the population, as in this case where it is necessary to project doses for very long periods. Second, we believe that the RMEI approach is sufficiently conservative and that it is fully protective of the general population (including women and children, the very young, the elderly, and the infirm). The risk factor upon which the dose level was established is 5.75 chances in 10,000,000 per mrem for fatal cancer for any year in which the exposure occurs. The lifetime risk then is this factor multiplied by the total dose received in each year of the individual's lifetime. We believe that the risk prior to birth is very similar to this risk level; however, relative to the rest of that individual's lifetime, the difference is small. Third, we believe that it provides protection similar to the CG recommended by NAS. The RMEI model uses a series of assumptions about the lifestyle of a hypothetical individual. This belief was supported by NAS in its comments on the proposed 40 CFR part 197. The NAS agreed that EPA's RMEI approach is "broadly consistent with the TYMS report's recommendations" (Docket A-95-12, Item IV-D-31). Fourth, it is possible to build the desired degree of

conservatism into the model through choices of assumed values of RME parameters. These values, however, would be within certain limits because we require the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR part 197, we establish a framework of assumptions for NRC to incorporate into its implementing regulations. Fifth, the approach is straightforward and relatively simple to understand. And, finally, the dose incurred by the RMEI is calculated using some maximum values and some average values (similar to the NAS's concept of using "cautious, but reasonable" assumptions).

Issue Z: Support use of EPA's RMEI approach.

1. We also support strongly, as you might imagine, the application of the standard to a hypothetical Reasonably Maximally Exposed Individual. (81) We also support the application of the standard to a hypothetical reasonably maximally exposed individual (RMEI). (304, 497)

Response to Issue Z:

The commenters supported the use of the RMEI approach as opposed to the CG approach. EPA believes that RMEI is the better approach to apply to these site-specific standards, for the reasons discussed in the Response to Issue Y above.

Issue AA: The RMEI should be someone other than a rural-residential individual.

1. We call on EPA to make the reasonably maximally exposed individual the fetus carried by the subsistence farmer, because this individual would be much more vulnerable to harm from radiation than would be the assumed world residential assumption in this proposed rule. (6)

2. The definition of the reasonably maximally exposed individual doesn't take us where we believe a proper policy of prudence with regard to protection would end up. And that would indeed be with protection of the embryo and fetus during the critical periods of gestation. (29, 431, 484)

3. The RMEI should be pregnant women and children. (197)

4. [W]e would hope that the individual exposed would be the one that would experience the most critical health and safety affects. This would be the young and the elderly. (121, 484)

5. The exposed individual considered for compliance purposes should be a subsistence farmer who represents a weighted age gender average person. (130, 181, 378) The exposure scenario of the weighted age/gender subsistence farmer should be specified, consistent with that of a maximally exposed individual drinking 2 liters of water per day from a well located in ground water with maximum radionuclide concentration and living and growing all his food at a location adjacent to or near the boundary of the repository, using water produced from the same well. (379)

6. This is a disturbing departure from the usual practice of "subsistence farmer" scenario to assess maximum exposure. To be sure, such a life-style does exist in Amargosa Valley. (145) We support an individual-protection standard that uses a subsistence farmer as the reasonably maximally exposed individual for compliance purposes. (209, 432)

7. The proposed rule should be subject to Executive Order 13045... The main pathway that EPA has identified is food/drink by RMEI. As children are growing they eat more food per unit body mass than adults. Therefore, they will be given a larger dose. (187)

8. In fact the use of RMEI allows far too high a proportion of a population to receive a dose higher than that of the RMEI reference individual. (358) "Reasonably maximally exposed" gives too much latitude and does not identify the maximally exposed person. Dose to the average member of the critical group or average dose occurring within the critical group is, if anything, even worse. (364)

9. Although the EPA has indicated that there are no Indian reservations located within the Yucca Mountain area or its immediate vicinity, the Paiute and Shoshone Tribes use the area for traditional and customary purposes including traditional gathering. It is the Tribe's contention that these traditional and customary Tribal uses need to be incorporated into the formula upon which the draft standards are based. For example, the location and the qualities of EPA's current RMEI, as discussed in the proposed rule, do not consider traditional and customary Tribal uses in the area. There may be traditional and customary uses of natural springs, wildlife, and vegetation, in certain locations, which would significantly impact the RMEI calculations. Additionally, in light of the potential for ground water contamination and the movement of that groundwater, the location of the RMEI may need to be expanded. (790)

Response to Issue AA:

EPA believes that it is most appropriate that the RMEI in the individual-protection scenario have a rural-residential lifestyle. As discussed in detail in Section III.B.1.d of the preamble to the final 40 CFR part 197, we selected a rural-residential RMEI as the basis of our individual exposure scenario (see also Chapter 8 of the BID, beginning at 8-52). We believe this lifestyle is similar to that of most people living in Amargosa Valley today -- specifically at the location of the closest residents to the Yucca Mountain site. The RMEI specified in Section 197.21 is assumed to be exposed through the same general pathways as a subsistence farmer; however, this RMEI would not be a full-time farmer, although it might do personal gardening and earn income from other sources of work in the area. Further, we assume that the RMEI drinks two liters per day of water contaminated with radionuclides, and that some of the RMEI's food is assumed to be locally derived. The EPA believes that the RMEI assumptions regarding drinking water and food will result in dose estimations that represent "reasonable maximal exposure."

Comments 6, 29, and 484 asserted that the RMEI should be the fetus and/or embryo during the critical periods of gestation; comment 187 discusses children; comment 197 said that the RMEI should be pregnant women and children; and 121 and 484 stated it should be the young and

elderly. As discussed in the preamble in Sections II.C and III.B.1.a, the primary risk factor considered in our risk assessment is incidence of fatal cancer. EPA has derived a risk value for the onset of fatal cancer that is an overall average risk value (see Chapter 6 of the BID for more details) that includes all people [i.e., both genders and all ages (from birth to the elderly)], and most radionuclides. But, the risk factor does not cover the fetus. It is thought that the risk of fatal cancer to the unborn is similar to that for those who have been born, but the exposure period is very short compared to the rest of the individual's average lifetime, so the risk of fatal cancer to the unborn is proportionately lower and would not have a significant impact upon the overall risk of fatal cancer incurred by an individual over a lifetime (see Chapter 6 of the BID for a discussion of the risk of fatal cancer resulting from *in utero* exposure). Also, we do not believe that the elderly are at a greater risk from potential exposures to releases from Yucca Mountain. The risk to the elderly would be less than the overall risk value since they have fewer years to live and, therefore, fewer years for a fatal cancer to develop. Overall, we believe that the annual risk which we associate with 15 mrem CEDE/yr, between 8 and 9 fatal cancers in a population of one million people, and which includes people of all ages and both genders, is protective of the RMEI and the general population. Of course, we expect the dose assessment to be carried out using the attributes of the RMEI which we have specified and the specific attributes of the RMEI which are assigned by NRC and DOE.

Comments 130, 181, 209, 378, 379, and 432 stated that the exposed individual considered for compliance purposes should be a subsistence farmer. As discussed in Section III.B.1.d of the preamble, EPA has given substantial consideration to the subsistence-farmer CG approach discussed by NAS (NAS Report, Appendix D), as well as the comments on this issue, that the RMEI be a subsistence farmer; however, we believe that it would be inappropriate to identify the RMEI as a subsistence farmer because we have not identified substantial evidence of the subsistence-farmer lifestyle at, or downgradient from, Yucca Mountain. DOE has conducted a demographic survey of Amargosa Valley in which no current resident with a lifestyle corresponding to a subsistence farmer was identified (DOE/VA, Docket A-95-12, Item V-A-5). In addition, we have examined the past use of the region around Yucca Mountain and have determined that subsistence farming has not at any time been a predominant use, and is not likely to be possible under current conditions (see Section 8.2 of the BID). Moreover, we have not received information demonstrating that such a lifestyle is common at Yucca Mountain, or its vicinity. Finally, given the lack of substantiation of the subsistence farmer lifestyle in Amargosa Valley, use of this lifestyle for the RMEI would be inconsistent with the NAS recommendation to use current technology (NAS Report, p. 122).

Comment 790 contends that EPA has not adequately considered the characteristic use of the Yucca Mountain region by Native American Tribes, and that such use would influence the exposures incurred by the RMEI. We disagree. The information available to us indicates that the rural-residential RMEI we have defined, residing year-round at Lathrop Wells, would fully account for exposures incurred by Native American Tribes during their traditional and customary use. We believe that the rural-residential RMEI location and lifestyle (including diet and use of ground water) leads to higher exposures than would an RMEI whose characteristics were based on Native American traditional and customary use (see Section 1 of this document for responses

to comments on issues of importance to Native American Tribes, including more detail on the selection of the RMEI and see Section III.B.1.d of the preamble to the final rule).

Comments 358 and 364 assert that the use of RMEI allows far too high a proportion of a population to receive a dose higher than that of the RMEI reference individual, and does not identify the maximally exposed person. EPA agrees that the RMEI approach does not identify the "maximally exposed person." This was intentional, since we tried to be consistent with the NAS recommendation of "cautious, but reasonable" assumptions for Yucca Mountain-specific dose assessments (NAS Report, p. 6). While using the maximally exposed individual might be cautious, for the site-specific situation at Yucca Mountain, we do not believe that it is reasonable since we have seen no evidence of individuals living in Amargosa Valley who have all of the living style characteristics that would lead to the highest possible dose. However, we intend for the dose incurred by this person to be in the "high-end" of the potential exposure range, although, as noted in the comments, this would not be the theoretically maximally exposed individual. In practicality, given the limited population in Lathrop Wells, there could not be a large number of persons exposed above the level of the RMEI. Even with a somewhat larger population, we expect this to be true based upon the construct of the concept, namely, of the factors that are used to project doses incurred by the RMEI, one or a few of the most sensitive factors (i.e., those which have the most influence on the outcome) are set at their maximum value. The rest, which, by definition, are less influential in estimating the dose, may be set at their average values. We have specified that the location of the RMEI is in the accessible environment above the highest concentration in the plume of contamination, a distance no greater than about 18 km south of the repository footprint, and the 2 L/day of water consumed by the RMEI from the aquifer directly underlying the RMEI are two of the maximum values. The NRC is free to name additional factors that must be kept at their maximum values. We chose the RMEI approach because we believe it is less speculative to implement than the CG approach given the unique conditions present at Yucca Mountain.

Issue BB: EPA should use the CG approach, which is consistent with NAS recommendations and international practice. (422)

1. The average member of the CG approach as proposed by the NRC in 10 CFR Part 63 would be more appropriate. . . The NRC proposal is also more consistent with the NAS recommendation. (223)

2. Adoption of the CG approach is much more appropriate and more consistent with the NAS Report. Regarding EPA's further request for input on the level of parameter detail that would be appropriate in specifying a CG, we endorse the CG approach proposed by the NRC in 10 CFR Part 63 as containing an appropriate level of detail. (243)

3. One of the main reasons to use the subsistence farmer critical group is that it eliminates speculation about future lifestyles. Trying to define future population characteristics introduces unacceptable elements of speculation into dose estimates, vitiating the estimates to the point that they may have little value for protecting future populations. (282) The central reason for EPA to

use the subsistence farmer critical group is that it eliminates speculation about future lifestyles, as it provides an upper bound on the potential human exposure from contaminants leaching from Yucca Mountain. (440) EPA has abandoned the subsistence farmer as the critical group, in favor of a "reasonably maximally exposed individual." This approach is fundamentally flawed. (333)

4. CG should be rural-residential as suggested by NAS. This would be better than RMEI because exposures can be estimated with much greater confidence. (461)

5. The Commission continues to recommend that exposures should be assessed on the basis of the mean annual dose in the critical group. (509)

6. The NRC staff, consistent with the National Academy of Science (NAS) recommendations and international practice, intends to use the "average member of the critical group" approach to determine the population that should be the focus in implementation of the individual protection standard. The EPA should conform to the recommendations of the NAS and international practice by adopting the use of the "average member of the critical group." (601)

7. A single, all-pathway standard is protective of both individuals and the general public health when the standard is applied to a CG (i.e., those individuals in the population expected to receive the highest dose equivalent using cautious but reasonable assumptions). (609)

8. The NRC staff disagrees with the EPA's use of "a RMEI as the representative of the rural-residential CG" because: 1) it unnecessarily confuses the CG concept, recommended by the NAS, by advancing a second, less widely-used, concept (i.e., RMEI); 2) the CG concept has been accepted both internationally and nationally and thus has meaning to a wider audience than the RMEI; and 3) specification of a particular group (i.e., rural-residential RMEI) is a matter of implementation to be determined in the NRC's implementing regulation. (610)

Response to Issue BB:

EPA has conducted a close and searching examination of the CG approach that was recommended by NAS. See the discussion in the preamble at Section III.B.1.d; Chapter 8 of the BID; and one of our technical support documents, "Characterization and Comparison of Alternative Dose Receptors for Individual Radiation Protection for a Repository at Yucca Mountain" (Docket A-95-12, Item V-B-3). In addition, we examined the RMEI approach that has been used in setting other EPA regulations. In both the RMEI and CG approaches, the objective is to determine the magnitude of the potential dose using reasonable, but not extreme, assumptions to find a dose that is high within the group of highest exposed people, but is not the highest theoretical dose. Both approaches are designed to account for differences in age, size, metabolism, habits, and environment to avoid heavily skewing the results based upon personal traits that make certain people much more or less vulnerable to radiation releases than the average within the group. Considering this and the other reasons we cited in the preamble, and summarized below, we believe that the RMEI approach is more prudent at this time.

EPA relied upon many factors in making the decision to use the RMEI concept. First, this approach is consistent with widespread practice, current and historical, of estimating dose and risk incurred by individuals even when it is impossible to specify or calculate accurately the exposure habits of future members of the population, as in this case where it is necessary to project doses for very long periods. Second, we believe that the RMEI approach is sufficiently conservative and that it is fully protective of the general population (including women and children, the very young, the elderly, and the infirm). The risk factor for fatal cancer upon which the dose level was established is small, 5.75 chances in 10,000,000 per mrem. The lifetime risk then is this factor multiplied by the total dose received in each year of the individual's lifetime. We believe that the risk prior to birth is very similar to this risk level; however, relative to the rest of that individual's lifetime, the difference is small. Third, we believe that it provides protection similar to the CG recommended by NAS. The RMEI model uses a series of assumptions about the lifestyle of a hypothetical individual. This belief was supported by NAS in its comments on the proposed 40 CFR part 197. The NAS agreed that EPA's RMEI approach is "broadly consistent with the TYMS Report's recommendations" (Docket A-95-12, Item IV-D-31). Fourth, it is possible to build the desired degree of conservatism into the model through choices of assumed values of RME parameters. However, these values will be within certain limits because we require the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR part 197, we establish a framework of assumptions for NRC to incorporate into its implementing regulations. Fifth, we believe that the RMEI approach is more straightforward in its application than the CG approach (particularly the probabilistic CG approach). The RMEI can reasonably be assumed to be living above the direct path of the plume of contamination. By locating the RMEI above the plume's direct path, high-end dose estimates will result. A probabilistic CG implies some, or even many, locations of the members across a broader geographic area than the plume covers. This dispersal inescapably involves additional decisions for the method to be used for combining dose estimates for the group members and comparison against regulatory limits and could average some, or many, doses with a zero magnitude. Given the characteristics of the plume of contamination projected by DOE (see, for example, Docket A-95-12, Items V-A-4, V-A-5, V-A-27), a dispersed CG would be very likely to include members who incur no dose. Such a situation would be inconsistent with the basic concept of a CG. In addition, specifying certain assumptions regarding consumption habits (e.g., requiring the assumption that the RMEI drinks a high-end estimate of 2 liters/day of ground water and that dietary intake is determined using surveys of today's population in Amargosa Valley), assure that the RMEI is "reasonably maximally" exposed (§197.21). We believe this approach is consistent with the NAS recommendation of "cautious, but reasonable" assumptions for repository dose assessments (NAS Report, p. 6). With these assumptions about location and food and water consumption, we believe that the RMEI approach would result in dose estimates comparable to a small CG. For a CG, food and water consumption patterns would also be determined from surveys of the local population and, possibly, by some assumptions to push the dose assessments toward higher-end dose estimates. The important difference between the RMEI and probabilistic-CG approaches is in the assumed distribution of the group members relative to the projected path of radionuclide contamination from the repository. Sixth, and finally, we previously have used the RMEI approach in our regulations (see 57 *FR* 22888, 22922, May 29, 1992). We have not used the CG approach. For example, the WIPP certification criteria (40 CFR

part 194) use an approach involving estimating doses incurred by individuals rather than a defined CG.

Issue CC: The proposed location of the RMEI (the vicinity of Lathrop Wells, roughly 20 km from the repository) is appropriate.

1. EPA has selected the most appropriate of the three areas, but we suggest that further evaluation continue as the comments from the Yucca Mountain DEIS are received by DOE. We do believe that land use controls should be considered as part of the repository planning and implementation. Certainly, the fact that the Nevada Test Site has been exposed to radioactive contamination during nuclear weapons testing and the federal government owns or controls most of the land in the Yucca Mountain vicinity suggests that no additional development should be expected close to the repository site. (263) We also support the location of the RMEI north of the Lathrop Wells intersection. (304)

2. I urge you to choose a compliance location no closer than 20 km, because there are not likely to be communities established closer to the site. (464)

3. [T]he determination should be made by NRC at the time of licensing. For this same reason, it would be premature to designate a location in any other of the sub-areas at this time. However, if a point of reference for assessment purposes is needed at this time, Lathrop Wells appears appropriate. (556)

Issue DD: The 20-kilometer distance to the compliance point is not the most appropriate distance.

1. The use of a 20-kilometer distance as the starting point for calculating the dose to the members of the public is unjustified. (354)

2. The present patterns of population and of land use unquestionably will vary over time. And thus we need to take into consideration a potentiality for changes that would permit the uses of land closer to the boundary of the site. In fact, perhaps a more extreme but reasonable view would be that the calculation of dose should begin at the site of release, from within the repository. Calculate dose at the site of the release or at the footprint. (30, 355, 379) The location for the source of the water used by the subsistence farmer critical group should be at the downgradient edge of the footprint of the repository, where the maximum radionuclide concentration can be expected. (284)

3. Given the uncertainties in the evolving groundwater flow and transport models and the likelihood that considerable uncertainties will remain with whatever conceptual models are finally used in performance assessment, it is important to calculate potential doses based on differing flow and transport models and variations of flow paths associated with each. While the 5 km boundary of the controlled area is a reasonable limit that should be adhered to in principle, if the flow paths are such that the RMEI could not sustain himself at that location due to topography

and lack of soil, the dose at the nearest realistic location on a contaminated flow path should be calculated. Depth to groundwater should not be a consideration in determining the location since just as future human activities can not be predicted, neither can future economic imperatives. (382)

4. The point should be closer than Amargosa Valley; 5 km would not be unreasonable. (497, 498)

5. DOE believes that the commercial farming scenario is sufficiently cautious and reasonable and that the use of such a scenario would lead to a different determination regarding location of the RMEI or critical group (i.e., 30 km, where a farming community currently exists). However, DOE would not object to the use of a rural residential scenario at the 20 km location, if EPA determines that such additional conservatism is necessary and reasonable for ensuring adequate protection of public health and safety. (628)

Response to Issues CC and DD:

A major part of the exposure scenario is the location of the RMEI. In proposing a location for the RMEI, EPA collected and evaluated information on the pertinent natural geologic and hydrologic features of Yucca Mountain and its vicinity, including topography, soil type, geologic structure, aquifer depth, aquifer quality, and the quantity of ground water (BID, Chapter 8). Based upon these factors and the current understanding of ground-water flow in the area of Yucca Mountain, we believe that an individual could reside anywhere along the projected radionuclide flow path extending from Forty-Mile Wash, approximately 5 km from the proposed repository location, to the southwestern part of the town of Amargosa Valley, Nevada, where the ground water is close to the land surface and where most of the farming in the area is done. However, other factors need to be considered to determine a cautious, but reasonable, location.

EPA considered locations within this area for the location of the RMEI (discussed in detail in Section III.B.1.d of the preamble, and in Chapter 8 of the BID) and proposed that the Lathrop Wells area, in the vicinity of the intersection of U.S. Route 95 and Nevada State Road 373, would be the appropriate place for the RMEI's location. Also, this location was chosen because we determined it to be a cautious, but reasonable, choice considering the current conditions in the downgradient area. We consider it improbable that the rural-residential RMEI would occupy locations significantly north of U.S. Route 95, because the rough terrain and increasing depth to ground water nearer Yucca Mountain would likely discourage settlement by individuals where access to water is considerably more difficult than it is a few kilometers farther south. We agree with the commenter who stated that future human activities cannot be predicted. However, by using depth to ground water as a factor for determining a location for the RMEI, we have followed the NAS recommendation to use "present knowledge and cautious, but reasonable, assumptions" (NAS Report, p. 100). We believe that given the current water usage patterns, economics, and site-specific factors that our reasoning is sound. Also, there are currently several residents and businesses near this location whose source of water is the underlying aquifer (which

we understand flows beneath Yucca Mountain). Therefore, we believe it is reasonable to assume that a rural community could be located at this location.

Commercial farming occurs today farther south, in the southwestern portion of the town of Amargosa Valley in an area near the California border and west of Nevada State Route 373. However, soil conditions in the vicinity of Lathrop Wells are similar to those in southwestern Amargosa Valley. Therefore, it should be feasible for the RMEI to grow some food, and possibly even one or more grazing domestic animals, using water obtained from personal wells that is not used for household purposes. Since commercial farming today occurs farther south, we believe that it also is reasonable to assume that the RMEI would obtain other food from the local area, also grown with contaminated water, to supplement any gardening and grazing domestic animals (see Appendix IV of the BID). Regardless of "feasibility", however, we expect that selected parameters, such as the percentage of food grown by the RMEI or the likelihood that the RMEI will own one or more grazing domestic animals, will reflect the current residents of the town of Amargosa Valley.

Finally, EPA believes a rural-residential RMEI between U.S. Route 95 near Lathrop Wells and the southern edge of NTS would be among the most highly exposed individuals downgradient from Yucca Mountain, even though the ground water nearer the repository could contain higher concentrations of radionuclides. If individuals lived nearer the repository, they would be unlikely to withdraw water from the significantly greater depth and in the much larger quantities needed for gardening or farming activities because of the significant cost of finding and withdrawing the ground water. It is possible, therefore, for an RMEI located closer to the repository to incur exposures from contaminated drinking water, but not from ingestion of contaminated food. Based upon our analyses of potential pathways of exposure, discussed above, we believe that irrigation would be the most likely pathway for most of the dose from the most soluble, more mobile radionuclides (such as technetium-99 and iodine-129). The percentage of the dose that results from irrigation would depend upon assumptions about the fraction of all food consumed by the RMEI from gardening or other crops grown using contaminated water. Therefore, the exposure for an RMEI located approximately 18 km south of the repository (where ingestion of locally grown contaminated food is a reasonable assumption) actually would be more conservative than an RMEI located much closer to the repository, who is exposed primarily through drinking water.

EPA does not believe that an RMEI likely would live much closer to Yucca Mountain than the Lathrop Wells area (up to the current southern edge of NTS) because of the increasing depth to ground water and the increasing roughness of the terrain (see Chapter 8 of the BID for more description of the site-specific factors that were considered). Also, we agree with one commenter that it is reasonable to consider the presence of NTS in determining the location. Even though we were citing NTS in discussing a potential controlled area (64 *FR* 47010), it is still our belief that: "...NTS has existed under the control of DOE for about 50 years....we believe that future generations will be aware of the extensive, well-publicized nuclear activities that occurred there....The NTS is well-known around the world for many reasons but most notably for the approximately 900 tests of nuclear weapons conducted there. This makes NTS unique in the Western Hemisphere." In addition, we believe that, near Lathrop Wells, a rural resident is likely

to have the highest potential doses in the region because of a higher concentration of radionuclides in the ground water than will exist farther away from Yucca Mountain. Also, with the RMEI growing a garden using contaminated water, the rural resident at 18 km downgradient from the repository will receive a higher dose than would an individual living much closer because the cost of water likely will allow only drinking the water and not having a garden capable of supplying a portion of an individual's annual food consumption (see Chapters 7 and 8 of the BID). Likewise, we do not believe that hypothesizing that the RMEI lives 30 km downgradient from the repository is either a cautious or reasonable assumption because: (1) at 30 km, the RMEI likely would use water in which the radionuclides are much more diluted; (2) the downgradient residents closest to Yucca Mountain are currently near Lathrop Wells; and (3) Nye County's short-term projections (20 years) show growth and development north of U.S. Route 95 up to the current boundary of NTS (near Lathrop Wells) through the development of a science center and research and industrial areas (Amargosa Valley Science and Technology Park Master Plan, March 1998, Docket A-95-12, Item V-A-16). Therefore, assuming that the RMEI lives in the Lathrop Wells area adds to the conservatism and provides more protection of public health, relative to one commenter's suggested distance of 30 kilometers. In our final rule, we require the RMEI to be located "in the accessible environment," which begins at the edge of the controlled area. We have specified that the controlled area can extend no farther south than about 18 km from the repository. However, if the controlled area does not extend that far south, the RMEI would presumably also be located closer to the repository (above the highest concentration in the plume of contamination). If so, the RMEI must still be assumed to have living style and diet reflective of residents of the town of Amargosa Valley (i.e., be a rural-residential individual).

Issue EE: The location of the RMEI needs to take into account site-specific factors.

1. While we can agree with the RMEI approach, we disagree with attempting to choose, in advance, the most limiting location of the receptor. Whatever group, groups, or individuals are to be analyzed for compliance against the standard, they must be representative of the existing population and exposure pathways at Yucca Mountain in order to be credible. Because this is a unique standard, specific to Yucca Mountain, the unique features of the site geology and hydrology need to be considered in determining the exposure scenarios and locations of the representative groups or individuals. (323)

2. The location should be based upon the ability of the RMEI to sustain himself consistent with topography and soil conditions. Depth to ground water should not be considered since neither future human activities nor economic imperatives can be predicted. (382)

Response to Issue EE:

The point of compliance for the IPS was determined using site-specific factors and the NAS recommendation to use current conditions (NAS Report, p. 54). In preparing to propose a location for the RMEI, EPA collected and evaluated information in the natural geologic and hydrologic features such as topography, geologic structure, aquifer depth, aquifer quality and the quantity of ground water, that may preclude drilling for water at a specific location (see the

response to Issues CC and DD above and BID Chapter 8). For example, we do not believe that a rural-residential individual would occupy areas much closer to Yucca Mountain than the area between the Lathrop Wells intersection and the current boundary of NTS because of the increasing rough terrain and the increasingly depth to ground water. With increasing depth to ground water, comes higher costs: (1) to drill for water; (2) to explore for water and (3) to pump the water to the surface. In addition, we believe that it is appropriate to use depth to ground water as a factor for determining the location for the RMEI. In so doing, we have followed the NAS recommendation to use "present knowledge and cautious, but reasonable, assumptions" (NAS Report, p. 100). We believe that given the current water usage patterns, economics, and site-specific factors that our reasoning is sound.

EPA agrees that this standard must incorporate assumptions about current conditions as the basis for projecting doses. This approach avoids the potentially endless need for speculation regarding future human activities and economics.

Issue FF: Although EPA's assumptions appear reasonable, NRC should determine the location of the RMEI.

1. [O]ur answer to EPA's request on Page 46990, Column 2, for comment on whether or not to leave location determination up to the NRC is yes, this should be left up to NRC. (244 (Q6))

2. [T]he determination should be made by NRC at the time of licensing. For this same reason, it would be premature to designate a location in any other of the sub-areas at this time. (556 (Q6))

3. The EPA should not go beyond considerations that are cautious and reasonable. Specification of additional assumptions for determining the compliance location are unnecessary. The NRC staff recognizes that the EPA has a need to discuss who is being protected by their standard. However, specification of the exposure scenario is a matter of implementation, and specification of the compliance location should be determined in the NRC's implementing regulation. [613 (Q6)]

Response to Issue FF:

EPA believes that specification of the location of the RMEI is entirely within the province of EPA's responsibility to promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at Yucca Mountain. By specifying the location of the RMEI, we seek to ensure that the standard is implemented in a manner that is appropriate for the assumptions and conditions that underlie it. Moreover, specification of the location of the RMEI is consistent with the recommendation of the NAS.

> Any approach to assessing compliance with the standard must make assumptions about the nature of the human activities and lifestyles that provide pathways for exposure. For example, people could drink water containing radionuclides,

> irrigate crops with the water, eat these crops, and bathe in the water. Quantification of the doses received from the various pathways requires detailed data on these pathways. For the example above, the average amount of water ingested per day (not including other beverages constituted with uncontaminated water) should be known, as should the types of crops grown, the amount eaten, and the frequency of bathing. The set of circumstances that affects the dose received, such as where people live, what they eat and drink, and other lifestyle characteristics including the state of agricultural technology are part of what we refer to as the exposure scenario (NAS Report, p. 97).

Thus, the location of the receptor clearly is a fundamental characteristic of the exposure scenario. Moreover, NAS recognized that it is the responsibility of the entity that is establishing the standard to specify this characteristic:

> The problem is how to pick an exposure scenario to be used for compliance assessment purposes. Given the lack of a scientific basis for doing so, we believe that it is appropriate for the regulator to make this policy decision. One specific recommendation we make is to avoid placing the burden of postulating and defending assumptions about exposure scenarios on the applicant for a license. The regulator appears to be better situated than the applicant to carry the responsibility because of the perception that any future scenario developed by the applicant could have been chosen to give the desired outcome. On the other hand, the results of calculations from a scenario specified by the regulator in an open process designed to consider the views of all the interested parties might be seen as a fair test of the suitability of a site and design (NAS Report, p. 98).

EPA has done this in the final rule. This is not to say, however, that in discharging its responsibility as regulator to identify this important characteristic of the exposure scenario, EPA is establishing an unchangeable location for the RMEI. Rather than at a specific point, the RMEI is to be located in the accessible environment above the highest concentration in the plume of contamination.

Issue GG: Support use of current population characteristics and avoiding speculation on future populations, lifestyles, and biosphere.

1. While we do not endorse the RMEI concept. . . we agree with the use of current population characteristics as the basis for evaluating radiation exposure scenarios. It would not be appropriate to require speculation about future populations as a basis for any repository licensing decision, as such characteristics cannot be known with any reliable degree of certainty. (224) EPA should follow the NAS recommendation by using the characteristics of the current population in the vicinity of Yucca Mountain to specify the CG (i.e, cautious but reasonable assumptions). (568, 611)

2. The EPA's conclusion on the location of the target population does represent a reasonable and conservative assumption, and further supports specifying that future populations be assumed to live in the same locations as those living in the Yucca Mountain vicinity today. (226, 241) The habits and characteristics assumed for the group should be chosen on the basis of reasonably conservative and plausible assumptions, considering current lifestyles as well as the available site or region specific information. (510) EPA should adopt its proposed approach to allow the use of current lifestyles and diet in determining the characteristics of the RMEI (or CG). DOE should be allowed to use surveys of current residents in the Amargosa Valley as a basis for determining receptor diet and lifestyles. NRC would determine the appropriateness of these surveys. (626)

3. On Page 46933, Column 1, EPA notes "that consideration should be given to changes on population near the location of the RMEI". This would be inconsistent with the approach taken elsewhere in the standard to limit speculation. (245)

4. We consider that it would be impossible to bound future attributes for projecting individual doses. [774 (Q5)]

Response to Issue GG:

As discussed in Section III.B.1.d. of the preamble, the NAS recommended that the exposure scenario "use assumptions that reflect current technologies and living patterns." (NAS Report, p. 122. NAS also recommended that the assumed population should "be defined using present-day knowledge with cautious, but reasonable, assumptions" (NAS Report, p. 10). EPA has implemented these recommendations regarding the RMEI.

EPA has defined the location of the RMEI to be no farther away from the repository than about 18 km south of the repository (north of Lathrop Wells) based upon a comprehensive review of site-specific information (see Chapter 8 of the BID). In our analysis, we also considered short-term population projections developed by Nye County, which are part of the present-day knowledge base. We believe that it is a cautious, but reasonable, assumption based upon this present-day knowledge to project an increase in population in the Lathrop Wells area (see Chapter 8 of the BID). Comment 245 asserts that "[o]n Page 46933, Column 1, EPA notes 'that consideration should be given to changes in population near the location of the RMEI.' This would be inconsistent with the approach taken elsewhere in the standard to limit speculation." This comment quotes only a fraction of our actual statement (appearing on page 46993), and misperceives or misrepresents our unmistakable intent:

> We agree with the NAS on this point and propose that speculation concerning some characteristics of the future should not be the focus of the compliance determination process. Instead, we believe that it would be more appropriate to assume that those characteristics will be the same as they are today. No one should interpret this assumption so literally that only current residences and lifestyles of individuals living in the area on the day of promulgation of this part can be considered. Rather, we intend that, based upon current knowledge, DOE and

> NRC may use those characteristics in combinations in a cautious, but reasonable, manner as input into the Yucca Mountain performance projections. Future characteristics [that] NRC and DOE may assume to be the same as they are today include the level of human knowledge and technical capability (including medical), human physiology and nutritional needs, general lifestyles of the population, and potential pathways through the biosphere leading to radiation exposure of humans. Also, we propose that it is inappropriate to speculate upon extreme changes in the number of residents, but that consideration should be given to changes in population near the location of the RMEI. (64 *FR* 46993).

Thus, far from being inconsistent with EPA's general approach in this rule to limit speculation on potential futures, this statement, when placed in its proper context, merely indicates EPA's intent that the short-term population projections developed by the local government – population projections that are part of the present-day knowledge base and are present in EPA's rulemaking docket – should be considered as part of the exposure scenario.

Where EPA specifies factors in the exposure scenario EPA has used cautious, but reasonable, assumptions. For example, we require the assumption that the RMEI drinks 2 liters per day (L/day) of ground water, which is taken from the location where the RMEI lives (above the highest concentration in the plume of contamination). We assume further that some of the food (based upon surveys) consumed by the RMEI is from the local area. We consider the consumption of 2 L/day of drinking water to be a high-exposure value for ground-water consumption even though in a desert environment intake rates could be higher, however, in the rural-residential scenario other liquids and possibly some of the RMEI's 2 L/day will be from outside sources, such as commercial products. We intended that it would result in dose estimates towards a reasonably maximal exposure. Similarly, we assume that local food production will use water contaminated with radionuclides released from the disposal system. We believe this lifestyle is similar to that of most people living in town of Amargosa Valley today. Therefore, under our standard, the RMEI will have food and water intake rates, diet, and physiology similar to those of individuals in the town of Amargosa Valley.

Issue HH: The EPA should take future changes in population, land use, climate, and biota into consideration.

1. The present patterns of population and of land use unquestionably will vary over time. (30)

2. The climatic changes by the year 12,000 A.D. should be based on the climate 8,000 B.C. or look at 10,000 years from now. (163)

3. Population densities and distributions will reflect climate and biota. . . The climate and biosphere will play a key factor in location as will as the definition of who and what occupations are represented by the CG & the RMEI. (165)

4. It is, of course, unrealistic for EPA to assume that future population distribution will be static, patterned as it is today. (365, 367, 383, 543, 547)

Response to Issue HH:

While EPA agrees that it is likely true that the present patterns of population and of land use unquestionably will vary over time (comment 30), and that future population distributions may not be patterned as they are today (comments 365, 367, 383, 543, 547), we have chosen not to engage in what, ineluctably, must be unfounded speculation concerning what those potential population distributions and land use changes may be. The NAS concurred with this decision:

> In view of the almost unlimited possible future states of society and of the significance of these states to future risk and dose, both EPA and we have recommended that a particular set of assumptions be used about the biosphere (including, for example, how and where people get their food and water) for compliance calculations. Both EPA and we recommend the use of assumptions that reflect current technologies and living patterns (NAS Report, p. 122).

Therefore, the only future changes that EPA considered with respect to population distributions were the relatively short-term population changes that are planned by Nye County north of U.S. Route 95 in the vicinity of Lathrop Wells (i.e., toward the NTS boundary). We also compared current land use with the soil conditions that would be conducive to allowing the rural-residential RMEI do some gardening or have a grazing cow. We found that soil types similar to those in the agricultural area in southern Amargosa Valley exist around Lathrop Wells, and that given adequate water, the soil should support crop production (see Chapter 8 and Appendix III of the BID). Therefore, we find this assumption to be reasonable. Comment 165 asserts that population densities and distributions will reflect climate and biota and that climate and biosphere will play a key factor in location as will as the definition of who and what occupations are represented by the RMEI. Climate change will be taken into account as part of the performance assessment rather than part of the exposure scenario, i.e., we require that the values describing it be varied over time rather than assuming that it always will be the way it is today. In response to comment 163, the time frame which is considered in the process of establishing the parameter values for climate change will be determined by DOE and NRC in the licensing process. The biota are considered to be part of the current biosphere and, as such, are assumed to be the same during the compliance period as they are today, this includes the interaction between the RMEI and the biota in the environment. To do otherwise, we believe, would result in unfounded speculation.

Issue II: The EPA should be more specific on the characteristics (parameters) of the RMEI.

1. EPA may want to be even more specific in setting location, behavior, and lifestyle or pass that responsibility to NRC. (393)

2. The location for the source of water used by the subsistence farmer CG should be at the downgradient edge of the footprint of the repository, where the maximum radionuclide concentration can be expected. (284)

Issue JJ: NRC should specify the parameter values of the CG or RMEI.

1. EPA should not specify parameter values for the RMEI. (261)

2. I do not recommend that EPA specify parameter values for the RMEI. (462)

3. DOE does not object to EPA specifying a parameter value of 2 L/day for drinking water consumption or a hypothetical location for the RMEI in the range of 20 to 30 km from the repository. However, other parameter values should not be specified in EPA's standards and should instead be determined during the licensing process. (627)

4. We find the argument compelling in EPA's choice of Lathrop Wells as the compliance location and agree with EPA's conclusion in this respect. We also support EPA's choice of Lathrop Wells and the ingestion rate of two liters per day of water as appropriate high-end values for parameters to be used to project doses. However, having agreed in principal to EPA's choices, we consider that these are implementation parameters to be set by the NRC, not through EPA's rulemaking process. (765)

Response to Issues II and JJ:

In the final rule, EPA establishes the basic parameters and their values for the exposure scenario. In so doing, we are following the NAS recommendation that EPA establish the exposure scenario (NAS Report, pp. 97-103). We also recognize that NRC will implement the standard and, therefore, we believe that we have specified just the necessary details regarding the characteristics of the rural-residential RMEI for NRC to implement the concept as we intend it to be implemented. The parameters and the values that we have defined are those that we believe are cautious, but reasonable, to estimate doses that would occur toward the high-end of the spectrum of potential doses (i.e., the process that is key to using the RMEI methodology) (see the response to Issue Y for more details). Those assumptions are that the RMEI drinks 2 L/day of ground water, lives in the accessible environment above the highest concentration in the plume of contamination, and has a diet the percentage of which consists of the same percentage of locally grown food eaten by residents of Amargosa Valley today. The definition of other biosphere parameters has been left to NRC. We believe that this division of responsibility is appropriate given the respective roles of the agencies and the NAS recommendation.

Comment 284 advocated placing the withdrawal well at the downgradient edge of the repository footprint. We believe that this is inappropriate in the case of Yucca Mountain. This issue is discussed in Section III.B.1.d. of the preamble for the final standards, where we conclude, after studying the area downgradient from Yucca Mountain, that it is improbable that the rural-residential RMEI would occupy locations significantly north of the current southern boundary of NTS because the rough terrain, increasing depth to ground water, difficulty of drilling through tuff, and the fractured nature of the rocks nearer Yucca Mountain would likely discourage settlement by individuals because access to water is more difficult than it would be a few kilometers farther south near Lathrop Wells.

Issue KK: The RMEI approach does not appear to provide adequate protection from atmospheric pathways.

1. It is not clear how the proposed RMEI affords protection from atmospheric exposure for persons residing down-wind from the repository. An additional RMEI related to atmospheric exposure pathways should be developed and utilized in the final rule. The final rule must make clear the protection afforded persons from atmospheric exposure pathways. (521, 524, 525)

Response to Issue KK:

EPA disagrees. The IPS in § 197.20 applies to the dose received by the RMEI through all pathways, including the air pathway. We agree with NAS (NAS Report, p. 88), and it is our requirement, that doses from gaseous releases be included in the calculation of the dose incurred by the RMEI. Therefore, any dose from the radionuclides arriving in the vicinity of the RMEI through the air are included in the protection afforded the RMEI by the IPS just the same as radionuclides arriving via ground water.

EPA notes that NAS estimated the dose to an individual by averaging its calculated global population dose of 37 person-Sv/yr over 12 billion people to arrive at an individual dose of 0.3 μSv/yr (NAS Report, p. 59). It then notes that this is well below the individual-dose limit in 40 CFR part 191 (which is the same as in 40 CFR part 197) of 15 mrem CEDE/yr. We have not performed our own analyses of air releases, but we do not question the general outcome of the NAS estimate, i.e., that air releases from the waste will result in very small individual doses. Therefore, the impact upon any particular individual will be very small. We have seen no information that supports a contrary conclusion.

Issue LL: At Superfund sites, the EPA would assess risks using lifestyle assumptions that limit the doses to the most highly exposed individuals. EPA's general policy has been to protect against "high-end individual exposure." In contrast, the proposed Yucca Mountain standard allows DOE to assess the risks for the average person currently residing near the site. (591)

Response to Issue LL:

The hypothetical person being used in 40 CFR part 197 for calculational purposes is not "the average person living near the site," it is the "reasonably maximally exposed individual." EPA intends for the dose incurred by this person to be in the "high-end" of the exposure range, although not the absolutely maximally exposed individual. This is the same concept used by the Superfund program. Of the factors that are used to project doses incurred by the RMEI, one or a few of the most sensitive factors (i.e., those which have the most influence on the outcome) are set at their maximum value. The rest, which are, by definition, less "sensitive," may be set at their average value. We have specified that the location to the north of Lathrop Wells and the 2 L/day of water consumed by the RMEI from the aquifer underlying that location are two of the maximum values. The NRC is free to name additional factors that must be kept at their maximum values.

Issue MM: [T]he proposed RMEI concept forces DOE to assume the RMEI will withdraw water from the highest concentration plume without consideration of the likelihood. Forcing such an assumption neglects a very important site-specific aspect of the Yucca Mountain system. (242)

Response to Issue MM:

The approach suggested by comment 242, which would use a probabilistic method to determine the radionuclide concentration withdrawn by the RMEI, is similar to one of the example CG approaches that NAS provided in its report (NAS Report, Appendix C). The NAS's approach would use statistical sampling of various parameter values, i.e., considering the probability of various conditions existing, to arrive at a dose for comparison to the standard. EPA did not use this CG approach for the following reasons: (1) there is no relevant experience in applying the probabilistic-CG approach; (2) the probabilistic-CG approach is very complex and is difficult to implement in a manner that assures it would meet the requirements of defining a CG (i.e., a small group of people who are homogenous in regards to exposure characteristics, including receiving the highest doses among the general population); and (3) we are concerned that this approach does not identify clearly which individual whose dose is being projected. Also, current understanding of the site indicates that contamination plumes from repository releases would not disperse broadly downgradient from the repository. Rather, it appears that releases will be confined to relatively narrow plumes in the ground-water flow system (see Chapters 7 and 8 of the BID). A probabilistic approach for CG exposure could include members that would receive little or no exposure and members that would receive much higher exposures, which is not consistent with the basic concept of a CG. We believe that use of an RMEI is a more conservative approach, based upon site-specific conditions, because the RMEI serves to represent

those few individuals who would receive the highest doses, based on cautious, but reasonable, assumptions. Finally, a significant majority of the comments on the NAS Report opposed the use of the probabilistic-CG approach. We further believe that prudent public health policy requires that our approach be followed to provide reasonable, but not excessive, conservatism. To allow the probability of any particular location being contaminated is not a realistic approach to the ultimate goal of testing acceptable performance.

Issue NN : The RMEI approach is overly conservative.

1. We consider that the average member of the CG approach recommended by the NAS provides a reasonable algorithm for determining public health and safety. We consider that the approach the EPA has proposed, the RMEI as the representative of a future "rural-residential" population group, is also protective, but we are concerned it may be overly conservative, as EPA has defined it here. (764)

Response to Issue NN:

EPA believes that the RMEI exposure scenario is consistent with widespread practice, current and historical, of estimating dose and risk to highly exposed individuals even when the exposure habits of future people cannot be specified or accurately calculated, as in this case where doses must be projected for very long periods. This approach is straightforward and relatively simple to understand. The RMEI approach uses a series of assumptions about the lifestyle of a hypothetical individual. The desired degree of conservatism can be built into the model through choices of assumed values of RME parameters. These values, however, must be within certain limits, since we require the use of Yucca Mountain-specific characteristics in choosing those parameters and their values. In subpart B of 40 CFR part 197, we define the values of a few of the parameters that we believe are critical to implementing the concept as we intend it to be used and, therefore, incorporated into NRC's implementing regulations (see the response to Issues II and JJ, above, for more discussion on the particular parameters and their values which we have defined).

EPA does not believe that the results obtained using the RMEI approach would be "overly conservative" relative to the CG approach. In fact, we believe that the results will be similar to those that would be obtained by using the subsistence-farmer CG approach put forth in Appendix D of the NAS Report. In both cases, the objective is to determine the magnitude of the potential exposure using cautious, but reasonable, assumptions. The RMEI approach, however, requires only a few of the parameters that are used to calculate the doses be placed at their maximum values, whereas the NAS subsistence-farmer is "the individual at calculated maximum risk. Thus, the subsistence-farmer approach is conservative and bounding" (NAS Report, p. 161). We have chosen not to use a bounding calculation, but, rather, a method that reflects current lifestyles in Amargosa Valley, given that we are unaware of any subsistence farmers (defined as raising all their own food and drinking only water from the aquifer) in that area. This assumption of using current knowledge is in keeping with the NAS recommendation regarding the reference biosphere (NAS Report, p. 10). Our intent is to use a theoretical individual whose potential dose is near the

"calculated maximum risk," but reflects more realistically possible doses based upon today's conditions.

Issue OO: The calculation of the dose and risk in the CG.

1. In the long-term, homogeneity of the critical group should not be a major concern if due attention is paid to the choice of the habits and characteristics of such group. Additionally, it is reasonable to calculate the annual dose/risk averaged over the lifetime of the individuals which means that it is not necessary to calculate the doses to different age groups. (512)

Response to Issue OO:

Since EPA has chosen to use the RMEI rather than a CG, these issues are moot relative to the current rulemaking. However, in general, we believe that paying "due attention" to the habits and characteristics is tantamount to defining homogeneity within the CG. In addition, homogeneity is a fundamental basis of a CG – on page 52 of its report, NAS stated: "The critical group has been defined by the ICRP (1977, 1985b) as a relatively homogenous group of people...." Therefore, we believe that homogeneity is a necessary factor in determining a CG. By contrast, the RMEI is defined to be representative of the rural-residential lifestyle and is described by many parameters to which we have paid due attention. We have defined or outlined several factors, i.e., water drinking rate, location, diet, and general lifestyle. Some of the values of these parameters are held at their maximum level and others are an average level. This relieves the need to "worry" about homogeneity within a group.

As stated in the response to Issue AA (comments 6, 29, and 484, specifically), we have derived a risk value for the onset of fatal cancer that is an overall average risk value (see Chapter 6 of the BID for more details) that includes all exposure pathways, both genders, all ages, and most radionuclides and, this is the basis of the individual-protection CEDE limit. Therefore, we agree with the commenter and do not require that calculations be done on an age-specific basis.

Issue PP: EPA's standards for Yucca Mountain should employ the linear, no-threshold hypothesis in determining doses.

1. I am deeply concerned that we are seeing a concerted move away from the linear hypothesis of dose response, when in fact a substantial body of literature now exists to indicate that we should be moving to substantially more conservative, not less conservative protection of people and the environment. (38)

2. The EPA should use the linear, no-threshold hypothesis even for very small doses. The fact is that all incremental doses are above a considerable background radiation dose. Therefore, even very small doses may produce proportionate effects, since any threshold that might exist may already be exceeded by the biological damage caused by natural background radiation and other background carcinogenic risk factors. [286 (Q7)]

3. You cannot refute that any increase in exposure to ionizing radiation results in a constant and proportionate increase in the potential for developing cancer. (541)

Response to Issue PP:

EPA does apply an LNT model to estimate radiogenic cancer risks. This model is applied because the probability of a radiation-caused cancer or genetic effect is related to the total amount of radiation accumulated by an individual and based upon current scientific evidence, any exposure to radiation can be harmful (or can increase the risk of cancer). We used the current risk per unit dose conversion factor of 5.75×10^{-2} cancer deaths per person-Grey (Gy) for low-dose, low-LET uniform whole-body irradiation provided in Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20) to estimate the lifetime excess fatal cancer risk associated with the IPS. This conversion factor is based upon an LNT model and a dose and dose rate reduction factor of 2. Our IPS sets a limit of 150 μSv (15 mrem) CEDE/yr. This limit corresponds approximately to an annual risk of developing a fatal cancer of 8.5 chances in 1,000,000 (8.5×10^{-6}) which is within NAS's recommended starting range of 1 in 100,000 to 1 in 1,000,000 (NAS Report, p. 5, Docket A-95-12, Item II-A-1). The NAS's recommended risk range corresponds to approximately 2 to 20 mrem CEDE/yr. Therefore, based upon similar calculations, EPA rejected a 25 mrem/yr standard because the associated risk (i.e., 1.2×10^{-5}) exceeds the NAS range.

Issue QQ: EPA's risk assessment did not properly consider the mixtures of radionuclides and their combined effects, and of heavy metals.

1. Number one, in YMP risk assessment and EPA assessment, they did not take into account the effects of radionuclides mixtures. Second, EPA assumed that the total affect of all radionuclides is additive. This is incorrect. (98)

2. And the mechanism of radiation damage is the production of free radicals. I have not seen this being addressed in YMP or EPA approach. (99)

3. You don't know what the hell is going on with all of the radionuclides. To make it work, we have a problem of the complex mixture from radionuclides and the heavy metals. It was not – has [not] been taken into account. (102)

Response to Issue QQ:

EPA accounted for the combined effects from all radionuclides and decay products in its assessment (see Chapter 6 of the BID and Federal Guidance Report No. 13, Docket A-95-12, Item V-A-20). These effects (doses and risks) are considered to be additive. We base our radiation risk estimates on epidemiological studies, which implicitly include all types and mechanisms of damage caused by ionizing radiation. Our specific and limited authorities under the EnPA restrict the scope of Yucca Mountain assessments to radiogenic cancer risks only. We

did not analyze or include the potential health risks from heavy metals that may be also be released from the repository.

Issue RR: Does EPA's risk assessment model for Yucca Mountain consider both the inhalation and drinking water pathways?

1. Because 15 millirem, if you're going to use it as a risk assessment, using alpha particle inhalation and drinking has different effect [on] different tissues. What is the total effect? (100)

Response to Issue RR:

The models used by EPA address all pathways of exposure, and the metabolic models include calculations of the dose to various organs and at all times up until death. Therefore, the calculated dose includes assessment of all of these factors. For additional, detailed discussions regarding our models and assumptions (see Chapter 6 of the BID and Federal Guidance Report No. 13, EPA 402-R-99-001, Docket A-95-12, Item V-A-20).

Issue SS: EPA should use the most current dose conversion factor from Part 20 of the NRC regulations.

1. With respect to dose conversion models, we note that the conversion factor (latent cancer fatalities per rem) cited in the proposed rule is different than that specified in ICRP 60 by about 15 percent. We recommend that whatever version of Part 20 of the NRC regulations is current at the time of licensing be used. This will assure that the agency with the most expertise in this area has adopted appropriate dose conversion factors and calculational methods through the most current public rulemaking process. (325)

Response to Issue SS:

As explained in the response to Issue PP, EPA used the current cancer mortality risk per unit dose conversion factor in Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20) to estimate the lifetime excess fatal cancer risk associated with the YM standard. As explained in Federal Guidance Report No. 13 and in EPA's 1994 report Estimating Radiogenic Cancer Risks (EPA 402-R-93-076, Docket A-95-12, Item V-A-28), this conversion factor is based upon the latest scientific information and understanding about radiation-related health effects. It integrates age-, gender-, and cancer-site-specific radiogenic risks, incorporates updated vital statistics for the U.S., and accounts for competing forms of death. We considered, but rejected, using a similar factor recommended by the ICRP in 1990, primarily because the ICRP value is obsolete and not as comprehensive.

Issue TT: Use of organ-weighting factors may be unrealistic.

1. Moreover, the use of organ weighting factors in the calculation of the effective dose equivalent may be unrealistic for the actual organ doses experienced by an individual. (360)

Response to Issue TT:

The weighting factors represent the proportion of the stochastic risk from the tissue to the total stochastic risk when the total body is irradiated uniformly. The organ weighting factors are independent of organ dose calculations, and the dose calculations are our best estimates. For additional discussion, see Chapter 6 of the BID, Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20), and Estimating Radiogenic Cancer Risks (EPA 402-R-93-076, Docket A-95-12, Item V-A-28).

Issue UU: EPA should take a conservative approach in determining the committed effective dose equivalent based upon current, incomplete knowledge.

1. The CEDE has been based on our current, but incomplete, knowledge of full and long-term radiation health effects and on numerous unstated assumptions. It is therefore important for EPA to take a more conservative position as the basis for protection than CEDE affords. (362)

Response to Issue UU:

EPA has investigated the assumptions and uncertainties in its dose and risk models. In general, we believe that, while our estimates are not upper bounds, they tend to overestimate, rather than underestimate, the true doses and risks. For additional discussion, see Chapter 6 of the BID, Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20), Estimating Radiogenic Cancer Risks (EPA 402-R-93-076, Docket A-95-12, Item V-A-28), and Estimating Radiogenic Cancer Risks: Addendum (EPA 402-R-99-003, Docket A-95-12, Item V-A-28).

Issue VV: The use of dose suggests that one or more individuals will have to be exposed at levels in excess of the standard before a violation of the standard would be considered to have occurred. Lincoln County and the City of Caliente cannot agree with the use of residents of or visitors to Nevada as "environmental markers"... (519)

Response to Issue VV:

There is no intention of making any organism, either human or any other, an environmental marker. The disposal standards are prospective standards, i.e., they apply to projections of potential exposures. EPA does not believe that it is realistic to require or assume that monitoring will be occurring for as many as 10,000 years. Therefore, we are attempting to limit the amount of exposure that is projected to occur to levels that are acceptable to most of society today. The principle would be the same if we used risk for the standard. On the other hand, the storage

standards are written as operational standards. While NRC will be responsible for enforcing these standards, we assume that the standards will be enforced using computer modeling and environmental monitoring, just as radiation regulations are enforced at operating facilities today.

Issue WW: How can EPA allow a certain dose if no amount of radiation is safe?

1. I don't see how you can allow a certain dose of radiation as "safe?" How do you know the history of the person irradiated? (535)

Response to Issue WW:

The exposure history of the RMEI is hypothetical because the RMEI is a hypothetical individual. Of course, if this person were real, it would be unreasonable to attempt to write a standard which takes into account every person's exposure history. Rather, EPA must write the standard based upon the policy judgment of what level of dose is an acceptably small addition to individuals' risk. We established the dose limit using the risk of developing a fatal cancer. The level of risk, 8.5 fatal cancers per million members of the population per year (see Section III.B.1.c. of the preamble to the final rule), is a level EPA has judged to be acceptable taking into account many factors, including existing radiation standards (such as subpart B of 40 CFR part 191), Congressional action (WIPP LWA), NAS's recommended risk range (NAS Report, p. 49), and the comments received on the proposed standards. As stated earlier, the judgment of what risk level is acceptable is a matter of public policy, it is possible that the level could change if future decision-makers make a different judgment as to the level of risk acceptable to the general public.

Issue XX: The radiotoxicity rankings of most fission and activation products are unfortunately more conjecture than science. (150)

Response to Issue XX:

EPA categorizes all radionuclides as known human (Group A) carcinogens. This decision is based upon the extensive weight of evidence of cancer induction in animals and humans exposed to moderate and high doses of ionizing radiation. As explained in Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20), to calculate the lifetime cancer risk associated with the ingestion or inhalation of a given radionuclide, EPA uses very specific and detailed models that account for the intake, absorption, distribution, retention, and excretion of that radionuclide over the lifetime of the individual. We combine the results of these models with knowledge about the specific types and amounts of ionizing radiation emitted by each radionuclide to estimate the absorbed dose to each organ over time. Finally, based upon the calculated organ-specific doses and on age-, gender-, and organ-specific risk per unit dose factors, we sum all organ-specific risks over time to yield a total lifetime risk per unit intake. Given the specificity and detailed nature of the models employed, we believe that our estimates of radiation doses and risks associated with radionuclide intakes are reasonable and comprehensive.

Issue YY: One risk of ionizing radiation is genetic mutations in the children of exposed people. As dose (risk) increases with years of exposure, you should really be concerned about accumulated dose up to the end of child bearing period (say about 40 years). Therefore integrated (CEDE) doses should be calculated from birth or conception to 40 years of age to correctly assess this adverse effect. (188)

Response to Issue YY:

The CEDE might be considered an overestimate. The CEDE would be integrated from birth (or what ever age exposure starts) to age 50 or age 70. EPA uses an estimate of dose to age 30, the approximate median age for human reproduction, to estimate dose for genetic effects. As discussed in Chapter 6 of the BID, as well as in Federal Guidance Report No. 13 (EPA 402-R-99-001, Docket A-95-12, Item V-A-20) and in Estimating Radiogenic Cancer Risks (EPA 402-R-93-076, Docket A-95-12, Item V-A-28), we believe that the potential genetic effects associated with radiation exposure will be small compared to the carcinogenic risks.

Section 5 Human Intrusion[1]

Issue A: The human intrusion scenario analysis is an implementation detail that should be left up to DOE and NRC to deal with and should not be included in the EPA standard.

1. Specifying potential scenarios for human intrusion is an implementation issue that falls completely within NRC's authority. (230, 237)

2. EPA feels that the human intrusion standard is inconsistent and unnecessary. If however it is decided such a standard is necessary in view of the NAS recommendations it should be made qualitative and the fixed location could be made less prescriptive by proposing any drill site above the repository footprint or leaving that implementing detail to NRC. (558)

3. Prescription of the stylized calculation for evaluating human intrusion should not be part of EPA standards. Specification of the stylized calculation more appropriately belongs in the NRC's implementing regulations. (311, 604)

4. Specification of a calculation for NRC to use to evaluate the consequences of human intrusion on repository performance is a matter of implementation to be determined by NRC. NRC has proposed implementing regulations at 10 CFR part 63, that include a proposal for evaluating the consequences of an assumed intrusion, on which we have received significant comment. We will fully consider these comments prior to finalizing the rule. The EPA should eliminate the separate provisions for evaluating human intrusion by deleting §§197.25 and 197.26. (617)

5. EPA recommends that the standard for human intrusion should be part of this rulemaking, but the implementation should not. Human intrusion scenarios are a matter of implementation of and compliance with the proposed radiation standard. We consider that potential scenarios definitions fall within NRC's mandated authority. (770)

[1] All acronyms are defined in Appendix B.

Response to Issue A:

Comment on this issue expressed opinion that the framing of the human intrusion scenario should be left as an implementation detail for NRC, or that the intrusion scenario standard is unnecessary. EPA disagrees with these comments for the reasons discussed below, and we also believe that framing the basic elements of the stylized intrusion scenario is a necessary part of the standard in order to supply the context for the more detailed implementation effort NRC will perform.

Under the mandate from the EnPA to develop a standard to protect public health, EPA believes that human intrusion is an appropriate component of the standard. There are two means by which radionuclides can be released from the repository: (1) by the expected gradual degradation of the waste containment barriers (the engineered components of the repository, e.g., the metallic waste containers) through natural processes and events and the consequent slow release of radionuclides in the wastes, or (2) by either deliberate or inadvertent disruptions of the waste containment and isolation system. Human intrusion is the prime example of disruption of the repository system with consequent releases of radionuclides to the environment and exposures to the population. Under the EnPA mandate to develop protective health and safety standards, developing a standard for any deep geologic repository requires both avenues for potential radionuclide releases to be considered so that the standard is complete and protective. For these fundamental reasons we believe that human intrusion is an appropriate component of the Yucca Mountain standard. The relative importance of these two release modes can differ depending on the specific geologic setting involved. For example, releases from the gradual degradation of the natural and engineered barriers in a salt repository would be very minor because of the isolation the geologic setting provides from the surrounding ground waters. For this setting, the human intrusion into the repository offers the most important potential for releasing radionuclides to the surrounding environment. Salt formations are also often the host for exploitable resources and, consequently, intrusion has a higher probability than less resource-rich geologic settings. Therefore, performance analyses of human intrusion scenarios play a major role in regulatory decision making. In contrast, a repository site in fractured rocks, through which ground water can more easily access the disposed wastes, would have a higher potential for releases through degradation of the repository containment barriers. For this case the relative importance of human intrusion caused releases would depend on the abundance of exploitable resources in that geologic setting. Although the relative importance of the two release modes will vary, they must both be included to assure a protective approach to developing the standard.

Reflecting the rationale above, there are two basic sources for guidance in developing the site-specific standard for the Yucca Mountain repository: the guidance and recommendations provided in the NAS Yucca Mountain Report, and the generic performance standards contained in 40 CFR part 191. Specific guidance for framing details of the human intrusion scenario appropriate for the Yucca Mountain site is given in the NAS Report. The NAS guidance acknowledged that analyses of human intrusion have value in terms of providing insight into "the degree to which the ability of a repository to protect public health would be degraded by intrusion" (NAS Report, p. 108). The NAS Report provided additional recommendations on the nature of the intrusion scenario it believed appropriate for the Yucca Mountain site; the approach to be taken for

construction of the scenario to be addressed in a consequence analysis; the acceptable level of risk against which the results of the consequence analysis should be judged; and the relation of the human intrusion assessments to the expected case assessments for repository performance used to judge compliance with an individual protection standard (NAS Report, Chapter 4). In addition, NAS recommended, "Because the form and frequency of intrusions cannot be predicted ... To provide for the broadest consideration of what scenarios might be most appropriate, we recommend that EPA make this determination in its rulemaking to adopt a standard" (NAS Report, p. 111). From the extensive recommendations in the NAS Report, it considered the assessment of human intrusion to be an appropriate component of the Yucca Mountain standard, and we agree with its assessment.

Moreover, as explained in Section I of the preamble to the final rule, 40 CFR part 191 contains the generic standards appropriate for any deep geologic repositories used for disposal of SNF, HLW, or TRU radioactive waste. Without a sound site-specific rationale for omitting a component of the 40 CFR part 191 standard, the major components of the 40 CFR part 191 standard (i.e., individual protection, and ground- water protection, containment standard and assessment of human intrusion) may serve as starting points for the development of any site-specific standard. Human intrusion is included in 40 CFR part 191 as a component of the standard.

In summary, the inclusion of human intrusion into the Yucca Mountain standard is appropriate from very fundamental principles, i.e., the intrusion is a way in which exposures to the population can occur and therefore has potential health consequences. NAS, in its recommendations to EPA, supported the inclusion of human intrusion analyses in the standard and the development of intrusion scenarios for consideration in the EPA rulemaking process. In addition, human intrusion has been established as a generic component of repository regulation, i.e., it is included in the generic standards (40 CFR part 191) established by law and intended for any and all repositories for the type of waste intended for the Yucca Mountain repository. We therefore disagree that the provisions in the rule addressing human intrusion should be removed from the standard (comments 237, 558, 617).

A number of comments offered opinion that human intrusion scenarios and assessments should be considered as implementation issues and left to the discretion of NRC as the implementing authority (comments 230, 558, 604, 617, 770).

For the reasons described above, EPA believes that human intrusion assessments should be a fundamental part of the health and safety standards for the Yucca Mountain site, and as such we believe the analysis of human intrusion scenario consequences should not be left to the discretion of the implementing agency to include or omit from the licensing process. In fact, NAS explicitly stated, "EPA should specify in its standard a typical intrusion scenario to be analyzed for its consequences on the performance of the repository" (NAS Report, p. 108). We agree with this position and we believe that specifying the general components of the intrusion scenario is necessary to assure that it is assessed appropriately during implementation. As explained below,

we also believe we have left sufficient flexibility for NRC to more fully define the intrusion scenario so that actual consequence analyses can be performed.

The NAS also made other more specific recommendations about the approach and requirements for the treatment of human intrusion in the EPA standard, with which we agree and have incorporated into the standard. The NAS recommended, among other details, that:

> (1) "EPA should specify in its standard a typical intrusion scenario to be analyzed" (NAS Report, p. 108) - and we have defined a stylized drilling intrusion scenario (Section 197.26) consistent with other NAS recommendations (NAS Report, Chapter 4);
>
> (2) "Because the assumed intrusion is arbitrary ... the analysis should not be integrated into an assessment of repository performance ..... but rather should be considered separately" (NAS Report, p.109) - we have separated the individual protection and human intrusion standards (Section 197.25);
>
> (3) "EPA should require that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels .... acceptable for the undisturbed repository case" (NAS Report, p. 113) - we apply the same exposure limits to both the individual protection and human intrusion standards (Section 197.25).

EPA believes that specifying the most basic aspects of the human intrusion scenario to be assessed, and the standard against which the results of the consequence analysis must be judged, are necessary in order to supply the context for the more detailed implementation that NRC will perform as part of its licensing functions. We note that the NAS comments conclude that, "..the proposed EPA approach to human intrusion appears to have followed the TYMS recommendations very closely" (Docket A-95-12, Item IV-D-31). We have specified sufficient details concerning the stylized intrusion to assure it is assessed as we (and the NAS recommendations) intended, but we have left considerable flexibility to NRC in further defining the details of the assessment. In fact, our requirements for the stylized intrusion scenario are limited, so additional details must be specified before any actual consequence calculations could be performed, leaving considerable flexibility to both DOE and NRC for implementation issues. For example, although we have specified that the intrusion breaches a waste package and establishes a connection with the saturated zone below the repository [consistent with NAS recommendations (NAS Report, p. 111)], we have not specified the mechanism(s) by which radionuclides would migrate from the waste package, through the poorly sealed borehole and along the ground-water travel path. These potential variations allow NRC to exercise considerable flexibility in implementing the standard. In addition, our standard does not preclude NRC from requiring analyses of additional intrusion scenarios if, in its judgement, such scenarios are important for compliance purposes. We note that the NRC comments (comments 604, 617) about this implementation issue did not support its position that specifying an intrusion scenario and a consequence calculation for compliance purposes is an inappropriate action for the EPA rulemaking, other than to say that an intrusion scenario had been incorporated into its draft standard for the Yucca Mountain repository. As explained above, we believe that human

intrusion analyses are appropriate for the standards, we have specified sufficient detail to assure the stylized intrusion scenario is assessed as we (and NAS) believe is appropriate. We have, however, left sufficient room for NRC to exercise its discretion on implementation. We believe that our standard sets the context in which the intrusion assessment analyses and decision making should be implemented. Additional discussion on implementation details is presented in the responses to comments (grouped under Issue D below) dealing with our framing of the intrusion scenario.

One comment suggested that the intrusion scenario be treated qualitatively and the scenario be modified to leave placement of the drill hole as an implementation detail (comment 558). As noted above, the NAS recommendations about the level of risk from the intrusion releases unquestionably implies a quantitative assessment of potential release consequences, rather than a simple "qualitative" assessment. The NAS also explicitly stated a measure for the repository "resilience" assessment, "EPA should require that the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels ... acceptable for the undisturbed repository case" (NAS Report, p. 113). EPA believes that only a quantitative calculation, and a comparison against a set limit, allows the intrusion analysis to be evaluated as intended by NAS and EPA. We are not aware of any "qualitative" approach that would allow the consequences of an intrusion to be definitively judged in a licensing process. Unless the results of the consequence analyses are compared against a set limit, their use in compliance determinations is ambiguous, particularly if a wide range of speculative scenarios (with equally speculative and varied dose estimates) are assessed, any one of which is no more defensible than any other in terms of the probability of their occurrence.

On the question of leaving the placement of the intruding drill hole as an implementation detail, the intent of the stylized intrusion scenario is to avoid speculative scenarios while allowing the "resilience" of the repository to be evaluated by an intrusion scenario that would unquestionably result in some level of exposure. By requiring that the waste package be penetrated and a connection established with the underlying ground-water flow system, a pathway leading to some level of exposure is assured and an analysis is possible. If the borehole placement was left undefined, other drill hole placements that would not directly penetrate the waste packages are possible, and the release pathways and mechanisms involved would be highly speculative, making their use in regulatory decision making ambiguous. For a drilling intrusion that does not penetrate a waste package, a case can be made that no releases and consequently no doses to the public would occur. By having intrusion scenarios that vary between some level of exposures to none at all, the decision making process becomes dependent on judgements between speculative assumptions of competing scenarios, resulting in an extremely difficult decision making process and limiting the potential for consensus between the parties involved. In our opinion, the NAS recommendations are intended to avoid such a situation by proposing a limited "worst-case" type of stylized scenario where releases are possible and then examining this single scenario against the expected undisturbed repository case as the test of resilience against a fixed marker for performance. For these reasons, we believe the placement of the drill hole can be an implementation detail; however, it must be assumed that it penetrates the waste package and establishes the connection to the saturated zone.

Issue B: The human intrusion analysis should be used as a test of repository resilience only and not as a standard with a specific dose limit in the EPA rulemaking.

1. The proposed intruder scenario is incredible and no performance standard for it should be established. The intruder scenario should be evaluated only to assess the repository's resilience. (218, 573)

2. The alternatives proffered in proposed 40 CFR § 197.25 do not clearly limit the analysis of human intrusion to an RMEI dose arriving through the pathway created by the presumed human intrusion. The requirement in both alternatives to consider "all potential environmental pathways of radionuclide transport and exposure," unnecessarily confuses the purpose of the human intrusion analysis with the overall system performance assessment and should be deleted. (278)

3. The NAS findings and recommendations make clear that any human intrusion analysis should be separate from the calculation of compliance with the risk limit and should be limited to a measure of the consequences to the general public of such a highly improbable event. The EPA acknowledges and purports to concur with this recommendation in its discussion of the proposed rule and should conform the text of the final rule to this principle. (279)

4. It appears that EPA has interpreted the NAS' guidance as drilling into a failed canister sometime in the far future and still meeting the individual dose limit for an unpenetrated canister system. This then becomes a limiting design requirement for the repository as interpreted by EPA. We believe that it is instructive to understand the consequences of such a stylized scenario, but using it as a design requirement does not make sense. Thus, setting a dose limit is unnecessary for such an intrusion. (321)

5. A postulated human intrusion (e.g., a bore-hole through a canister and continuing into the saturate zone) would be an important way to analyze the resilience of the disposal system. (345)

6. The single-borehole scenario seems to be a reasonable basis to judge the repository's resilience to human intrusion. (467)

7. Drilling for water, although an important resource for the region, is not likely to occur above the repository, as opposed to nearby dry washes, where the depth to ground water is significantly less. ...The results of the human intrusion analysis should be considered only as a qualitative indicator of resilience of the repository, rather than be compared to a finite limit. If Alternative 1 in the rule is not changed to eliminate any comparison to [a] finite limit, DOE believes that Alternative 2 should be selected for the final rule. (644)

8. This circumstance seems inconsistent with §197.15, which states that DOE must assume that human knowledge will remain constant. With present day knowledge of the occurrence of ground-water resources, no reasonable party would explore for ground water in the area of the Yucca Mountain repository, because the terrain is too rugged for either agriculture or community use, . . (558)

9. We find it far-fetched to imagine a scenario in which drillers would seek to drill vertically on the slopes of Yucca Mountain through the repository field, happen to strike a decomposed waste package, withdraw the drill with radioactive contamination and not realize they have contacted the radioactive material. If drillers are drilling for water, why would they choose to start their drilling at a greater vertical distance from the likely water table in the nearby valleys? (266)

10. [T]he proposed EPA approach to human intrusion appears to have followed the TYMS recommendations very closely. (399)

Response to Issue B:

EPA believes it is appropriate to closely follow the recommendations of NAS on human intrusion, as explained in more detail below and in Issue A above. The text below discusses comments we received on the framing of the intrusion scenario as a test of repository resilience.

Some comments stated that a single borehole penetration is a reasonable test and preserves the NAS intent that human intrusion be kept separate from, and not confused with, the individual protection standard and used as a test of the repository's resilience to an inadvertent intrusion (comments 345, 467). EPA agrees with these comments, particularly in consideration of the NAS recommendations, which we have followed closely in framing the standard. We believe, as NAS pointed out, that it is not possible to scientifically defend an assertion that human intrusion can be unequivocally eliminated by any system of institutional controls, and that there is no scientific basis for "estimating the probability of inadvertent, willful, or malicious human action" (NAS Report, p. 107). The NAS recommendations clearly mean that institutional controls in themselves cannot preclude the possibility of human intrusion into the repository. As explained in the responses under Issue A, human intrusion is a means through which the repository containment function can be disrupted with resultant exposures to the public and therefore should be considered in setting standards to protect public health. Since the potential for intrusion cannot be completely eliminated, we believe it is a prudent and protective approach in the Yucca Mountain standard to assume such an intrusion occurs, since exposures are possible from an intrusion.

Some comments stated that the proposed intrusion scenario at Yucca Mountain is not credible (i.e., drilling for water at the crest of Yucca Mountain rather than in the adjacent valleys), and should only be evaluated to assess the repository's resilience (comments 218, 266, 558, 573, 644). Relative to these points, the NAS recommendations were exhaustive in pointing out that predictions about human activities, states of technology, effectiveness of institutional controls, etc., are not amenable to scientific analyses and justification (NAS Report, Chapter 4). While the attractiveness of drilling for water resources over the reference repository layout is small and an actual intrusion is improbable, it cannot be completely eliminated, as NAS pointed out. The NAS concluded it would not be scientifically defensible to develop arguments about the probability of inadvertent human intrusion or to drive the requirements with the aim of preventing such intrusions. Rather, NAS recommended that an inadvertent intrusion be assumed to occur, regardless of arguments about the relative probabilities of different intrusion scenarios, that the intrusion be assumed to connect a breached waste package to the underlying ground water, and

that the consequences be evaluated in the same manner used to evaluate the individual protection standard. NAS further qualified the situation by eliminating consideration of the effects of radioactive materials brought to the surface by the intruder or their dispersal into the environment. The intent was simply to evaluate the expected repository performance in a stylized way through a limited by-passing of the engineered barrier system as a test of the repository's resilience to such a disturbance. In this way, the issue of intrusion probability is not raised, but rather, the more important concern over potential consequences is addressed directly. The point of the intrusion scenario is to test the repository system for a limited containment breach scenario, not to make probability assessments about a wide range of hypothetical intrusion scenarios and their resulting dose assessments. The stylized framing of the scenario and the performance measure applied are intended for the resiliency test alone. Low probability arguments about the actual potential for an intrusion serve as additional supporting information lending increased confidence that excessive doses to the population are unlikely if the repository passes the "resiliency test" from effects of a limited "worst-case" type of hypothetical intrusion event. We do not believe, in the light of the NAS conclusions, that low-occurrence probability arguments are sufficient justification for deleting human intrusion considerations from the standard. We have treated the intrusion assessment as a "resilience" test for the repository; however; we believe a quantitative standard (the exposure limit) is necessary to assess the results meaningfully in regulatory decision making and therefore a performance standard is needed and appropriate.

Another comment specifically stated that the intrusion scenario should not become a limiting design requirement (comment 321). EPA is not requiring that the repository design be developed to minimize the potential for human intrusion, again following the intent of the NAS recommendations to avoid driving requirements or design by speculative assumptions. As a simple test of repository resilience, the intrusion scenario as defined in the standard (Sections 197.25 and 26) would apply no matter what specific design is used, and we believe NAS considered it in this light (NAS Report, pp. 111-112). The stylized scenario assumes a waste package is penetrated rather than requiring any specific design measures to prevent or minimize the possibility of such a penetration, which would be the form of the standard if it were to function as a design constraint. In fact, the repository design already contains features that in reality argue against a high probability of penetrating a waste container during routine drilling for water (the only currently known resource in the repository area). The use of thick-walled waste packages would tend to deflect drill bits in the open waste emplacement drifts, as would the use of drip shields in the current design (see the BID, Chapter 8). We consider it a sufficient test of repository resilience to assume an intrusion occurs and evaluate the consequences using the same analytical assumptions and methods used to assess releases and transport of radionuclides under the expected performance case. In this sense also, we believe that the stylized intrusion scenario in no way imposes design constraints on the repository, because a penetration of the waste package is assumed to occur (regardless of the waste package design) and the rest of the engineered barrier is by-passed by assuming a connection is made from the breached waste package to the underlying saturated zone. We also believe the specifics we have defined for the drilling intrusion also limit the range of possible stylized intrusion analyses that could be envisioned in their absence, and therefore pose no constraints on repository design to address an otherwise large number of possibilities for drilling scenarios.

One comment stated that the requirement to consider "all potential environmental pathways of radionuclide transport and exposure" (Section 197.25), unnecessarily confuses the human intrusion assessment with the performance assessment used to address the individual protection standard (comment 278). EPA incorporated that phrasing to be consistent with phrasing used for the individual protection standard (Section 197.20), and also to follow the NAS recommendation that the consequences of the intrusion should be assessed in the same manner as the expected case repository performance relative to the individual protection standard (NAS Report, p. 112). We recognize that under the range of expected conditions the ground-water pathway is the important pathway for potential doses, and we have framed the standard to require analyses through this pathway. We anticipate that the container penetration scenario will not be inappropriately biased to other pathways not similarly treated in the individual protection compliance assessments. The potential for such a bias could come during implementation of the standard, but we believe that we have given sufficient direction in setting the basic framework for the stylized scenario (establishing a connection from a breached waste package to the underlying saturated zone below the repository) that it is clear the ground-water pathway is the focus of the analyses. Section 197.26 (e) clearly limits the analyses to those radionuclides released from the breached waste package and transported to the saturated zone, thereby eliminating pathways other than through the ground water. We also believe the NAS description of the intent of the intrusion scenario is clear – that the analyses is to be a test of the resilience of the repository system under expected conditions and not as an assessment for the creation of new pathways not included in the assessment of anticipated repository performance. More specifically, as an example, NAS recommended that hazards from bringing radioactive materials to the surface during a drilling event should not be considered (NAS Report, pp. 114-115), but rather that the analysis should focus on "modification of the repository's barriers and the consequences of these modifications for the ability of the repository to perform its intended function" (NAS Report, p.115). Thus, EPA believes that the concerns of both comments 278 and 279 are adequately addressed.

Two comments stated that the human intrusion analyses should not be compared against a specific limit, but rather be a qualitative measure only (comments 558, 644). EPA has followed the NAS recommendations in separating the analyses from the expected performance case and in this way we have assured that the results do not obscure or confuse the issue of the expected performance of the repository system. However, NAS also recommended that the standard require a consequence analysis for the intrusion scenario (NAS Report, p. 111), and that the "risk as a result of the assumed intrusion should be no greater than the risk levels that would be acceptable for the undisturbed repository case" (NAS Report, p. 113). We agree with these recommendations, which imply that projected releases would have to be compared against the same fixed limits imposed for the undisturbed performance case. We have therefore specified that doses to the receptor during the regulatory time frame must be compared against the same level as that used for the undisturbed performance. We believe that to be meaningful, a test of repository "resilience" would have to involve a comparison of potential doses from the intrusion scenario against the same fixed limit applied to the expected performance case. Otherwise no conclusive judgement could be made that the repository is in fact resilient to the intrusion.

Comment 558 also suggests that the location of the intrusion penetration be either left to NRC or allowed to be anywhere over the repository. This proposal is discussed under Issue A above. The exact placement of the drill hole can have an effect on the calculated doses by allowing some additional travel distance for radionuclides released to the saturated zone. However, we consider this an implementation detail that should be left to DOE and NRC to determine in their efforts to evaluate uncertainties in these and other performance assessments; ultimately measuring compliance with the standard.

Issue C: Has the framing of the human intrusion standard reasonably addressed the time frame, probability and consequence implications of an intrusion?

1. The DOE should assume a penetration and assess the consequences. (82, 311)

2. It is extremely likely that the EPA scenario will occur, as there will be drilling during exploration for resources or intentional drilling in pursuit of the SF and HLW. (169)

3. ICRP has no special opinion on the scenario proposed by EPA. What [is] missing in the EPA proposal is rather a consideration of specific associated radiological criteria to be complied with, as human intrusion means both that there is no scientific basis for predicting the likelihood of such an event and by definition an intrusion has bypassed all the barriers. (516)

4. The same individual protection standard should apply in the case of human intrusion as for an undisturbed repository, and so of course support the EPA proposal to apply the same 15 mrem limit here. (311)

5. I[t] has always seemed futile to argue about the probability of human intrusion into the repository. A much more reasonable and conservative approach is to assume that an intrusion would take place, within the regulatory period, and to assess its consequences. (305)

6. It is unclear if the HI assessment considers or excludes unlikely or very unlikely natural events from consideration when compared to the individual protection standard. EPA should clarify whether the standard includes or excludes such events. (650)

Response to Issue C:

As discussed in Issue A, human intrusion is one way releases from the repository can occur, and consequently it is an appropriate component of the standard. The NAS recommendations also considered human intrusion to be an appropriate part of a standard for the Yucca Mountain site as explained previously in Issues A and B. EPA agrees with the NAS recommendations and has followed them closely in framing the intrusion scenario in the standard.

A common focus of a number of comments is the assumed probability of the intrusion (82, 169, 305). Some comments state that intrusion is likely (169), or that an intrusion should be assumed (82), or more specifically that it should be assumed to occur within the regulatory period (305).

A fundamental question in evaluating an intrusion scenario for any repository situation is determining the nature of the intrusion and the probability it will occur. These aspects were critically examined by NAS in its recommendations to EPA for developing the Yucca Mountain standard.

Comment 169 suggests that a drilling intrusion is likely due to resource exploration or intentional drilling in pursuit of the repository contents. While other comments disagree relative to the probability of drilling intrusions at Yucca Mountain (see comments under Issues B and D), EPA has assumed that an intrusion occurs (see earlier discussions in previous issues for the rationale for this assumption) and should be treated in a stylistic way to test the performance of the repository system to a limited by-passing of the engineered barrier system, as NAS recommended (NAS Report, Chapter 4). In this sense we agree with the intent of the comments, i.e., that the intrusion should be assumed. We have identified the nature of the drilling (water well drilling, Section 197.26) so that the size of the penetration is fixed to reduce the unnecessary arbitrary assumptions about this characteristics of the stylized scenario, as NAS suggested (NAS Report, p. 111). This comment also proposes that deliberate intrusion into the repository is possible. The NAS considered this possibility and concluded (NAS Report, p. 114) it is unproductive to attempt to determine means to protect against risks from deliberate actions, i.e., if there is a deliberate attempt to intrude no design measures could assure the intrusion could not occur. We agree in this assessment and we assume that the drillers would be aware of the risks and potential consequences of such intrusions. We believe that assessing the effect of deliberate intrusions would be fundamentally different than the repository "resilience test" NAS recommended (and we have adopted), and the analyses would supply no useful information about the repository's performance. If a deliberate intrusion were to occur to tap the repository contents, there would not be a connection established between the repository level and the underlying ground-water system. Releases would be from repository wastes brought to the surface during drilling (or subsequently excavated) and the pathways for human exposure would be completely different than the stylized drilling intrusion proposed. The consequences of such an intrusion analysis would not be a test of the repository resilience relative to the expected undisturbed performance case and therefore offer no measure of the repository's "resilience", as the NAS recommendations emphasize (NAS Report, pp. 114-115). We have therefore not included consideration of deliberate intrusion as a component of the standard.

The question of when the intrusion occurs is important for defining the parameters of the intrusion performance assessment. Comment 305 suggests that the intrusion should be assumed to take place sometime during the regulatory period (10,000 years), while other comments imply no set time period (comments 82, 169). The text below explains the approach EPA has used to set the time for the intrusion.

The time frame for the intrusion is simply a means to determine the radionuclide source term appropriate for the analyses after the penetration occurs. Intrusion very shortly after repository closure would make a very different waste inventory available for possible transport from the repository than an intrusion taking place thousands of years after the repository is closed. However, it is not certain whether an early intrusion would necessarily result in significantly higher doses than one later in time, since short half-life radionuclides would undergo significant decay during transport through the ground-water system. If ground-water travel times from beneath the repository to the location of the RMEI were long enough, the short half-life waste inventory could be reduced sufficiently that effectively the same dose could result as for intrusion releases at much later times.

The NAS concluded that "it is not possible to make supportable predictions of the probability that a repository's engineered or geologic barriers will be breached as a result of human intrusion over a period of 10,000 years" (NAS Report, p. 11). With respect to the timing of the intrusion, NAS recommended, "we believe it is useful to assume that the intrusion occurs during a period when some of the canisters will have failed..." (NAS Report, p. 112). As a test of repository performance, this recommendation is consistent with the idea that intrusion be tied at least in some way to the specific features of the repository. EPA believes linking the time frame to actual performance expectations for the repository is more reasonable than fixing the time frame arbitrarily. In this case the connection is with the projected service lifetime of the waste packages. As the waste containers are gradually degraded over time by expected processes in the repository, unnoticed penetration by the current water-well drilling technology we specified (Section 197.26) increases. When some of the waste containers have degraded sufficiently to fail and begin releasing radionuclides, we believe the potential for unnoticed penetration is reasonable. While the containers are fully intact, the potential for current drilling technology to penetrate these containers is less likely since the drill bits can be deflected by the waste package (BID, Chapter 8). Because DOE will have to project waste package containment lifetimes for the expected case performance assessment, the time when waste containers begin to fail will be easily identified and the time for the intrusion easily determined. In turn, this time sets the waste inventory and the source term needed for the intrusion assessment. Whether this time is during the first 10,000 years or beyond is then a site-specific function of the repository, and is compatible with the concept of testing the repository system for the consequences of by-passing the engineered barrier system. We have therefore not required that the intrusion must be assumed to occur with the first 10,000 years. If we were to make such a requirement, we would still have to specify a fixed time, or a means of determining a time. Setting a fixed time would be arbitrary and we have tried to avoid arbitrary requirements. We have selected a means of setting the time for the intrusion based on site-specific performance factors, which we believe is a consistent with the intent of the NAS recommendations.

One comment asked for additional clarification on whether the intrusion assessment included unlikely or very unlikely natural events (650). In Section 197.26 of the standard, EPA states that releases from unlikely natural processes and events are not to be included in the assessments. Very unlikely events would also be excluded from the assessments. See also Section 7 of this document for more discussion of low-probability features, events, and processes.

Comment 311 supported EPA's use of the 15 mrem/yr CEDE exposure limit for the human intrusion standard, consistent with the limit we applied for the individual protection standard. Our choice is consistent with the NAS recommendations on this subject (NAS Report, p. 113). We believe that the same limit set for the individual protection standard should be applied in the case of intrusion releases so that the health-based foundation of the standard is not used inconsistently for the two basic ways releases from the repository can occur – by the gradual degradation of the system or by deliberate disruption of the system. Comment 516 asked that we specify a measure of significance for the intrusion scenario and radiologic criteria for compliance. By setting a standard for exposure limits from the intrusion scenario we have set the radiological compliance criteria requested by the comment. During the licensing process, the implementing authority will review DOE's assessments of the human intrusion exposure scenario, including the uncertainties in these assessments, and make a decision on the compliance question. The measures used to assess the quality and acceptability of DOE's intrusion assessments is an implementation question that must be addressed by NRC.

Comment 516 stated that EPA did not establish a radiologic criteria for protection. The health based exposure limit we have established (15 mrem/yr CEDE) is the radiological criterion against which the performance of the repository will be judged in the licensing process relative to the human intrusion standard.

Comment 516 also suggested that a radiologic performance criteria be used to indicate when intervention is justifiable. The decision to take actions to alter the repository after the wastes are emplaced and the repository is closed would presumably be based on information gathered by some type of monitoring program – an active institutional control. Institutional controls (both active and passive) are assurance measures which EPA has left to the discretion of NRC. EPA does not believe that establishing such measures are appropriately a part of this standard, but are more aptly considered as potential implementation measures for the licensing process. The time period over which active monitoring can be assumed to be effective is a subjective decision based at least in part on judgements about the inherent uncertainties in projecting repository performance. If after consideration of the uncertainties in the DOE assessments of repository performance, NRC feels that a period of active monitoring is necessary, then it would be incumbent on NRC to develop measures that would trigger intervention efforts.

Issue D: EPA should reconsider the assumptions in its human intrusion scenario.

1. More than one intrusion (borehole) should be assumed, as is likely over long time periods (8). One borehole would not adequately discover the geologic variability of the mountain and is therefore unreliable. (371) Future exploration activities would probably result in more boreholes than anticipated in the standard. (371, 502) A more reasonable scenario would be a borehole intercepting a waste package about every 100 years for a period of the first 1,000 years after loss of institutional controls. Our proposed intrusion scenario is sensitive to both the short (up to 1,000 year) and long-term performance requirements of the repository (387b). The possibility of multiple intrusions and their frequency and locations must be considered. (435)

2. Hazards to the intruders and to the public from material brought to the surface should be considered. (435)

3. Deliberate intrusion (sabotage, etc.) within the pre-closure period, that DOE estimates may last 150 years, may be of greater risk. (267)

4. EPA should specify that the repository should have features that would reduce the likelihood of deliberate intrusion. (296)

5. Technology advances that may be economically viable in the future should be considered, such as laser rock cutting. (297, 338)

6. EPA should not assume, based on current DOE package designs, that a driller would recognize penetration of a waste package within 10K years. (545)

7. If the object of the stylized single-borehole scenario is to test the resilience of the system following human intrusion, the scenario should first assume waste package penetration without regard for the resistance of the container. DOE designs have changed considerably over time and likely will again. (387a)

8. If a relatively thin ceramic waste container were used, would it resist a drill bit the same way as a heavy metallic container? (387c)

9. The standard should be at least consistent with the standard applied to WIPP for disposal of transuranic wastes. (377)

10. Human intrusion should be considered in an analogous way to a pre-closure Category 2 design basis event as treated in 10 CFR part 63 (Section 63.111). In this approach there would be no attempt to assess the likelihood of human intrusion, but rather a straightforward consequence-only analysis that would be compared to a compliance limit more appropriate for deterministic evaluation. (237)

Response to Issue D:

The NAS Report recommended that EPA assume that an inadvertent human intrusion to the Yucca Mountain repository would occur and that EPA should specify an intrusion scenario for DOE and NRC to use to evaluate the "resilience" of the repository. "The key performance issue is whether repository performance would be substantially degraded as a consequence of an inadvertent intrusion" (NAS Report, p. 121). Thus, the resilience test should be an analysis of the robustness of the waste isolation system under expected conditions, rather than an assessment of "off-normal" events intended to be design tests. In accordance with the NAS recommendation, EPA proposed a single-borehole intrusion scenario based upon conditions specific to Yucca Mountain. EPA proposed a stylized intrusion in which a waste canister is penetrated during drilling for water resources below Yucca Mountain.

A number of comments stated that more than one drilling intrusion into the repository should be considered for a variety of reasons (comments 8, 371, 387b, 502, 435). While arguments for multiple penetrations can be made, we believe that the NAS conclusions about the difficulties in scientifically determining intrusion probabilities in a reliable manner are correct (NAS Report, Chapter 4), and that arguments for multiple intrusions are therefore unavoidably speculative in nature. For example, comment 387b suggests that a borehole penetration of the waste package should be assumed every hundred years for the first 1,000 years after disposal so that the analysis would use both the short and long half-life radionuclides. This intrusion frequency is inherently an arbitrary selection and the frequency no more defensible than any other frequency for the first 1,000 or the remaining 9,000 years of the 10,000 year regulatory period. Assessing multiple intrusions also opens up numerous variations for the dose assessment calculations - for the timing of these intrusions and their potential interactions, again requiring arbitrary decisions to be made for analysis of many alternative scenarios. We believe that, to the degree possible, speculation should be avoided in framing performance scenarios so that regulatory compliance decisions can be made without involving arbitrary decisions about speculative scenarios. We have therefore followed the NAS recommendations that a single stylized drilling intrusion be examined for its consequences (NAS Report, p. 111). As mentioned previously, we have specified sufficient information in Section 197.26 of the standard to ensure that the intrusion scenario is implemented as we intend, consistent with the NAS recommendations, but with sufficient flexibility remaining for the implementing authority to more fully define an appropriate site-specific performance scenario (see discussions under Issue A). Exactly how the analysis is performed is an implementation detail that EPA believes should be left to the implementing authority. As an illustration of this implementation perspective, one comment (8) stated that more than one borehole would be necessary to assure that the analyses covered the varying geology at the repository site. The comment refers to variations in the geology beneath the repository and possibly along the projected radionuclide travel path in the saturated zone between the repository and the down-gradient exposed population. We believe that how the radionuclide transport pathway from the breached container to, and within, the saturated zone is modeled in detail is properly left to DOE and NRC to determine in the licensing process, since numerous alternatives are possible for modeling. Deciding between alternatives would require a more thorough data base of site parameters than is currently available or necessary to define the stylized intrusion scenario and the exposure limit which are EPA's responsibility in setting the standard. We believe that the single bore-hole stylized intrusion analysis is an adequate test of repository resilience to an intrusion, consistent with the NAS reasoning and recommendations. If the implementing authority, NRC, determines that additional intrusion scenarios are of value in judging the suitability of the site (for example, the early time frame intrusions proposed in comment 387b), it is free to require additional analyses as part of its implementing authority. We have given direction to a limited extent to ensure an intrusion analysis is performed as we intend by stating in Section 197.26(e) that only releases to the saturated zone are to be assessed, and by requiring (in Section 197.25) that "all potential pathways of radionuclide transport and exposure" must be assessed, wording paralleling the individual-protection standard requirements (Section 197.20) and intended to assure that the same approaches and methods used in modeling the undisturbed case are used for the intrusion case also so that a comparison can be drawn between the two. The NAS recommendations for the analytical approach are consistent with our approach (NAS Report, p. 112). In summary,

assumptions for multiple bore-hole intrusions are inherently speculative in nature and offer no significant advantage over the stylized single bore-hole penetration as a test of repository performance and therefore we have retained the single-bore-hole intrusion framework. As noted, NRC may require additional analyses as it implements the standard.

One comment (435) stated that the hazards from radioactive material brought to the surface during drilling should be evaluated. EPA agrees with the NAS recommendation that the intrusion analysis should be a stylized test of repository resilience, i.e., would the expected performance of the repository be compromised by the intrusion? Since the expected performance does not involve this type of waste exhumation to the surface, it would be inappropriate to include hazards from these materials in an assessment of repository resiliency. The NAS also pointedly recommended (NAS Report, pp. 114-115) that consideration of surface dispersal of exhumed wastes during drilling would not provide useful information about any specific repository site or design and therefore would be of little value, i.e., not an appropriate test of repository resiliency. We agree with this conclusion and have not included such considerations in the stylized drilling intrusion described in the standard.

Comment 267 stated that deliberate intrusion into the repository should be assumed. We believe that such intrusions are not appropriate for consideration of compliance with repository performance standards because these standards are not derived to address deliberate disruptions of the repository containment systems. In terms of testing repository resilience as recommended by NAS, a drilling intrusion through the repository, either deliberate or inadvertent, would be treated in the same way, i.e., releases are assumed to be from the breached waste package to the saturated zone and the transport down gradient modeled in the same fashion as an inadvertent intrusion. If the intrusion into the repository was deliberate during the preclosure period, as suggested by comment 267, the intruder would be aware of the hazards involved and no standard EPA established would have any bearing on the deliberate act, particularly for the example of sabotage mentioned in the comment. The NAS concluded that there is "no scientific basis for estimating the probability of inadvertent, willful, or malicious human action" (NAS Report, p. 107), and we agree with that conclusion. We see no value in attempting to develop exposure limits for deliberate acts that willfully expose the participants to radionuclide exposure or are intended as malicious acts. Any standard for exposure limits would also have no meaning or control over deliberate malicious acts. Also, institutional controls (which will include access control - see NRC proposed rule 10 CFR 63.51, 63.121) will be established by the implementing authority for the purpose of preventing disruption of the repository system during the preclosure period and for some time after permanent closure, so the actual potential for deliberate intrusion during the preclosure period should be minimal.

One comment recommended that EPA should specify that the repository have features to reduce the likelihood of deliberate intrusion (comment 296). EPA does not believe that repository design features would be effective in reducing the likelihood of deliberate intrusion. The intruder, being aware of these measures or being determined to proceed with the intrusion, would simply use what ever means necessary to complete the deliberate penetration into the repository. We believe that the institutional controls that will be established for the repository are intended to prevent

deliberate intrusion. Institutional controls, both active controls such as land control measures, and passive controls such as markers, are intended to reduce the potential for inadvertent intrusion. Therefore there will be measures to limit the potential for deliberate intrusion. These measures are referred to as assurance measures and will be included in implementing regulations developed by NRC for the Yucca Mountain site. Institutional controls have no direct link to repository releases and exposure limits which are the focus of the EPA standard, and are more appropriately considered as measures aimed at increasing confidence that the repository system will perform as intended. In addition to the intended function of institutional controls, the repository engineered barriers in the most current DOE design (see the Yucca Mountain Science and Engineering Report, Docket A-95-12, Item V-A-27) will also tend to reduce the actual potential for a drilling intrusion to breach a waste container. The thick-walled metal waste package would tend to deflect drill bits thereby limiting the potential for penetration, as would the titanium drip shields emplaced over the waste packages. In actual instances of drilling intrusions, there is a strong possibility that these materials in the repository would resist penetration of waste packages by water-well drilling and alert drillers that anomalously hard material had been encountered thereby minimizing the actual potential for inadvertent penetration. A related comment asked if thin ceramic waste packages would provide the same level of resistance (comment 387c) as metal waste packages. The answer to this question depends on the nature of ceramic material and cannot be answered in the absence of a specific waste package design, which have not, up to this time, included specifics on ceramic waste package designs. In any event, the resistance of the waste package to drill penetrations serves only to set the time frame for the intrusion so a radionuclide inventory in the breached package can be identified for the assessments. Whether the waste packages are metal or ceramic, DOE will have to determine their longevity in the repository environment for the performance assessments necessary to make release projections for the individual protection standard, and these estimates will serve to set the time frame, and consequently the radionuclide inventory, for the intrusion assessments. We believe the lack of attractive natural resources at Yucca Mountain (Chapter 8 of the BID), the institutional controls that will be imposed through the implementing regulations, and the nature of the engineered barrier system, will provide adequate features to reduce the actual likelihood of actual drilling intrusions.

Other comments (297, 338) stated that technological advancement should be considered in the assessments and that drillers should not be assumed to be able to recognize a waste package penetration occurring within 10,000 years (545). The thrust of these comments is that advances in drilling technology could significantly reduce the potential that drillers would recognize a breaching of the waste packages as it was occurring and stop the intrusion. In agreement with NAS, EPA believes that speculative assumptions should be avoided to the extent possible in framing the standard. Assumptions about advancements in drilling and resource exploration technology in the future cannot be scientifically defended relative to assumptions about what technologies would be available and whether they would be used in resource exploration or exploitation drilling at the site. To avoid unnecessary and unsupportable speculation, we have stated that current drilling practices be assumed for the drilling scenario [Section 197.26 (c)]. With this position, we assume that recognizing the limitations of current drilling technology provides a reasonable bound to establishing the time frame for any possible intrusion, as well as limiting the range of assumptions that would be possible for other details of the release scenarios

analyzed, such as the sizes of the penetration of the waste package and pathway through the unsaturated zone. By framing the scenario in this stylized way, speculative questions about whether a driller would or would not recognize when a waste package penetration occurs are also eliminated, since this particular question relies heavily on the drilling technology used.

One comment (387) stated that the resilience test should assume breaching of the package without regard to the resistance of the waste package to penetration. EPA agrees that the stylized intrusion should assume the waste container is penetrated. The question of whether the waste containers provide resistance to penetration is connected to determining the time frame for the container penetration. As an important (and defining) part of the stylized scenario, the time is important because it determines the radionuclide inventory available in the package for release. The NAS recommended the intrusion be assumed to occur when some of the waste containers have failed but before migration of releases to the ground water (NAS Report, Chapter 4). This recommendation offers a way of estimating an intrusion time frame so that the radionuclide inventory can be estimated. Since the DOE waste packages are designed for long service life times regardless of the specifics of the design and its evolution, the time frame for the stylized intrusion envisioned by NAS is sufficiently long that the short half life portion of the radionuclide inventory will have decayed, leaving only the longer lived component. We agree with the thrust of the NAS recommendation and we have embodied it in Section 197.25 of the standard. By setting the intrusion time as the point where waste containers have degraded sufficiently to allow the penetration to go unnoticed, we have implied that the time should be sufficiently long that the some of the waste packages will have failed or are close to failure.

Comment 377 states that the Yucca Mountain standard should be at least consistent with the standard used for the WIPP transuranic disposal facility. As a matter of policy, this may be appropriate. The EnPA, however, requires EPA to promulgate these public health and safety standards for protection of the public from releases from radioactive materials from Yucca Mountain. Moreover, Sections 8(a) and 8(b) of the WIPP LWA expressly prohibit application of the 40 CFR part 191 radioactive waste disposal regulations, which are applicable to WIPP, to Yucca Mountain. These express statutory mandates require that the Yucca Mountain standard be a site-specific standard specifically applicable to Yucca Mountain. That said, however, EPA believes that the site-specific standard that we promulgate for Yucca Mountain is consistent in approach to that applied for the WIPP facility, with appropriate provisions to address the unique site-specific characteristics of the Yucca Mountain site.

Comment 237 suggests that the human intrusion scenario assessment be considered in a manner analogous to a category 2 design basis accident as treated in the NRC proposed standard 10 CFR part 63. For the reasons we have explained in the previous issues in response to questions about the justification for a human intrusion standard, EPA believes that human intrusion is an appropriate component of the standard. We have also explained that we do not believe it appropriate to treat the human intrusion scenario as a design constraint (see comment 321) as this comment would imply should be the case. For these reasons, we have retained the intrusion scenario as a separate component within the Yucca Mountain standard. The performance objectives from the draft NRC standard referenced in the comment apply to the geologic

operations area during operations until the time of permanent closure. We do not believe that such a short-term consideration of human intrusion is consistent with the approach recommended by NAS. The comment also suggests that the exposure assessment be treated by a deterministic analysis. We have not precluded such an approach to the dose assessment in the language in Sections 197.25 and 26 of the final rule. The choice of performance assessment approaches used by DOE and NRC in the licensing process are implementation concerns, and we have made no requirements about the approach required for the intrusion assessment.

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Section 6 Ground Water Protection[1]

i. Summary of Final Decision and Rationale for Compliance Location

EPA presented four alternatives for comment prior to determining the compliance location for the ground-water standards [see the preamble to the proposed regulation (64 *FR* 47000-47004)]. These four alternatives correspond to downgradient distances of approximately 5, 18, 20 and 30 km from the repository footprint. Alternatives related to the 5 and 18 km distances also incorporate the concept of a controlled area, with the former adopting the definition of controlled area as it appeared in 40 CFR 191.12 while the latter represents a combination of the 40 CFR 191.12 definition of controlled area and the contiguous area within the boundary of the adjacent Nevada Test Site. The alternatives related to 20 and 30 km are essentially designated areas at specified distances from the repository footprint. We received numerous public comments on the appropriate distance for the point of compliance (see Issues H and I below), but did not receive

[1] All acronyms are defined in Appendix B.

comments that specifically addressed the use of the controlled area in determining compliance with the ground-water standards.

After reviewing and evaluating the public comments, various precedents, and NAS's recommendations, EPA adopted the concept of a controlled area as an essential precondition to assessing compliance with the ground-water standards. We chose to set a maximum size limit for the controlled area, while also specifying the maximum distance the controlled area may extend from the repository footprint. We have also defined a representative volume for use in calculating radionuclide concentrations in ground water at the controlled area boundary, for comparison with the regulatory limit during the compliance period (10,000 years). The accessible environment includes any location outside the controlled area. The controlled area is limited to 300 km^2 in area and may extend no farther than 5 km in any direction from the repository footprint, except that in the direction of ground-water migration, the controlled area may extend no farther than any point on a line described by 36 degrees, 40 minutes, 13.6661 seconds north latitude. This latter distance is roughly 18 km from the repository footprint. The southwesternmost corner of the NTS and its southern boundary correspond to this latitude designation (Docket A-95-12, Item V-A-29). As a part of the licensing process, DOE and NRC must agree on the specific shape of the controlled area. Two purposes are served by the controlled area. First, it serves to encompass that geology dedicated to the natural barrier portion of the repository system, and thereby serves as a compliance measure by identifying the location where the standards are to be met. Second, the controlled area is used to limit access around the repository site during the period of institutional control.

EPA's mandate through the EnPA is to develop a site-specific standard for the Yucca Mountain site. In doing this, we have used radiation protection principles and approaches we have used in the past if they are appropriate for the Yucca Mountain repository setting, as described in the rule's preamble and in this document. The concept of a controlled area is embodied in the radiation protection approaches we incorporated into the generic rule, 40 CFR part 191, and we believe the concept is appropriate for the Yucca Mountain setting as well – to protect individuals from inadvertent exposures and to define the limits of the natural barrier system dedicated to waste isolation. In the proposed rule, we proposed for comment alternatives for ground-water compliance demonstrations that involved controlled area variations (proposed §197.12). In defining the controlled area for the final Yucca Mountain rule, we have been primarily concerned with its functions as a regulatory compliance measure and as an institutional control for access restriction. We also considered information on the projected behavior of the disposal system in framing the controlled area, since the unique aspects of the repository design play a role in determining the magnitude and direction of potential radionuclide releases into the natural barrier system and the potential exposures from these releases. The potential variations in repository performance provide insight for our determination of an appropriate upper bound to the controlled area for the site that will provide protection from inadvertent exposures from human activities within it that could lead to unacceptable exposures (such as tapping ground water for drinking water or other uses that could give unacceptable radiation exposures). These considerations directed us to examine three types of information about the Yucca Mountain repository setting: information about potential repository design lay-outs (since potential releases could come from

any point in the repository); the uncertainty in ground-water flow paths from the repository location to the compliance point - since ground water would transport released radionuclides; and the magnitude of potential releases during the regulatory time period.

In EPA's effort to determine an appropriate site-specific limit on the size of the controlled area, we examined the same type of information that DOE will have to use in proposing an actual size and shape of the controlled area for licensing review. Since the dominant pathway for exposures from repository releases is through the ground water, we examined information about the potential ground-water flow paths from the repository to the farthest extent of the controlled area. This information is summarized in the BID (Chapter 7 and Appendix VI) and also presented in the DOE/VA (Docket A-95-12, Item V-A-5), the DEIS for the Yucca Mountain site (Docket A-95-12, Item V-A-4), and the recently completed Yucca Mountain Science and Engineering Report (Docket A-95-12, Item V-A-27). This information reveals that radionuclides released into the repository unsaturated zone will migrate with ground waters traversing the repository level in a generally vertically downward movement, through the matrix porosity of the tuff rocks and along the generally vertical fractures that exist in these rocks. When the ground waters reach contacts between the tuff rock units, some of the ground water will be diverted in an easterly direction along the slightly tilted tuff rock unit contacts until the waters either encounter open fractures or are absorbed into the porosity of the underlying rock unit. In either case, the generally vertical movement continues until the next rock unit contact is encountered. In this way, the movement of potentially contaminated ground waters through the unsaturated zone is vertically downward with some degree of easterly displacement. When the migrating ground water enters the saturated zone, it joins the general flow direction (generally to the south of the site) and moves toward the border of the controlled area. From examination of Figure 3-67 in the DOE/VA (Docket A-95-12, Item V-A-5), it can be seen that the total extent of easterly displacement of ground water moving through the repository level and into the saturated zone is about 5-6 km from the repository location. However this particular representation of the ground-water movement is not the only possible interpretation. A more direct southerly path from the repository location can also be supported by available data and modeling results (BID, Appendix VI). Therefore the uncertainty in ground-water flow directions leads to an envelope of potential flow paths around the repository layout. The envelope extends directly south of the repository in the direction of ground-water flow and east for a distance of 5-6 km from the easternmost limit of the repository layout. Ground waters in the saturated zone within this envelope could potentially contain radionuclides released from the repository.

The second area of information EPA considered was the potential size and shape of the repository layout. The repository size is a function to two considerations; the total inventory of wastes to be emplaced in the repository and the thermal loading strategy adopted by DOE for the final repository design carried into the licensing process. Because the repository design is not yet finalized, there is uncertainty about the exact repository layout. However, DOE has presented information in the Yucca Mountain DEIS document in sufficient detail to allow a good estimation to be made of possible variations. In Appendix I of the DEIS (Docket A-95-12, Item V-A-4), repository layouts are presented for several thermal loading variations for the inventory considered in the DOE Viability Assessment, along with layouts for some expanded inventory options.

This information coupled with the envelope of ground-water flow paths from the repository, as discussed above, allowed us to estimate the potential size of areas that could potentially contain contaminated ground waters from repository releases. These areas vary from less than 100 km^2 for the smallest repository layout and assuming the ground-water flow is either in the easterly then southerly direction or the southerly direction alone; to areas of approximately 300 km^2 based on the larger repository layout options and assumptions that contaminated ground water could equally well move easterly or directly to the south from the repository.

The final element of EPA's assessments involved examining the potential magnitude of radionuclide releases from the repository. The magnitude of releases would determine whether contaminant concentrations in ground waters could exceed the regulatory limits when these waters reach the boundary of the controlled area. For low levels of releases, mixing of contaminated ground water with uncontaminated ground waters along the flow path could result in concentrations that do not exceed the regulatory limits. In contrast, higher levels of releases could exceed the limits and therefore expectations of the engineered barrier performance play a role in defining a controlled area.

DOE's assessments of repository engineered barrier performance for actual repository designs were first reported in the DOE/VA (Docket A-95-12, Item V-A-5). External review of the assessments pointed out a number of uncertainties DOE had not addressed, which prompted DOE to initiate a repository design review that ultimately resulted in the adoption of a new enhanced design (the EDA II design) that offers considerably longer waste package containment lifetimes under expected conditions. The containment lifetime of the waste packages in the new design are well in excess of 10,000 years and are estimated to be in the many tens of thousands to over 100,000 years (Docket A-95-12, Item V-A-24, and Docket A-95-12, Item V-A-27). Such waste package lifetimes suggest that a small controlled area is sufficient since releases under anticipated conditions would be very low. However, these estimates are not the entire picture of possible releases from the repository.

Even though waste package lifetime under expected conditions (the very slow degradation of the engineered barrier system) is very long, a small number of waste packages would be anticipated to fail from undetected manufacturing defects. Typically such failures would occur from the failure of improperly made welds, and these premature failures (often referred to as juvenile failures) could allow ground waters entering the emplacement drifts to enter the waste package through the failed welds (see Section 4.2.4.3.1 of the Yucca Mountain Science and Engineering Report, Docket A-95-12, Item V-A-27 for an extensive discussion of premature failure mechanisms evaluated by DOE). Although these premature failures can and will be minimized through the application of strict quality control measures during the manufacturing process, it is not possible to completely eliminate them. Therefore, although the performance of the new waste package design is anticipated to contain radionuclides for very long time frames under expected conditions, premature failures to some degree are unavoidable and these releases are of concern in defining a controlled area around the repository. The important point in this regard is that the timing and location of these premature failures within the repository cannot be predicted with high confidence.

They could occur anywhere and could be separated in time or occur relatively close together in time. The magnitude of releases from a prematurely failed waste package, and the resulting contaminant concentrations in ground waters moving through the disposal system, is dependent on many assumptions about radionuclide release mechanisms and subsequent mixing with surrounding ground waters. For assumptions that involve maximum potential releases from the waste package and minimum dilution of the contamination through the ground-water flow path, narrow contamination plumes of relatively high concentration could move through the flow system. Remembering that one function of a controlled area is to restrict access to an area of potential contamination so that human activities do not result in inadvertent exposures, the prudent choice in framing the controlled area would be to include all potential ground-water flow paths within its boundaries. Since the location of the premature failures cannot be reliably predicted, the maximum size of a controlled area would be determined by repository layouts and the envelope of flow paths. It is important to note that by this reasoning, it should not be assumed that the land within the controlled area will be contaminated in its entirety. The premature failure scenario would generate a small number of potentially narrow contamination plumes that may or may not exceed the regulatory limits depending on the assumptions for waste package and subsequent transport in the ground-water system. EPA has placed an upper bound on the size of the controlled area as a conservative safety precaution to assure that the controlled area would not contain any narrow high-concentration plumes that may be possible. A more detailed analysis of the factors that would be used to define a controlled area is given in Docket A-95-12, Item V-B-7.

DOE will have to define the size and shape of the controlled area when it presents its compliance case to NRC in the licensing process. EPA's rule provides for an upper bound on the size of the controlled area, but does not mandate that an area of that size must be assumed. DOE may propose a smaller controlled area based on its analyses of repository performance, including potential releases from juvenile waste package failures, or any other type of failure it proposes (see Docket A-95-12, Item V-A-7), and its assessments of other engineered barriers and the ground-water system at the site. Because the Yucca Mountain site characterization and repository design efforts are still in progress, we believe it is not possible for us to define the size of the controlled area more precisely. In addition, we do not believe we should constrain the repository development effort by defining a controlled area more specifically. We believe that DOE should design an optimum disposal system consistent with the inherent characteristics and uncertainties of the site, and that it is NRC's responsibility to critically review DOE's analyses.

The protection of ground-water resources has been one of EPA's most important priorities, Agency-wide, for many years. In establishing the size of the controlled area and its maximum distance in the predominant direction of ground-water flow, we tried both to follow long-standing Agency policy regarding the protection of ground-water resources and to account for the unique characteristics of the Yucca Mountain site. Please see Section III.B.4 ("How Does Our Rule Protect Ground Water?") of the preamble to our final standards for a full discussion of our ground-water policy, our reasons for including a separate ground-water protection standard in our standards for Yucca Mountain, and a more complete discussion of the rationale for the controlled area.

Issue A: Ground-water protection standards should apply to the proposed Yucca Mountain repository.

1. Given that the ground-water pathway is likely to be a major source of radiation exposure, inclusion of a separate ground-water protection standard is necessary and appropriate. (7, 26, 67, 54, 83, 141, 142, 205, 291, 405, 428)

2. The ground-water protection standard should provide protections equivalent to, or better, than those presently in effect for public water systems under the purview of the Safe Drinking Water Act. (25, 59, 88, 120, 129, 178, 194, 295, 306, 342, 356, 390, 428, 444, 529)

3. [By applying for only 10,000 years] EPA's current proposed standards deviate substantially from the requirements of the SDWA - at the peak dose, EPA's repository standards would permit contaminant levels 350 to 2,300 times the SDWA standards. (444)

4. Ground-water protection provisions are needed to protect the scarce ground-water resources in the vicinity of Yucca Mountain for future generations. Future water users should not have to clean up the ground water before it can serve as drinking water. (50, 67, 73, 205, 390, 481)

5. Extensive underground nuclear testing at the Nevada Test Site has left behind vast number of large-scale source terms containing long-lived, radionuclides. Indeed, the presence of other major source[s] in the area is one reason that a separate groundwater standard is so important. These source terms must be incorporated into EPA's analysis. (136, 295, 445)

6. The citizens of Nevada near Yucca Mountain should have their ground water protected to levels at least equivalent to the protections afforded ground water near the Waste Isolation Pilot Plant in New Mexico, a deep geologic repository for defense transuranic waste. (129, 178, 306, 424)

7. If the repository should survive the environmental review and licensing process, the application of a groundwater compliance standard to the repository should be accompanied by the development of an array of monitoring wells at the periphery of the site extending into the Lower Carbonate Aquifer. Such a system should be designed to determine whether the repository is in compliance with its design standard to provide early warning of contamination and to augment the data requirements for the repository modeling of groundwater flow and contaminant transport. (133)

Response to Issue A:

The purpose of the ground-water standard is to maintain and protect the significant ground-water natural resource in the vicinity of Yucca Mountain. Ground water is one of our nation's most precious natural resources because of its many uses. This is especially true in the vicinity of Yucca Mountain, where ground water is currently used as drinking water, as a resource to support a diverse agricultural economy, and as an ecological habitat supporting sensitive ecosystems.

In general, ground water is a valuable resource with many potential uses. EPA believes that ground-water resources should be protected according to their use, value and vulnerability to contamination. In the case of Yucca Mountain, water from the aquifers that flow beneath the proposed repository is currently used both as a source of drinking water and for a variety of domestic and agricultural purposes 20 to 30 km south of Yucca Mountain. These ground-water resources also supply water for a variety of agricultural activities in the Amargosa Valley, such as crop irrigation, dairy farming, and other domestic purposes (showering, cooking). These aquifers also have the potential to serve a substantially larger population than that presently in the area (NAS Report, p. 92). Moreover, while the individual-protection standard limits total human radiation exposures, including drinking water and non-drinking water exposures, the IPS addresses resource protection less effectively. EPA believes that the ground-water protection standards will provide adequate protection from all potential uses of the ground-water resource that could lead to exposures by limiting the contamination of ground water that would discharge to the surface, such as springs or seep areas. These purposes for the ground-water protection standard are consistent with EPA's longstanding policy for ground-water protection, as set forth in "Protecting the Nation's Ground-Water: EPA's Strategy for the 1990s" (EPA 21Z-1020, July 1991, Docket A-95-12, Item II-A-3).

EPA began developing its ground-water strategy in the early 1980s at a time when we had received numerous Congressional mandates to protect human health and the environment, such as the SDWA, RCRA, and Superfund, among others. It soon became clear that ground-water protection was an integral part of each of these mandates, and that we needed to have a more consistent approach. In August 1984, the Agency's Office of Ground-Water Protection published its "Ground-Water Protection Strategy" (Docket A-95-12, Item II-A-13), which provided overall direction for our ground-water protection efforts. In addition to addressing internal resources and our relationship with external institutions, the 1984 strategy advised protecting ground water according to its use, value, and vulnerability to contamination. Although this strategy was a valuable first step, it became apparent that more specific guidance would be more useful. EPA subsequently established a ground-water task force to address comprehensive protection of the ground-water resource. EPA actively sought participation of interested stakeholders and the public, and extensive input was provided by state and local governments, other Federal agencies, environmentalists, industry and public interest groups. In July 1991, EPA issued "Protecting the Nation's Ground-Water", the purpose of which was to guide future EPA and State activities in ground-water protection and cleanup. Our policies, programs, and resource allocations reflect this approach. The key element of our Strategy is the overall goal of preventing adverse effects upon human health and the environment by protecting the environmental integrity of the Nation's ground-water resources. We believe that it is important to protect ground water to ensure that the Nation's currently used and potential sources of drinking water are preserved for present and future generations.

In carrying out the policies set forth in Protecting the Nation's Ground-Water, EPA typically uses the MCLs, established under the SDWA, as important reference points when the ground water in question is a current or potential source of drinking water. The MCLs are health-based limitations that serve to define drinking water that is safe to drink. Thus, we use the MCLs to protect ground

water in numerous regulatory programs where ground-water contamination is a significant possibility. This approach is reflected by our regulations pertaining to hazardous waste disposal (40 CFR part 264), municipal waste disposal (40 CFR parts 257 and 258), underground injection control (UIC) (40 CFR parts 144, 146, and 148), and uranium mill tailings disposal (40 CFR part 192). We have also incorporated MCLs to protect ground-water resources in our generic spent nuclear fuel, high-level waste and transuranic radioactive waste disposal regulations (40 CFR part 191). These regulations apply to the land disposal of these materials everywhere in the United States except Yucca Mountain. As several commenters pointed out, all analyses projecting the performance of the Yucca Mountain repository indicate that ground water is by far the most important pathway for transport of radionuclides (comments 26 and 405, for example). Therefore, we agree with the comments that the ground-water standards should provide protection at least equivalent to those presently in effect for public water systems under the purview of the Safe Drinking Water Act (comments 25, 59, 120, 129, 178, 194, 295, 306, 342, 356, 390, 428, 444, 529). However, comment 444 further states that limiting the compliance period to 10,000 years ultimately violates the SDWA, since concentrations beyond 10,000 years may exceed the MCLs. We disagree. Although our standards to protect the ground-water resource use the same levels as the MCLs developed under the SDWA, the Yucca Mountain disposal system itself is not subject to radiation standards under the SDWA. A further discussion of the 10,000-year regulatory timeframe is in Section 3 of this document.

In the case of pollution prevention activities, reaching the MCL is considered a failure of prevention. Assuring that ground-water contamination will not exceed the MCLs prior to facility operation means that the burden of environmental protection is borne by those benefitting from the facility in question, rather than having future generations expend resources to clean up contamination from the facility. Assuring that the proposed Yucca Mountain repository is protective of ground-water resources is also consistent with a basic principle of radioactive waste disposal; namely, that no undue burdens from radioactive waste disposal should be imposed upon future generations. (See "The Principles of Radioactive Waste Management," Safety Series No. 111-F, International Atomic Energy Agency, Vienna, Austria, 1995, Docket A-95-12, Item V-A-10.) We believe that it is appropriate to apply this fundamental and widely accepted concept to the Yucca Mountain repository (comments 50, 67, 73, 205, 390, 481).

Comments 295 and 445 assert that the ground-water standard should apply to man-made radionuclides from all sources in the vicinity of Yucca Mountain, such as numerous past and present activities at NTS, and contributions from the closed Beatty low-level radioactive waste disposal site. EPA does not agree that the Yucca Mountain ground-water protection standard should necessarily apply to those source terms; however, we refer to DOE's DEIS. Section 8.3.2 of the DEIS evaluates the potential impact of radionuclides at NTS on ground water downgradient of Yucca Mountain, and finds that it would not approach the MCLs within 10,000 years, even under conservative assumptions. Over longer time periods, the effect of contamination from NTS is a small fraction of the peak doses projected from the Yucca Mountain repository. Since other activities at NTS and at the Beatty site represent a much smaller radionuclide inventory, exposures from those sources would be a fraction of that from weapons-related radionuclides. We believe that a more rigorous analysis likely would result in even lower estimates.

With respect to whether EPA is providing "equivalent" protection to ground water at Yucca Mountain as has been provided at the WIPP TRU radioactive waste repository in New Mexico, we believe that the site-specific considerations that have informed our regulatory decisions are appropriate and do result in equivalent protection. The 1987 amendments to the NWPA specify that the Yucca Mountain site is the only potential repository site at which DOE may conduct site characterization activities. Therefore, since passage of the 1987 amendments, the Yucca Mountain site has been under an intense site characterization effort by DOE. Because of these efforts, we have a significant amount of information regarding past, present, and planned population patterns; land use; engineered design; and the hydrogeological characteristics of the host rock. It is apparent that ground water will flow predominantly in a southerly path from the Yucca Mountain repository. See the Yucca Mountain Draft Environmental Impact Statement, Chapter 3 (DOE/EIS-0250 D, July 1999, Docket A-95-12, Item V-A-4), and the Viability Assessment (Docket A-95-12, Item V-A-5). In addition to this extensive data base, we have the scientific recommendations of the Yucca Mountain NAS panel. Significantly, the NAS panel endorsed the use of present knowledge using "cautious but reasonable" assumptions in defining the exposure scenario (NAS Report, p. 100).

None of the information we have reviewed suggests that it is likely or reasonable that year-round residents will locate within 5 kilometers of the proposed repository footprint. As discussed in Chapter 8 of the BID, it would be extremely difficult to farm that close to Yucca Mountain, partly because extracting ground water at that location would be both technically challenging and prohibitively expensive for an individual or small group. In addition, much of this area has rough terrain and soils not conducive to farming. Our understanding of projections of future land development indicate limited population growth farther north of Lathrop Wells (see Appendix I of the BID), with the southernmost border of NTS serving as the limit of this projected development. Given the small likelihood of a year-round resident at 5 kilometers, we chose not to select a distance of 5 kilometers as a compliance point for the site-specific standards at Yucca Mountain. For additional discussion on other possible points of compliance for ground-water protection (see the "Summary of Final Decision" above, and Issues H and I below).

In evaluating the situation at the WIPP, we find that year-round residents already exist approximately 5 kilometers from the repository (see Chapter 2, Volume I, Title 40 CFR part 191 Compliance Certification Application for the Waste Isolation Pilot Plant, DOE/CAO-1996-2184, October 1996, Docket A-93-02, Item II-G-1). Also, the terrain surrounding the WIPP is much more accessible than that at Yucca Mountain. Some have argued that the quality, current use, and potential future use of the ground water at Yucca Mountain calls for more stringent regulation than the ground water at the WIPP, which is largely saline and not potable (comments 178, 342). However, taking the available information into account, we conclude that applying the MCLs at the boundary of the controlled area is consistent with our national policy to protect ground-water resources and our generic standards in 40 CFR part 191. The intent of using the MCLs as a compliance measure for the Yucca Mountain disposal system is to encourage a robust repository that will not result in unacceptable contamination during the regulatory time frame. We believe that the use of contaminated ground water for purposes that could result in exposures to

individuals should be of concern, and that avoiding contaminating useable ground-water resources is in the general interest of the public at large.

Comment 133 suggests specific ground-water monitoring actions that should be taken to provide early warning of releases and to assess repository performance. EPA included post-closure monitoring of the disposal system as an assurance requirement in 40 CFR 191.14. We requested comment as to whether we should specify such assurance requirements applicable to the Yucca Mountain disposal system, and declined to include them in our final rule. We have left this to NRC as a matter of implementation, and expect NRC to include such a requirement in its final 10 CFR part 63. DOE has been conducting ground-water monitoring for a number of years as part of its site characterization activities, and DOE and NRC will determine a monitoring program that is feasible and appropriate to implement during repository operations and after final site closure. Nye County has installed monitoring wells farther downgradient of the Yucca Mountain site.

Issue B: Separate ground-water protection standards are unnecessary or inappropriate at Yucca Mountain.

1. A separate ground-water protection standard for Yucca Mountain is redundant and unnecessary since an all pathways individual dose standard that includes the ground water pathway is fully protective of public health. (21, 203, 214, 233, 238, 270, 402, 420, 448, 550, 574, 595, 620, 631)

2. EPA was directed to develop an alternative MCL that would represent a risk comparable to that incurred from naturally-occurring radon in outdoor air. By our calculations, such an alternative MCL for a single radionuclide would correspond to an annual risk of 3.8×10^{-5} or more than twice that arising from exposure to an all-pathway, all-nuclide limit of 0.25 mSv (25 mrem) for Yucca Mountain. (621)

3. The proposed ground-water protection standard represents a misapplication of the Maximum Contaminant Levels (MCLs) of the Safe Drinking Water Act, which apply to drinking water provided by public water supplies. EPA should not require the expenditure of potentially significant amounts of taxpayer money to prevent potential contamination of ground water that may require treatment prior to use anyway. (277, 597)

4. [EPA's Groundwater Strategy] does not dictate generic imposition of tap water standards for all groundwater or a demonstration of compliance with such standards for 10,000 years. In fact, that strategy is flexible and allows for consideration of site-specific factors. . . There has been no analysis of the costs and feasibility to justify the strategy of applying tap water standards to groundwater. (635)

5. A separate ground water protection standard provides less, or no, additional public health and safety benefit. (2, 212, 634)

6. Since the most likely pathway of radiation exposure is ground water, the proposed ground-water protection standard effectively preempts the proposed 15 millirems/year individual-

protection standard and becomes the de facto standard instead of the individual protection limit called for by the Energy Policy Act of 1992. (276, 596)

7. The proposed ground-water protection standard lacks consistency with the individual-protection standard in terms of compliance location and dose methodology. The individual-protection standard is derived from EPA's latest dosimetry models, whereas the proposed ground-water protection standard is based on a 25-year-old regulation (i,e, the Safe Drinking Water Act), which in turn is based on 40-year-old dosimetry. (396, 397, 642)

8. A separate ground water protection standard is contrary to the statutory requirements. EPA is not required to promulgate a separate groundwater standard for Yucca Mountain. (420, 630)

9. A separate ground-water protection standard is inconsistent with the findings and recommendations of the National Academy of Sciences. The NAS did not recommend, and in fact specifically rejected, a separate groundwater protection standard. Therefore, adoption of a separate groundwater protection standard would be contrary to and inconsistent with the NAS findings and recommendations, and would constitute arbitrary and capricious agency action. (182, 189, 420, 530, 632)

10. A separate ground water protection standard may hinder/complicate the development/licensing of the proposed Yucca Mountain repository. (2, 586, 634)

11. A separate ground-water protection standard would force a non-optimal repository design. (235, 448)

12. It is inappropriate for a separate ground-water protection standard to regulate natural sources of radiation. EPA's proposal to combine estimated releases from the Yucca Mountain disposal system with the pre-existing naturally occurring or man-made radionuclides for radium-226, radium-228, and gross alpha activity to determine the concentration in the representative volume is acceptable. However, repository performance is not related to background radionuclides. (249, 637)

Response to Issue B:

EPA does not believe that the ground-water protection standards are redundant and unnecessary (comments 21, 203, 214, 233, 238, 402, 420, 448, 550, 574, 595, 620, 631), nor do these standards result in less public health and safety benefits (comments 2, 212, 634). Rather, EPA believes that the ground-water protection standards are complementary to the public health and safety standards that apply to the proposed Yucca Mountain repository, and serve a vital function. We have included a separate ground-water standard as a matter of policy. Because it is directed specifically at human health, the individual-protection standard of 15 millirems/year, by itself, would address ground-water resources and the viability of ecological habitats less effectively than would separate ground-water protection standards. We believe that ground-water protection standards will confer greater protection to aquatic or biological communities by limiting the

contamination of ground water that would discharge to the surface, such as springs or seep areas. Moreover, as discussed in the responses to the set of comments grouped under Issue A, we have a long-standing policy to encourage protection of ground-water resources in a consistent manner in our programs that may affect ground water quality directly or indirectly.

Comment 621 states that EPA was directed to develop an alternative MCL that would represent a risk comparable to that incurred from naturally-occurring radon in outdoor air, and asserts that such an alternative MCL for a single radionuclide would correspond to an annual risk of 3.8×10^{-5} or more than twice that arising from exposure to an all-pathway, all-nuclide limit of 0.25 mSv (25 mrem) for Yucca Mountain. EPA does not believe that the issue raised in this comment is relevant to the Yucca Mountain standard. The comment is a response to Question 15 in the preamble, which noted that some countries have established individual-protection limits higher than the level of 150 mSv/year (15 mrem/year) proposed by EPA for Yucca Mountain and, in fact, that other Federal authorities have also suggested higher individual-protection limits (e.g., 25 mSv/yr, or 25 mrem/year) with no separate ground-water protection provisions. (See 64 *FR* 47011, August 27, 1999.) In response to Question 15, the commenter pointed out that the approach for determining the radon MCL, based on Congressional direction, would result in a radon MCL well above the proposed limit of 15 mrem/year, or the 25 mrem/year limit recommended by this comment. This appears to support the commenter's contention that an all-pathways limit of 25 mrem/year, with no separate ground-water protection standards, would be sufficiently protective for Yucca Mountain. EPA is well aware of the complex issues associated with establishing an appropriate MCL for radon. Radon in drinking water is a naturally occurring contaminant, while EPA's standards for Yucca Mountain are primarily focused on limiting the releases of man-made radionuclides. While radon is ubiquitous in the environment and presents some cost and technical challenges to control at public water supplies, the radionuclides associated with the Yucca Mountain disposal system have been purposely created by man for energy and defense-related purposes. At each step, these man-made radionuclides have been managed and contained according to applicable regulations and the final challenge is to contain these radionuclides in a disposal system for extended periods of time. Naturally occurring radon in drinking water and the containment of man-made radionuclides in the Yucca Mountain disposal system are therefore two very different undertakings. Further, radon is not listed by DOE as a radionuclide in the expected inventory of radionuclides to be disposed at Yucca Mountain (see Table A-10 of the Yucca Mountain Draft Environmental Impact Statement, Docket A-95-12, Item V-A-4). In any case, the separate and distinct issues associated with establishing an MCL for radon have little if any bearing on establishing appropriate ground-water protection or individual protection standards at Yucca Mountain.

EPA does not believe that utilization of the SDWA MCLs in the ground-water protection standard constitutes a misapplication of those standards (comments 277, 597). As discussed above, EPA's Ground-Water Protection Strategy was developed as a comprehensive ground-water protection strategy that serves to guide Agency action where contamination of ground water is of concern. The Ground-Water Protection Strategy presents a clear statement of policy that emphasizes pollution prevention. It was developed based on significant input from state and local governments, other Federal agencies, environmentalists, industry, and public interest groups, among others. The Ground-Water Protection Strategy has guided the course of EPA and state

efforts with a clear priority on preventing ground-water contamination. If the Yucca Mountain repository is constructed and high-level radioactive waste disposed therein, it will result in disposal of a large inventory of long-lived radioactive materials directly over aquifers that presently supply ground-water resources to populations in the vicinity of Yucca Mountain. Part D (Agency Policy on EPA's Use of Quality Standards in Ground-Water Prevention and Remediation Activities) of the Ground-Water Protection Strategy states that, in the case of pollution prevention, allowing ground water that is a source of drinking water to be contaminated to a level that equals or exceeds the appropriate MCLs constitutes a failure of pollution prevention. Should this situation occur, future generations will have to decide whether to forego use of the ground-water resource or to expend substantial resources to clean up contaminated ground water. This would violate one of the primary principles in radioactive waste management, accepted nationally and internationally, that radioactive waste disposal should place no undue burdens upon future generations (see, for example, Principle 4: Protection of Future Generations in the IAEA's "The Principles of Radioactive Waste Management, Safety Series No. 111-F", 1995, Docket A-95-12, Item V-A-10). Therefore, use of the MCLs as part of the ground-water protection standard is appropriate.

The comment (597) that implies that EPA's ground-water protection standard will result in separate and additional expenditures to prevent potential ground-water contamination is incorrect. In the DEIS, DOE states that the repository design has evolved to address long-term uncertainty and concerns over licensing requirements that are not related to the EPA standard (page S-20, Summary, Yucca Mountain DEIS, Docket A-95-12, Item V-A-4). DOE's TSPA results indicate that the current design of the repository will meet both the individual-protection and ground-water standards by at least an order of magnitude (see Volume 3, Chapter 4 of the Viability Assessment, DOE/RW-0508, Docket A-95-12, Item V-A-5; Chapter 8 of the Yucca Mountain DEIS, Docket A-95-12, Item V-A-4, and Chapter 4 of the Yucca Mountain Science and Engineering Report, Docket A-95-12, Item V-A-27). Further, as stated in the Viability Assessment (Volume 1, Section 1), "uncertainties remain about the key natural processes, the preliminary design, and how the site and design would interact . . . DOE will continue to improve the repository design to provide extra margins of safety and will conduct additional research and testing to reduce remaining uncertainties." The expected performance for the current repository design, EDA II, projects no radiation doses for more than 100,000 years. Therefore, we conclude that our standard has virtually no impact on the ultimate cost of the repository [see Section 1 of this document, as well as our Economic Impact Assessment for a more complete discussion on this point (Docket A-95-12, Item V-B-2)].

Comment 635 states that the Ground-Water Protection Strategy does not dictate generic imposition of tap water standards for all ground water or a demonstration of compliance with such standards for 10,000 years; and states that there has been no analysis of the costs and feasibility to justify the strategy of applying tap water standards to ground water. The Ground-Water Protection Strategy allows EPA to exercise judgment in applying ground-water standards, in particular in consideration of site-specific factors. From a site-specific perspective, remediation of ground water contaminated as a result of releases from the proposed Yucca Mountain repository would be prohibitively expensive and technically daunting. Present information on the aquifers beneath the proposed Yucca Mountain repository indicates that existing water quality meets the

radiological MCLs and, therefore, do not have to be treated for radionuclides to provide drinking water. Many current residents rely on wells that directly supply drinking water (See Chapter 8 of the BID), and it would be reasonable to assume that such behavior would continue into the foreseeable future even if the population increases significantly. In the future, it is possible that contamination from previous underground testing and the Greater Confinement Disposal facility could contribute extremely small doses but not enough to cause the MCLs to be exceeded (see Sections 3.1.4.2.2 and 8.3.2 of the Yucca Mountain Draft Environmental Impact Statement, DOE/EIS-0250D, July 1999, Docket A-95-12, Item V-A-4). As a result, we see no conflict in using the MCLs to preserve the existing quality of ground water. We believe this to be a far more effective strategy than relying on the possibility of after-the-fact treatment. As stated above, we believe our standards will have no effect on the ultimate cost of the repository (see the EIA, Docket A-95-12, Item V-B-2).

Comments 276 and 596 assert that the proposed ground-water protection standard effectively preempts the proposed 15 millirems/year individual-protection standard and becomes the de facto standard instead of the individual protection limit called for by the Energy Policy Act of 1992. The intended purpose of the ground-water protection standards is not to preempt the individual protection standard. The ground-water protection standards are intended to protect a vital natural resource and, therefore, to serve a useful and complementary purpose to the all-pathways health and safety standard. While it is true that ground water would be the most likely source of exposure, it is possible that an individual or small group of nearby residents may receive significant radiation doses from a variety of pathways other than drinking water. Given that there are a variety of agricultural practices in the vicinity of Yucca Mountain (Chapter 8, BID, Docket A-95-12, Item II-A-10), an individual or small group would likely receive primary protection from the all pathways individual-protection standard. In such a case, drinking water would be only one of many pathways of exposure. Pathways other than ground-water may result in significant radiation doses due to bioaccumulation in certain environmental pathways (irrigation of crops, meat ingestion, fish farming). EPA believes that both the ground-water protection standards (incorporating the MCLs to protect ground-water resources), and the individual protection standards (as embodied in an all-pathways standard), are complementary and provide both public health protection and protection of the vital natural resource.

Comments 396, 397, and 642 assert that the proposed ground-water protection standards are inconsistent with the individual-protection standard in terms of (1) compliance location; (2) dose methodology, and (3) dosimetry. Regarding compliance location, we have selected the same location in our final rule for assessing compliance with the individual-protection standard and the ground-water protection standards.

The differences in dose methodology and dosimetry arise in acknowledgement of an existing approach for protecting ground water as opposed to the requirement to develop a new limit defining protection of individuals in the case of Yucca Mountain. Individual-protection standards have evolved over the decades and have been applied to a wide variety of radiation protection practices. Today, EPA is using the annual committed effective dose equivalent methodology for its new individual-protection standard, consistent with contemporary radiation protection practice.

In the case of ground-water protection standards, however, EPA has a long-standing policy to encourage protection of ground-water resources in a consistent manner. As pointed out earlier in these responses to comments, EPA has articulated its ground-water protection principles in the 1991 Strategy (Docket A-95-12, Item II-A-3) and further, has used the MCLs as a primary benchmark for environmental protection in a variety of regulatory programs.

EPA promulgated the 4 millirems/year MCL for man-made beta and photon emitting radionuclides in 1976 (41 *FR* 28402, July 9, 1976). This is a total dose equivalent to any organ or the whole body and incorporated the best scientific knowledge regarding the relationship between radiation exposure and risk that existed in 1975. Yet, the MCLs for radionuclides have a long institutional history and apply to thousands of public water supplies, serving to define when drinking water is safe to drink. The essence of the MCLs are radionuclide concentrations. Note that 40 CFR 141.16 lays out a clear methodology for determining the concentrations. In addition, EPA's publication "National Interim Primary Drinking Water Regulations," (EPA-570/9-76-003, Docket A-95-12, Item V-A-8) provides a listing in Appendix B of the concentrations of man-made radionuclides yielding an annual dose of 4 millirems/year (see Table IV-2A). At the same time, dose modeling to determine compliance with the all-pathways individual-protection standard will determine media-specific concentrations (e.g., air, surface water, ground water) as an intermediate step leading to the calculation of committed effective dose equivalents, taking into account each individual pathway of exposure (e.g., inhalation, ingestion of food or drinking water). While the dose methodologies for the ground-water protection standards and the individual-protection standards are different, they both begin with the same basic media-specific and pathway-specific concentrations. Given the well-established concentrations of the MCLs and the capabilities of today's sophisticated performance assessment modeling systems, we believe compliance with the ground-water protection provisions and the individual-protection requirements are feasible with minimal adjustments to the models in the case of Yucca Mountain.

While EPA does not believe the different dose methodologies will present any significant issues related to the ability to carry out performance assessments in support of compliance determinations, many commenters have questioned the risk levels represented by the MCLs, given that they were established in 1976 (see Issue C). However, a recent re-evaluation of the risk levels associated with each of the 1976 MCLs (the existing MCLs) using the methodologies described in Federal Guidance 13 finds that, in general, the existing MCLs for beta-photon emitters fall within the Agency's lifetime risk range goal of 10^{-4} to 10^{-6} (see 65 *FR* 76708-76717, December 7, 2000).

The comments grouped at 13 assert that the ground-water protection standards are contrary to the statutory requirements (420, 630). EPA does not believe that the ground-water protection standards are in any way contrary to the statutory requirements of the EnPA. Section 801(a) of the EnPA directs EPA to promulgate "public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the Yucca Mountain site." The Act specifically requires that EPA promulgate an individual dose limit as one element of the standards. The fact that Section 801(a)(2) states that EPA's standards, including an individual dose standard, "shall be the only such standards applicable to the Yucca Mountain Site," does not forbid EPA from establishing a separate ground-water protection standard for protection of the

vital ground-water natural resource. In specifying that EPA's public health and safety standards for protection of the public from releases from radioactive materials stored or disposed at Yucca Mountain "shall be the only such standards applicable to the Yucca Mountain site," (emphasis supplied), Section 801(a)(2) is not intended to preclude promulgation of any other environmentally protective standard. Rather, the legislative intent in specifying that these be the "only such standards" applicable to Yucca Mountain was two-fold. First, the intent was that no other governmental body be able to set public health and safety standards that supercede the EPA standard or that place additional restrictions on the Yucca Mountain repository. For example, even EPA's generally applicable environmental standards for spent nuclear fuel, high-level and transuranic waste at 40 CFR 191 are expressly prohibited from being applicable at Yucca Mountain, and NRC is required to adapt its proposed licensing process to conform with EPA's final Yucca Mountain standard (EnPA, Section 801(b)(1)). Second, EPA's public health and safety standard is required to prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository. We do not believe that there is any basis to interpret the language of the EnPA as prohibiting EPA from exercising its statutory authority to protect the environment, in this case, the vital ground-water natural resource, from degradation.

The comments grouped at 9 assert that the ground-water protection standards are inconsistent with the findings and recommendations of the National Academy of Sciences (182, 189, 420, 530, 632). Comment 530 further states that adoption of a separate ground-water protection standard - which it purports to be contrary to and inconsistent with the NAS findings and recommendations - would constitute arbitrary and capricious agency action. First, EPA disagrees that the ground-water protection standards are inconsistent with the findings and recommendations of NAS (182, 189, 420, 530, 632). In its report, NAS clearly identified the ground-water pathway as one of the significant pathways of exposure in the vicinity of the Yucca Mountain site (NAS Report, pp. 52 and 81). The NAS also acknowledged that separate ground-water standards have as a goal the protection of ground water as a resource (NAS Report, p. 121). The NAS did not, however, make a specific recommendation that EPA either include or not include a separate ground-water protection provision in our environmental protection standards for Yucca Mountain, but, rather, based its recommendations "on those requirements necessary to limit risks to individuals" (NAS Report, p. 121). In its comments on the proposed rule, NAS specifically addressed our proposal to include a separate ground-water protection standard for the Yucca Mountain site:

> "[i]n the preamble [to the proposed rule], EPA implies that there is a scientific basis for inclusion of separate ground-water limits in the standards – for example, EPA provides a detailed analysis of approaches to calculating such limits . . . .The [NAS] respectfully disagrees and does not believe that there is a basis in science for establishing such limits for the reasons described above. The [NAS] recognizes EPA has the authority under the Energy Policy Act to establish separate ground-water limits as a matter of policy, but if it does so it should explicitly state the policy decisions embedded in the proposed standard and ask the public to comment on those decisions.

> "If EPA wishes to establish such standards on the basis of science, it must make more cogent scientific arguments to justify the need for this standard" (NAS Comments, p. 11, Docket A-95-12, Item IV-D-31).

Thus, NAS specifically concluded that EPA has full regulatory authority to promulgate ground-water protection standards, as long as EPA does not misstate its rationale as based on scientific determinations regarding protection of public health and safety.

EPA also strongly disagrees that the adoption of a separate ground-water protection standard is arbitrary and capricious Agency action (530). Moreover, this comment stated that NAS specifically rejected a separate ground-water protection standard. This is either a misinterpretation or a misrepresentation of the NAS findings and recommendations. As discussed above, NAS neither recommended inclusion of a ground-water protection standard, nor explicitly recommended that EPA not include such a standard. The comment seems to imply that EPA cannot promulgate any standard or any aspect of any standard that was not specifically recommended by NAS, and, if it does so, such action is *per se* arbitrary and capricious. EPA disagrees with such a reading of the EnPA on the basis that it is directly contrary to the unambiguous meaning of the statute. In the Conference Report that accompanied the Energy Policy Act, the Conference Committee stated explicitly that the role of the NAS panel was to provide "expert scientific guidance," but that Section 801 is not intended to limit EPA's discretion in the exercise of its regulatory authority:

> The Conferees do not intend for the National Academy of Sciences, in making its recommendations, to establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards. Under the provisions of Section 801, the authority and responsibility to establish the standards, pursuant to rulemaking, would remain with the Administrator, as is the case under existing law. The provisions of Section 801 are not intended to limit the Administrator's discretion in the exercise of his authority related to public health and safety issues [H.R. Rep. No. 1018, 102nd Cong., 2d Sess. 391 (1992)].

Moreover, EPA's interpretation of the EnPA as not limiting the Agency's regulatory authority in this rulemaking is consistent with the views EPA expressed to Congress during deliberations over the legislation. The Chairman of the Senate Subcommittee on Nuclear Regulation requested EPA's views of the bill reported out of conference. The Deputy Administrator of EPA indicated that the NAS Report would provide helpful input. The Deputy Administrator pointed to the language, cited above, stating the intent of the Conferees not to limit our rulemaking discretion, and assured Congress that any standards for radioactive materials that we ultimately issue would be the subject of public comment and involvement [138 Cong. Rec. 33,955 (1992)].

EPA's interpretation also is consistent with the role that both NAS and Congress understood NAS would fulfill. During the Congressional deliberations over the legislation, NAS informed Congress that while it would conduct the study, it would not assume a standard-setting role because that is properly the responsibility of government officials [138 Cong. Rec. 33,953 (1992)].

Therefore, EPA does not believe that its proposal deviated in any respect from the legislative mandate of the EnPA. Thus, the legislative history of Section 801 of the EnPA speaks to this issue quite clearly and expressly belies any interpretation to the effect that valid exercise of the Agency's lawful and authorized regulatory authority in this context is somehow arbitrary and capricious.

Comments also asserted that a separate ground-water protection standard may hinder/complicate the development/licensing of the proposed Yucca Mountain repository (2, 586, 634), or that a separate ground-water protection standard would force a non-optimal repository design (235, 448). The primary purpose of the ground-water protection standards is to safeguard and protect the vital ground-water natural resource. It would be inappropriate for EPA to establish an environmental protection standard on the basis of licensing considerations. Moreover, the DEIS and Viability Assessment indicate that the current repository design would be able to meet the proposed standard.

EPA similarly disagrees that the ground-water protection standards will be detrimental to the performance of the repository. One commenter claims that the repository design must be adjusted to meet the ground-water standard, and refers to DOE's DEIS as showing that the best design from a ground-water perspective is the worst performer from an individual protection perspective. The commenter cites DOE's finding that meeting the ground-water standard requires additional excavation, ventilation, and material handling, increasing exposures from radon emissions and to workers over the operational period of the repository. The commenter also concludes that the ground-water standard adds additional expense to the design and construction of the repository without a corresponding increase in protectiveness. Finally, this commenter asserts that EPA has disregarded the NAS recommendation against sub-system performance requirements. We disagree that these comments accurately reflect the Yucca Mountain situation regarding the impacts of our standard on repository design. First, an evolving design is a natural phase of any large engineering or construction project, and we doubt that the commenter would expect DOE to consider only a single design while site characterization continues. Likewise, performance trade-offs, as well as trade-offs of performance, time, and cost, are to be expected in evaluating multiple project designs. Second, the commenter acknowledges that all of the various designs described in the DEIS "met both proposed NRC and proposed EPA standards for overall health protection."
Further, the DEIS shows that the increase in expected doses to the public attributable to Rn-222 during this period are insignificant (see Section 8.2.2 of the Draft DEIS for Yucca Mountain, Docket A-95-12, Item V-A-4). Also, the EPA standard in subpart A of the proposed rule (standards applicable to storage) does not apply to site workers. Workers are subject to NRC and DOE requirements, which allow higher exposures related to occupational activities than for the general public. As for sub-system requirements, we note NAS's comment that "[t]he proposed EPA standards do not contain subsystem requirements and, therefore, are consistent with the recommendations in the TYMS report" (Docket A-95-12, Item IV-D-31).

Comments 249 and 637 assert that it is inappropriate for a separate ground-water protection standard to regulate natural sources of radiation and that repository performance is not related to background radionuclides. EPA's Yucca Mountain standard only applies to radionuclides released from the Yucca Mountain disposal system. At the same time, EPA uses the MCLs as the

benchmark to limit the contamination of the representative volume of ground water. The MCLs incorporate provisions that relate to man-made and other [Ra-226 + Ra-228, gross alpha (excluding uranium and radon)] radionuclides. To the extent that these radionuclides are already present in the representative volume of ground water, the allowable releases from Yucca Mountain may be limited so that the radionuclides in the representative volume of ground water do not exceed the MCLs. This is to preserve the water quality of the resource at risk.

Information on the existing levels of radionuclides in ground water in the vicinity of the Yucca Mountain site indicates radionuclide concentrations "well below" the MCLs (see Table 3-19, Section 3.1.4.2.2 of the Draft Yucca Mountain EIS, Docket A-95-12, Item V-A-4). Further, projected impacts from past, projected and reasonably foreseeable future disposals are estimated at no more than a few percent of that to be expected from the Yucca Mountain repository. This includes a wide variety of activities, the most important of which are the residue from underground testing of nuclear weapons, the disposal of radionuclides at the Greater Confinement Disposal facility, and the shallow land disposal of low-level radioactive waste at the nearby Nevada Test Site (see Section 8.3.2 of the Draft Yucca Mountain EIS, Docket A-95-12, Item V-A-4). Based on the existing and projected radionuclide concentrations in ground water in the vicinity of the Yucca Mountain repository, the MCLs will serve as the effective limits to contamination of the representative volume of ground water.

Issue C: The MCL approach to ground water protection is misapplied to the Yucca Mountain site and is based on outdated dosimetry methodology that results in widely varying risk.

1. 1975 MCL's are NOT acceptable today. The dosimetry methods in the 1976 methodology are outdated particularly relative to equating them to risk. (74, 172, 546)

2. Current understanding of the risk posed to individual organs by radiation exposure demonstrates that the MCLs for individual radionuclides provide a level of protection that varies significantly. (594)

3. Application of a groundwater standard is without scientific basis in this case, in part because of the wide isotopic variability of the EPA MCL (and the resultant implied individual dose variability). We conclude that the groundwater calculation specified by EPA lacks scientific meaning due to outdated maximum concentration limits of isotopes and is an unnecessary compliance complication. (324)

4. If a separate groundwater standard is to be promulgated, we consider that it is appropriate for the EPA to abandon the more than 25-year old MCL methodology in favor of a standard of no less than 10 mrem/year CEDE. (771)

5. As aptly noted in EPA's preamble to the proposed Part 197 standards, application of the MCLs would render differing and inconsistent exposure levels that differ from the IPS.

Under these circumstances, the proposed GPS cannot be determined to be rationally related to ensuring adequate protection of public health and safety in the context of the Yucca Mountain site. (633)

6. Certain MCLs maintain a risk level so small that the individual, all-pathway dose limit is meaningless. . . Consequently, the groundwater protection criteria become the de facto standards instead of the individual protection limit called for by the Energy Policy Act of 1992. (596)

7. The MCLs were based on an analysis of treating contaminated water in public drinking water systems subject to the SDWA and not on an analysis of technology and costs of remediating groundwater at actual sites. In this rule, EPA proposes to apply the same MCLs to groundwater supplies before treatment rather than "at the tap" after treatment. Therefore, in the absence of an appropriate and comprehensive cost-benefit analysis, EPA should not require the expenditure of potentially significant amounts of taxpayer money to prevent potential contamination of groundwater that may require treatment prior to use anyway. (597)

8. Among other things, the MCLs under the SDWA apply "at the tap," after treatment, rather than to groundwater sources. Furthermore, the MCLs are required to reflect treatment feasibility and cost; such issues are not germane to, and have not been considered for, the proposed GPS. The MCLs are generally implemented through sampling and quarterly averaging; these concepts likewise are not applicable to and not incorporated into the proposed GPS. Many of the radionuclides at issue for the potential repository are not specifically addressed by the MCLs. (633)

9. EPA has not articulated a reasonable explanation for its use of ICRP-2 in this rulemaking while it has proposed the revised methodology of ICRP-30 in other related contexts such as the proposal on revised MCLs. Failure to consider this important aspect of the groundwater standard would render any final rule "arbitrary and capricious" under current case law. (642)

Response to Issue C:

Numerous comments asserted that the MCLs, which were originally promulgated in 1976, are based on an outdated methodology that results in varying risks for different radionuclides, thus providing levels of protection that vary significantly (comments 74, 172, 324, 546, 594, 633, 642, 771). Comment 324 went so far as to state that the ground-water standard "lacks scientific meaning due to outdated maximum concentration limits of isotopes and is an unnecessary compliance complication." It is true that the pertinent MCL does not represent a uniform risk for all radionuclides because the beta/photon MCL is based on a dose limit, not a uniform risk limit. Specifically, the MCL limits the *critical organ dose* from ingested beta/photon emitters to 4 mrem/y. For many radionuclides this type of dose limit leads to non-uniform, partial body irradiation and variable cancer risks; however, this does not render the standard scientifically meaningless. Different ingested radionuclides emit radiation of various energies, produce differing doses to nearby tissues, are transported to various locations in the body or are excreted, and decay

to other elements. These processes result in various risks of cancer in the body depending on the radionuclide and the tissue affected.

For example, ^{129}I concentrates predominately in one organ, the thyroid gland, whereas tritium (^{3}H) distributes fairly uniformly throughout the body. In the case of ^{129}I, the thyroid gland is the designated critical organ, and the derived activity concentration corresponding to the 4 mrem/y limit is 1 pCi/L (see Table IV-2A in "National Interim Primary Drinking Water Regulations", EPA-570/9-76-003, A-95-12, V-A-8). For ^{3}H, the total body is the critical organ, and the derived activity concentration at the MCL is 20,000 pCi/L. The table below presents EPA's current estimates of the individual lifetime excess fatal and total cancer risks associated with ingestion of these ^{129}I and ^{3}H activity concentrations, assuming a drinking water intake rate of 2 liter/day, 365 d/y, for 70 y, and using radionuclide-specific mortality and morbidity coefficients from Federal Guidance Report No. 13 (EPA 402-R-99-001, September 1999, Docket A-95-12, Item V-A-20).

Table of EPA estimates of the annual and lifetime fatal cancer risks associated with ingestion of ^{129}I and ^{3}H at activity concentrations corresponding to the 4 mrem/y beta/photon MCL.

Isotope	MCL (pCi/L)	Lifetime Excess Fatal Cancer Risk	Lifetime Excess Total Cancer Risk
I-129	1	8×10^{-7}	8×10^{-6}
H-3	20,000	4×10^{-5}	5×10^{-5}

As indicated by both the DOE/VA (Figure 4-12) (Docket A-95-12, Item V-A-5) and the DEIS for Yucca Mountain (Tables 8-42, 8-46, and 8-50, Docket A-95-12, Item V-A-4), the primary radionuclides of concern during a 10,000 year regulatory period are carbon-14 (^{14}C), technetium-99 (^{99}Tc), and ^{129}I. These are all beta emitting radionuclides that fall under the 4 millirem/year MCL limitation. When this level was derived in 1976, the cancer risk associated with whole body irradiation (as is the case for ^{14}C and ^{99}Tc) at 4 millirem/year equated to a lifetime cancer risk of 5.6×10^{-5}, assuming a 70-year lifetime. Comment 642 refers specifically to the methodology used to develop the MCLs in 1976 (ICRP-2), and questions EPA's rationale for relying on that methodology when the Agency proposes to use updated methodologies, such as ICRP-30, in its current actions. However, a recent re-evaluation, using EPA's Federal Guidance Report 13, of the risk associated with each of the 1976 MCL concentration levels corresponding to the 4 millirem/year limit found that "the risks associated with these concentrations, while varying considerably, generally fall within the Agency's current risk target range for drinking water contaminants of 10^{-4} to 10^{-6}" (see 65 *FR* 76716, December 7, 2000). The risk coefficients in Federal Guidance Report 13 were derived using ICRP-30 and later ICRP methodologies. Based on these generally consistent results, and despite the differing methodologies, EPA is not revising the MCL for beta-photon emitters at this time.

Moreover, EPA has applied MCL levels to waste disposal efforts throughout the country for many years, and the MCLs apply to the WIPP, a geologic repository for long-lived TRU radioactive wastes. Under the principle of inter-generational equity, EPA regards MCLs as an appropriate

measure to be applied to these types of activities to protect ground-water resources from potential contamination. By attempting to limit potential ground-water contamination to the MCL limits, we are acting consistent with the principle of intergenerational equity, i.e., by restricting pollution potential of the initial waste disposal practice, we are not allowing the burden of cleaning drinking water supplies to be passed on to future generations. We consider this approach to be consistent with Agency and national policy to protect ground-water resources for future use (see the responses to Issues A and B above on the need for separate ground-water standards).

Comment 596 asserts that the ground-water protection criteria become the *de facto* standards, rather than the individual protection limit expressly authorized by the EnPA. While this is certainly possible for individual radionuclides, protecting ground-water resources is an Agency and national policy. The two standards, individual protection and ground-water protection, derive from different rationales and apply to different considerations for the disposal system. The individual protection standard is aimed at health protection for individuals potentially exposed to repository releases from any and all pathways. This is a health based standard, to be set consistently with the Agency's judgement on acceptable risk levels for these total exposures. In contrast, the ground-water protection requirement is aimed at the protection of ground-water resources for future use by people. Considering that the Yucca Mountain repository is located above potable water aquifers that supply the water needs of current residents downgradient from the repository (BID for 40 CFR part 197, Chapter 7, Docket A-95-12, Item V-B-1), and could supply even larger populations, we feel that ground-water protection is a legitimate and important component of the environmental standard we are establishing. Also considering that potential releases of radionuclides after failure of portions of the engineered containment barriers are largely into ground waters below the repository site, protection of the downgradient water resources from contamination appears to be a prudent course and consistent with existing applications under the authority of the Agency (for additional information on the Yucca Mountain repository, see the BID for 40 CFR part 197, Chapter 7, Docket A-95-12, Item V-B-1). Whether the releases for any particular radionuclide are limited by the individual or ground-water protection requirements is a function of the specific conditions at any given repository site as well as the projected release performance of the repository over time. As mentioned above, the two requirements are derived from separate concerns, and so the justification for having both individual and ground-water protection standards is independent of these site-specific details.

Comments 597 and 633 assert that the MCLs apply under the SDWA at the tap and are inappropriately utilized as ground-water standards. These comments also assert that the MCL approach should not be implemented for the Yucca Mountain site without a cost-benefit analysis, since the MCL approach is technology based. EPA believes that it is appropriate to apply the MCLs to groundwater resources at Yucca Mountain for the following reasons:

First, as discussed above, this is a matter of inter-generational equity. The intent of applying the MCLs as part of the ground-water protection standard is to encourage a robust containment and isolation design that will not result in unacceptable contamination during the regulatory time frame, which would require future generations to shoulder the burden of water treatment due to contamination from the wastes. Second, inclusion of the ground-water protection standard is

consistent with EPA's certification process for WIPP; which is the only deep geologic disposal facility in the country that has actually gone through a regulatory review and approval process. We do not believe that we should not apply the same approach to protection for the Yucca Mountain disposal facility as we afforded to the population around WIPP. Moreover, the Yucca Mountain disposal system will be located above aquifers that are the ground-water supply for the residents living downgradient from the repository, whereas the aquifers potentially subject to contamination at the WIPP facility are highly saline, non-potable water sources. Third, we employ MCLs to protect ground water in numerous other regulatory programs. Our regulations pertaining to hazardous-waste disposal (40 CFR part 264); municipal-waste disposal (40 CFR parts 257 and 258); underground injection control (UIC) (40 CFR parts 144, 146, and 148); generic SNF, HLW, and TRU radioactive waste disposal (40 CFR part 191); and uranium mill tailings disposal (40 CFR part 192) all incorporate MCLs for purposes of protecting precious ground-water resources. These programs have demonstrated that such protection is scientifically and technically achievable, within the constraints that each program applies ("Progress In Ground-Water Protection and Restoration," EPA 440/6-90-001, Docket A-95-12, Item V-A-6).

EPA does not believe that a cost-benefit analysis is necessary for the application of the MCLs as part of the site-specific Yucca Mountain ground-water protection standard. Application of the MCL limits to other site-specific waste disposal activities is a matter of Agency policy and not predicated on the outcome of site-specific cost-benefit analyses. Analyses of potential ground-water contamination levels for the site performed by DOE show that the current MCL levels are not exceeded at any of the locations for which calculations were performed (distances of 5 to 30 km downgradient from the site). See the Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada (DOE/EIS - 0250D, Docket A-95-12, Item V-A-4), and Chapter 4 of the Yucca Mountain Science and Engineering Report (Docket A-95-12, Item V-A-27). More specifically, the Economic Impact Analysis for 40 CFR part 197 presents a series of arguments to demonstrate that the current repository design did not evolve as a direct response to EPA's ground-water protection requirements, and that demonstrating compliance with these requirements does not impose additional costs on the repository program for expensive site characterization studies or repository design efforts. In addition, the Yucca Mountain repository design has evolved in response to the changing understanding of the expected performance of the natural and engineered systems at the site and in an attempt to reduce the impacts of uncertainties in projecting the behavior of the disposal system for compliance assessments. It has not evolved in response to provisions of the EPA standard, or EPA's broader application of MCLs to waste disposal efforts, which have been in place in their current form for some considerable time [see the EIA for 40 CFR part 197 for a more extensive discussion (Docket A-95-12, Item V-B-2)]. EPA's ground-water protection approach in fact requires no additional expensive data collection beyond that necessary to show compliance with the individual protection standard, and therefore imposes no significant additional costs on the DOE effort (EIA for 40 CFR part 197, Chapter 6, Docket A-95-12, Item V-B-2). In addition, details of the compliance analyses (representative volume, use of averaged hydrologic characteristics and methods for calculating contamination plume concentrations) have been specified in §197.31 to reduce potential confusion in implementation and reduce uncertainties in the calculations; further minimizing the difficulty (expense) of demonstrating compliance.

Comment 633 stated that many of the radionuclides at issue for the potential repository site are not specifically addressed by the MCLs. Performance projections for the disposal system presented in the DOE/VA and DEIS documents (Docket A-95-12, Items V-A-4 and V-A-5) show that the radionuclides that contribute to potential doses within the regulatory time frame (10,000 years) are primarily technetium and iodine. These radionuclides do have established MCL levels.

Issue D: What is the appropriate representative volume (RV) for use in assessing compliance with the ground water protection standard? (619)

1. Since the problem is supposed to include the consideration of the critical group who will utilize ground water [inaudible] aquifer that could be impacted by Yucca Mountain, it is also appropriate to incorporate the ground water standard that is consistent with the use of the water for domestic purposes. (70)

2. The 4,000 ac-ft/yr RV is the appropriate value, others are too small for adequate implementation and ignore the current water availability in the region. (215, 470, 636)

3. The preamble to the standard requests comment on alternative dilution volumes that are extremely small (e.g. 10 and 120 acre-feet). These dilution volumes are not reflective of the resource to be protected (the EPA states the representative volumetric flow is 4000 acre-ft/year for the sub-basin in which the proposed repository is located). (598)

4. The RV should be as small as technically achievable. (441)

5. The 1,285 ac-ft RV appears appropriate although a case could be made for higher volumes, smaller volumes are technically not feasible to implement. (561, 307)

6. We consider that the EPA has presented a reasonable assertion and provided sufficient bases for the use of 1285 acre-feet per year as a dilution volume for the CG/RMEI. We do not support the use of any parametric value less than what EPA has proposed here. (772)

7. The requirement in the draft standard of a "representative amount of groundwater" appears to be inconsistent with the SDWA. The smallest public water system whose groundwater is protected under the SDWA may have as few as 15 connections or supply 25 people. The EPA should make its Yucca Mountain standard fully consistent with the SDWA. (294)

8. Modeling considerations based on low water volume available today should not be a principal factor in decision making on the withdrawal point. (293)

Response to Issue D:

A number of comments state that the perennial yield volume of 4,000 acre-feet/yr is the appropriate representative volume because the other volumes are too small for adequate modeling and ignore the current water availability in the region (comments 215, 470, 598, 636).

EPA disagrees that 4,000 acre-feet/yr is the appropriate value for the representative volume. First, there are few wells in the sub-basin and the data necessary to estimate the perennial yield are very poor. The database of hydrologic characterization information for the sub-basin is small and consequently there is a high level of uncertainty for any attempt to derive an accurate number for the perennial yield. Therefore, at best, the 4,000 acre-feet/yr number is a very rough estimate rather than a reliable number (see the BID, Chapter 7 for data on water resources in the Yucca Mountain area). Second, the use of a perennial yield number for calculations assessing the potential of ground-water contamination tacitly allows the entire sub-basin to be contaminated before compliance is an issue. In this connection, the perennial yield is an abstract concept used for the purposes of water budgeting, but does not have a physical reality in that it is not located at any given place in the aquifers potentially vulnerable to contamination by repository releases. Finally, the challenge of the repository effort is to project, with an acceptable level of confidence, the path of potential contamination released from the repository. Analyses to show compliance with ground-water protection requirements must be based on such projections of the path of contaminants (giving recognition to inherent uncertainties to be expected), rather than on a simple assumption that the entire sub-basin can be accepted as a volume of ground water available for contamination. For these reasons, we believe the 4,000 acre-feet/yr perennial yield number is not appropriate as the representative volume.

Comment 441 states that the representative volume should be as small as technically achievable. Comment 294 states that EPA should make the standard fully consistent with the SDWA; the smallest public water system protected under the SDWA may have as few as 15 connections or supply 25 people. EPA concludes that the 10 acre-feet/yr representative volume (which is equivalent to the smallest volume for a public water supply for purely domestic use), is too small a volume for defensible modeling calculations, considering the inherent uncertainties in projecting contaminant migration over the long time frames and distances involved. From a modeling feasibility perspective, we believe a minimum volume of about 100 acre-feet is the lower limit of defensible modeling, considering the uncertainties in time and scale involved in modeling the ground-water flow and contaminant migration downgradient from the repository site (Docket A-95-12, Item II-E-10). Thus, of the four options presented, EPA considers the 120 acre-feet/yr and 1,285 acre-feet/yr options to be practical water volumes for modeling purposes. These volumes were developed from considerations of actual water use information for the current inhabitants living downgradient from the repository site and their current water needs (see discussions in Section 8.2.3.2 of the 40 CFR part 197 BID). For a community large enough to use water for other than entirely domestic purposes, a per capita water use of 0.8 acre-feet/yr is consistent with actual uses. The 120 acre-feet/yr volume would then be consistent with a small rural residential community, which is consistent with short-term population growth projections for the area around 20 km downgradient from the repository. As explained in the preamble to the standard, the 1,285 acre-feet/yr volume corresponds to an alfalfa farm with 225 acres under cultivation (water allotment of 5 acre-feet/yr/acre under cultivation - an average size farm for the Amargosa Valley area with 10 acre-feet/yr for domestic use). Comment 70 states that a water volume consistent with domestic use should be included in the ground-water standard. The 1,285 acre-feet/yr representative volume includes a 10 acre-feet/yr volume for domestic use. As mentioned above, the practical limitations for ground-water and contaminant transport modeling have led us to the

conclusion that it is not feasible to confidently project potential contamination over long time periods using a small volume such as 10 acre-feet/yr. The domestic use of ground water is therefore incorporated into the representative volume we have defined. As explained in the preamble to the final rule, we have selected a representative volume of 3,000 acre-feet/yr as a figure more representative of the spectrum of water uses downgradient of the repository that would be protected by the ground-water standards.

Comment 293 states that modeling considerations based on low water volume available today should not be a principal factor in EPA's determination of the appropriate compliance location for the ground-water protection standard. We have not chosen a compliance location on the basis of a water volume consideration. The compliance location was selected as a protective measure to safeguard the water resource for the population directly downgradient from the repository. We selected the southwesternmost border of the NTS as the farthest extent of the controlled area in the predominant direction of ground-water flow because we believe that NTS will continue to be an area permanently withdrawn from public uses because of the activities that have been conducted there that could result in radioactive contamination. Therefore, future human activities are unlikely north of that location. The issue of water accessibility and cost, with deepening of the water table in the direction of the repository, also argues for a lower probability of future human activity in that direction. By placing the compliance location northward of the Amargosa Valley area where current farming activities are located, we are taking a protective approach to safeguarding the resource.

Issue E: Is it reasonable to assume that there will be some degree of mixing with uncontaminated ground water along the radionuclide travel paths from the repository? (293)

1. The degree of potential mixing along flow paths and the modeling approach are implementation details that should be left to NRC. (232, 332, 269, 772)

2. It is inappropriate for the EPA to prescribe any degree of belief in potential modeling approaches that could be part of DOE's license application. (619)

3. Although the proposed standard appears to have a groundwater standard, it is significantly weaker than and out of compliance with EPA's current ground water protection criteria as implemented under CERCLA (Superfund), the WIPP standard and the Safe Drinking Water Act. . . EPA should require strict adherence at all points/locations to the agency's groundwater MCLs without allowing for dilution by volume or distance. (590)

4. EPA should not assume that dilution or mixing with clean water is acceptable. (373)

5. It is reasonable to assume dilution of the pollution at increasingly distal locations. (171)

6. It is reasonable to assume that there will be mixing with uncontaminated groundwater, because preventing such mixing would be essentially impossible. (469)

7. [I]t is reasonable to assume there will be some degree of mixing but, from recent work, it appears the flowpaths beneath the repository will be along fractures, with the water moving generally to the south and southeast until it discharges from the tuff into the alluvial aquifer. This suggests that mixing will be limited for the first 15 to 20 km from the repository area, and probably negligible over the first few kilometers. (389)

8. DOE not only agrees that it is reasonable to assume that the mixing of uncontaminated water occurs along the radionuclide travel paths, but DOE's site characterization studies demonstrate that such mixing occurs. (641)

9. Parameter values should be derived from the collection of reasonably attainable field data and research directed to define more accurately the heterogeneity and variance of these parameter distributions, rather than by substitution of "expert-elicited" values. The analysis must also consider model uncertainty as well as parameter uncertainty, and particularly model linkages. Given the complexity of the saturated-zone flow system downgradient from Yucca Mountain involving both fracture and matrix flow, and contributions from the volcanic, alluvial, and carbonate aquifers, it is reasonable to assume that there will be mixing with uncontaminated ground water along the radionuclide travel paths from the repository. (559)

Response to Issue E:

In the preamble to the proposed rule, EPA specifically requested comment on (i) "[w]hat approach is appropriate for modeling the ground water flow system downgradient from Yucca Mountain . . ." and (ii) "[i]s it reasonable to assume that there will be some degree of mixing with uncontaminated ground water along the radionuclide travel paths from the repository?" (Question 12, 64 *FR* 47010). The purpose of requesting comment on these questions was to gain insight into how the ground-water protection standard could be applied to the Yucca Mountain site in a reasonable manner, given the currently known characteristics of the site. Recognizing that the ground-water flow regime beneath the repository is strongly controlled by water movement through the fractured rocks, the question of how releases from the repository will interact with the surrounding ground-water flow system is important to the approach taken to model the process.

Comments 232, 332, 269, and 772 express concern that the approach to modeling ground-water flow is an implementation issue that should be left to NRC as the licensing authority. EPA has not taken a position on the use of any particular modeling approach for use in assessing ground-water contamination downgradient of the site. We believe that this choice is the responsibility of DOE to propose and defend in the licensing process. We do, however, feel that extreme approaches to modeling the flow-system should be avoided, consistent with our "reasonable expectation" approach to demonstrating compliance with the standard. Extreme approaches to modeling radionuclide transport in fracture dominated flow systems could result in "worst-case" scenarios with assumptions that are unrealistic and excessively conservative as a consequence. Such extreme "worst-case" analyses have the potential to obscure the important processes that actually control the likely performance of the repository system most of the time. By obscuring these processes, it can make it difficult to reach a scientific consensus in the licensing process about whether the

processes that control repository performance most of the time are actually understood sufficiently well to make reasonable decisions about the adequacy of the compliance analyses. Consistent with our "reasonable expectation" approach to compliance demonstrations, we believe that the inherent uncertainties involved in understanding the natural processes and events should be recognized and treated realistically in performance projections and an understanding of uncertainties should play a role in compliance decisions.

Some comments point out that mixing of contaminated water from the repository with other water along the flow path is to be expected and can not be avoided (comments 171, 469, 389, 559, and 641), while other comments insisted that no potential mixing should be allowed. EPA believes that the extent of the mixing possible along the flow path from the repository to the compliance point is an important question that DOE's site characterization and modeling must answer. We believe that it would be excessively conservative, to the point of being unrealistic, to assume that repository releases can move from the immediate repository location to the compliance point without interacting, and mixing to some extent, with ground water along the flow path. The extent of potential mixing and the resultant radionuclide concentrations in ground waters at the compliance point is a question that DOE must establish on the basis of its site characterization and modeling activities, and which it will have to defend in the licensing process. As the licensing authority, NRC will have to assess the adequacy of the characterization data and modeling results presented by DOE.

Comment 559 stated that DOE is placing too heavy a reliance on expert elicitation to estimate characteristics of the ground-water flow system, rather than on collecting data from appropriate field testing. The degree to which DOE uses actual site data and expert judgements in its modeling is a decision it must make. EPA believes that expert judgements through expert elicitation processes should not be a substitute for site data that can be collected by a reasonably thorough characterization program. However, we also recognize the value of outside peer review and evaluations as a desirable adjunct to work done within the repository program. The acceptable mix of the two sources of information is a question that DOE and the implementing authority will decide during the licensing process. We believe that our direction embodied in the reasonable expectation approach should supply the context for considering these kinds of decisions.

Issue F: The technical description of the approaches to calculating radionuclide concentrations in the RV for ground water compliance determinations.

1. Clarify the meaning of Table 1 in the standard relative to the inclusion or non-inclusion of background levels for specific radionuclides in the RV. (563)

2. Although we oppose the application of these MCLs to groundwater in general, we find it highly inappropriate to attempt to regulate natural sources of radiation through a standard specifically intended for a high level waste repository at Yucca Mountain. (249)

3. It is appropriate for EPA to give DOE two alternatives for selecting the physical dimensions and orientation of the representative volume (the well capture-zone and slice of the plume methods were proposed). (643)

4. The "slice of the plume" and "well capture-zone" methods for calculating compliance are not adequately explained, and many aspects seem to be arbitrary. We are unsure of the scientific basis for either of these methods or how they would be implemented. (560)

5. The definition of "plume of contamination" under §197.12 states that releases from any other potential sources on or near the Nevada Test Site should not be included in comparisons to the standard. On the one hand, this will allow DOE to be responsible only for the potential releases from Yucca Mountain in meeting the standard. On the other hand, it seems unreasonable to set standards for one activity (i.e., high level radioactive waste disposal at Yucca Mountain) ignoring other nearby potentially significant sources of contamination, such as Pahute Mesa. (564)

6. Assuming there is a separate groundwater standard in the final rule, the dose limits in such standard should be fixed values no more stringent than those specified in Table 1 in §197.35. The dose limits should not be subject to revision before or after promulgation of the standard. (638)

Response to Issue F:

Comments 563 and 249 (1) request clarification regarding whether EPA is requiring the inclusion of background radiation in the representative volume and (2) assert that it is highly inappropriate to include natural sources of radiation in a standard that is intended to regulate releases from radioactive materials stored or disposed of in the repository at Yucca Mountain. Table 1 in Section 197.30 of final 40 CFR part 197 states whether natural background levels of radionuclides are to be included in calculating the ground-water concentrations for comparison against the MCL limits. For the MCL concerning beta and photon emitting radionuclides, which are expected to be the radionuclides that contribute to the potential dose to individuals during the regulatory time period (DOE Viability Assessment, 1998, Docket A-95-12, Item V-A-5), natural background levels are not considered, i.e., the calculations should only consider releases from the repository. The MCL levels for these radionuclides have always been described as man-made radionuclides and therefore background levels should be zero.

EPA's Yucca Mountain standard only applies to radionuclides released from the Yucca Mountain disposal system. At the same time, EPA uses the MCLs as the benchmark to limit the contamination of the representative volume of ground water. The MCLs incorporate provisions that relate to man-made and other [Ra-226 + Ra-228, gross alpha (excluding uranium and radon)] radionuclides. To the extent that these radionuclides are already present in the representative volume of ground water, the allowable releases from Yucca Mountain may be limited so that the radionuclides in the representative volume of ground water do not exceed the MCLs. This is to preserve the quality of the water resource at risk.
Information on the existing levels of radionuclides in ground water in the vicinity of the Yucca Mountain site indicates radionuclide concentrations "well below" the MCLs (see Table 3-19,

Section 3.1.4.2.2 of the Draft Yucca Mountain EIS, Docket A-95-12, Item V-A-4). Further, projected impacts from past, projected and reasonably foreseeable future disposals are estimated at no more than a few percent of that to be expected from the Yucca Mountain repository. This includes a wide variety of activities, the most important of which are the residue from underground testing of nuclear weapons, the disposal of radionuclides at the Greater Confinement Disposal facility, and the shallow land disposal of low-level radioactive waste at the nearby NTS (see Section 8.3.2 of the Draft Yucca Mountain EIS, Docket A-95-12, Item V-A-4).
Based on the existing and projected radionuclide concentrations in ground water in the vicinity of the Yucca Mountain repository, the MCLs will serve as the effective limits to contamination of the representative volume of ground water.

Comments 643 expressed support for EPA's inclusion of two alternatives for selecting the physical dimensions and orientation of the representative volume [Section 197.36(b) of the proposed rule, Section 197.31(b) of the final rule]. Comment 560 asserted that EPA's proposal did not adequately explain these alternatives, that they seem to be arbitrary, and their scientific basis is unclear. EPA proposed two alternative methods ("well capture zone" and "slice of the plume") to allow flexibility for DOE in applying the ground-water protection standard. Whichever of these two methods DOE uses to determine the dimensions of the representative volume, NRC must approve both the method selected and any underlying assumptions used by DOE.

The well capture zone approach is intended to allow a realistic evaluation of contaminant concentrations in contamination plumes intercepting a water supply well that could supply the annual water needs as defined by the representative volume. Specific limitations on certain assumptions that must be incorporated into the well capture zone calculation, e.g., the characteristics of the water supply well, the location of the screened interval, and the pumping rate, were defined to assure that the actual assumptions used in such calculations are consistent with current water uses and practices in the area downgradient from the repository. If this particular method is selected for the ground-water compliance calculations, a case must be made that the assumptions used are reasonable for the area, i.e., the assumptions should not be allowed to produce unrealistic well dilution effects simply for the purpose of demonstrating compliance more easily. To assure that use of this approach can be implemented in a reasonable and scientifically defensible manner, EPA has also clarified the language in § 197.31(b) of the final rule to acknowledge that multiple wells could be used to implement the compliance assessments. A more technically rigorous description of the well capture zone concept is given in Mark Bakker, Otto Strack, *Capture zone delineation in two-dimensional groundwater flow models*, Water Resources Research, 32(5):1309-1315 (1996) (Docket A-95-12, Item V-A-25).

The "slice of the plume" approach takes an alternate perspective in that it is intended for a situation where the contaminant migration is modeled as a broader plume, for example where modeling contaminant migration uses a "stream tube" type of simulation. In reality, the contaminant migration might be any number of individual plumes originating from different portions of the repository, but the modeling approach might use a more generalized approximation and model the migration as a broad plume with characteristics intended to average the behavior of smaller individual contamination plumes. In this approach the representative volume is a "slice of the

plume" taken at the compliance point for calculating average radionuclide concentrations in the "slice." The thickness of the slice is equal to the size of the representative volume (i.e., the amount of aquifer that would hold a water volume equal to the representative volume).
An important decision for this approach is defining where the plume ends, i.e., its three dimensional boundaries, which must be defined so that the contaminant concentrations can be calculated. This must be modeled by DOE, and approved by NRC. Presumably this decision would make use of information on the expected dispersion in the ground-water system downgradient from the site. DOE has conducted one expert elicitation to solicit input on values that should be assumed for downgradient dispersion effects. Information on this subject is difficult to derive through field testing, and we anticipate that external peer review and expert judgements would play a significant part in assessing dispersion effects in the ground-water flow system south of Yucca Mountain.

Comment 564 asserts that it seems unreasonable to set standards for the Yucca Mountain high level radioactive waste repository that "ignor[e]" other nearby potentially significant sources of contamination. The EnPA authorizes EPA to promulgate public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in Yucca mountain. The EnPA does not authorize EPA to promulgate this public health and safety standard to include releases from the entire NTS or other potentially previously contaminated areas. Moreover, the international radiation protection community has recommended that doses from all practices potentially giving exposures to the population be limited to no more than 100 mrem/yr (International Commission on Radiological Protection - Radiation Protection Principles for the Disposal of Solid Radioactive Waste", ICRP Publication 46, Annals of the ICRP, Vol. 15, No. 4, Pergamon Press, Oxford, UK, Docket A-95-12, Item V-A-12). The maximum dose limit promulgated in this standard is 15 mrem/yr, a number sufficiently below the recommended all sources exposure limit of 100 mrem/yr. This limit allows a significant margin of safety even considering other potential sources of radiation exposure from activities carried on at the NTS.

In addition, current information about the repository's expected performance indicates that the predominant pathway for exposures is through the ground-water system beneath Yucca Mountain and to the south. Current understanding of the ground-water flow systems in the broader area suggests that potential releases from other sources of radionuclide contamination, most importantly underground nuclear weapons detonations, will not mix significantly with releases from the repository [DEIS for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County, Nevada, DOE/EIS - 0250D, Docket A-95-12, Item V-A-4 (the DEIS)]. It appears that contaminant migration from these other activities are located in sub-basins other than Basin 227A where the repository is located, and are not anticipated to contribute to the potential exposure projections for the repository within the regulatory time period (DEIS, Docket A-95-12, Item V-A-4). The majority of underground nuclear tests were conducted in sub-basins to the north and east of Yucca Mountain and the direction of movement of the ground waters in these basins are not all in the direction of Yucca Mountain [Nevada Risk Assessment/Management Program (NRAMP), December 1996, Docket A-95-12, Item V-A-17]. There is significant uncertainty in the understanding of the hydrologic system in the NTS area and the flow rates and accurate projections of the flow patterns in the area

are not well established. The potential contaminant migration path for releases from Yucca Mountain are anticipated to be confined to the volcanic and alluvial aquifers downgradient from the site in sub-basin 227A (DEIS, Docket A-95-12, Item V-A-4). DOE has done some extremely conservative assessments of potential exposures from underground testing and estimated a maximum dose at the border of the NTS at 0.22 mrem/yr (DEIS, Section 8.3.2.1.1, Docket A-95-12, Item V-A-4). These assessments assumed the entire inventory of radionuclides from the testing was available for transport and all of it was assumed to move in the direction of projected repository releases. According to current understanding much of the ground water from the testing areas would discharge in areas other than that for Yucca Mountain projected releases. In the event that this understanding changes, the repository exposure limits are sufficiently low that a margin of safety is still likely. One last point on this question, based upon current understanding it would be highly speculative to make projections of scenarios where releases from other NTS activities could mix with potential repository releases. A consistent theme from the NAS recommendations is that regulatory standards and decision making should not be based on highly speculative assessments.

Comment 638 states that the contamination limits for the ground-water protection standard given in table 1 of § 197.35 of the proposed rule should be used for the final rule without the possibility of having these numbers revised to more stringent values. The values referenced correspond to the current MCL concentration limits. Based upon a recent review, EPA has decided to retain the existing MCLs, and these values are included in the final rule for Yucca Mountain (see 65 *FR* 76708-76717, December 7, 2000). The MCLs, like many other regulatory limits, are subject to periodic review to ensure that they are consistent with current scientific knowledge. The MCLs could be re-evaluated for a number of reasons, such as improved understanding of radiation risks for specific radionuclides. In the event that the MCLs are revised, the decision to incorporate such changes into the Yucca Mountain rule would consider whether the changes have any potential impact on the performance assessments for the potential repository site. As stated in § 197.37 of the final rule, EPA may amend the final Yucca Mountain rule, but any such proposed changes would be adopted only through notice-and-comment rulemaking, which gives all concerned parties the opportunity to participate in the process.

Issue G: The estimate of potential population sizes of "several hundred thousand" people to be supplied with drinking water from beneath Yucca Mountain appears highly unlikely.

1. We question the statement in Section III.F that the aquifer which flows beneath Yucca Mountain "theoretically, could supply drinking water for several hundred thousand people." We find that likelihood extremely improbable. (258)

2. The statement that, "It is also a potential source of drinking water for more distant communities and theoretically, could supply drinking water for several hundred thousand people," is in overstatement at best and requires speculation about the unknowable societal futures that are supposed to be assumed similar to those existing today. What is the basis for this statement and a similar statement made in the first paragraph on FR p.47002? The statement in the second

paragraph of FR p.47002, of "hundreds to thousands," is the more reasonable and believable. (583)

Response to Issue G:

EPA believes that the statement in question is not literally incorrect, since drinking water (at ~ 2 liters/day) alone can be supplied to more than hundreds of thousands of people by the perennial yield (4,000 acre-feet/yr, or 4.9 x 10^9 liters) in the basin containing the repository. Nonetheless, EPA recognizes that the total water demands for a population will include higher per capita water use than 2 liters/day, so the number of people that could be supported by the water resources south of the repository is significantly lower than what a simple drinking water only calculation would indicate. Still, the available ground water could satisfy the total demand of a substantial number of persons (a significantly larger population than is now served), making the resource a valuable one for current and future uses.

Issue H: The point of compliance for ground water should be within the Yucca Mountain site, or at the site boundary.

1. The point of compliance should be within or at the site boundary. (5, 483)

2. The point of compliance should be at the site boundary. (24, 179, 208, 292, 336, 430, 451)

3. Given mounting evidence that groundwater has risen and flooded the repository level in the geologic past, EPA should factor in the potential that there may be a large volume of highly contaminated water at the edge of the repository footprint. Moreover, given the uncertainty about future climate, the current availability of water near Yucca Mountain should not constrain the standard setting process for groundwater protection. The MCLs should be determined at the downgradient edge of the repository footprint and not several kilometers away. Modeling considerations based on low water volume available today should not be a principal factor in decision-making on the withdrawal point for the water. (293)

4. I think that the boundary should be closer rather than farther away from the repository. And in fact, I would question whether it should be at the door of the repository versus the 3 miles or 5 kilometers. (135)

Response to Issue H:

EPA rejected suggestions that it locate the point of compliance either within (comments 5, 483), or at the site boundary (comments 24, 135, 179, 208, 292, 293, 336, 430, 451) because we believe that this approach is unnecessarily conservative. In reaching this decision, we acknowledge the approach employed in our generally applicable standard for the land disposal of spent nuclear fuel, high-level, and TRU waste at 40 CFR part 191. The controlled area concept established in 40 CFR part 191 links a 5 km distance from the repository footprint (the area in which the waste is disposed) to a limit on the size of the controlled area (100 km^2). Within the controlled area,

compliance calculations related to ground-water protection would not apply on the basis that the geology surrounding the waste within this controlled area comprises an essential part of the total disposal system. Locating the point of compliance within the site boundary or at the site boundary would reverse this long-standing concept of geological disposal. As a generally applicable standard, 40 CFR part 191 necessarily had to incorporate flexibility in defining where the rule applies. Note that in the 1980s, when 40 CFR part 191 was developed, DOE was considering a total of 9 candidate repository sites. For a generic standard, this combination of controlled area and approach to protecting ground water is appropriate. It is able to account for the wide variety of site configurations, engineered alternatives, and population characteristics that may be encountered. We are implementing 40 CFR part 191 in the ongoing certification process for WIPP TRU repository in New Mexico.

By contrast, 40 CFR part 197 is a site-specific public health standard mandated under a new authority, the Energy Policy Act of 1992. With the 1987 amendment of the Nuclear Waste Policy Act, the Yucca Mountain site has been under an intense site characterization effort. EPA has a significant amount of information regarding past, present, and planned population patterns, land use, engineered design, and the hydrogeological characteristics of the host rock. We also have the recommendations of the NAS Yucca Mountain panel, which advises the use of present day knowledge and cautious but reasonable assumptions to define who is protected (NAS Report, p. 100). Given the wealth of site-specific information related to ground-water flow and present and planned population patterns in the vicinity of the Yucca Mountain site, we have sought to develop a protective point of compliance related to the ground-water resources near Yucca Mountain. Our final selection reflects present knowledge and where necessary, cautious but reasonable assumptions, related to the use of ground-water resources at Yucca Mountain. Also, as explained above, we have adopted the concept of a controlled area for Yucca Mountain as an essential precondition to assessing compliance with the ground-water standards.

None of the information EPA has reviewed suggests it likely or reasonable that year-round residents will locate at or within the site boundary of the proposed repository. As discussed in Chapter 8 (Section 8.2.3.2) and Appendix IV of the BID, it would be extremely difficult to farm that close to Yucca Mountain, partly because of poor soil conditions and because extracting ground water at that location would be technically challenging and prohibitively expensive for an individual or small group. In addition, much of this area has rough terrain and soils not conducive to farming. Our understanding of projections of future land use do not indicate significant population growth much farther north of Lathrop Wells (see Appendix I, BID). Given present and planned population patterns and the extreme difficulty in accessing ground water at or within the site boundary, we think it unreasonable that a year-round resident will locate there. Therefore, we have not chosen a point of compliance at or within the site boundary for the site-specific standards at Yucca Mountain.

One comment (293) supported the point of compliance at the edge of the repository footprint based upon geological evidence that ground-water levels have risen and flooded the repository in the geologic past. Present understanding of the Yucca Mountain site does not support a flooded repository. In addition, the present climate regime and its effects on the Yucca Mountain

repository are expected to persist for most of the 10,000-year regulatory period. Finally, the selection of the compliance point for purposes of ground-water protection relies upon present knowledge and cautious but reasonable assumptions, as suggested by NAS. These points are addressed in more detail below.

The impact of climate change, including the possibility that the repository might be flooded by a rise in the ground water, was considered in the NAS Report (pp. 91-92). Accordingly, NAS concluded:

> "There is a reasonable data base from which to infer past changes in the water table at Yucca Mountain. Although past increases under wetter climates are evidenced, a water-table rise to the point that the repository would be flooded appears unlikely."

Although it does not appear that the repository would be flooded, variations in climate may still affect subsurface hydrology. The NAS noted that the subsurface location of the repository provides a natural "temporal filter" for climate change effects on hydrologic processes. This delay in unsaturated zone flux changes at the repository "is probably in the range of hundreds to thousands of years. The time required for saturated flow-system responses is probably even longer. For this reason...the effects of climate change on the deep hydrogeology can be assessed over much longer time scales" (NAS Report, p. 92).

In evaluating the impact of climate change on projected repository performance, DOE has developed three different cyclic climate regimes to describe conditions that exist at Yucca Mountain. Current conditions fall within a dry pattern and are expected to last between the next 5,000 and 10,000 years. Beyond that are "long term average" conditions, which are expected to persist for about 90,000 years, and "superpluvial" conditions, which are expected to persist for about 10,000 years. Precipitation rates for the latter two climate regimes are estimated at 2X and 3X, respectively, higher than current precipitation levels (see Chapter 3, DOE/VA, Docket A-95-12, Item V-A-5, and Chapter 7 of the BID, Docket A-95-12, Item V-B-1). Given the current understanding of the climate regime at Yucca Mountain and the delay in climate change effects on the repository (identified by NAS above) due to its depth below the surface, it would appear extremely unlikely that climate change would cause significant changes in the ground water quality or accessibility in the vicinity of the Yucca Mountain repository within the 10,000- year regulatory period. Further, should DOE select any design enhancements presently under consideration [such as a more robust containers and/or drip shields (see Section 2.1.4 of the DOE DEIS, Docket A-95-12, Item V-A-4)], expected releases from the repository may begin much later, perhaps beyond the regulatory period.

Finally, the intent of EPA's ground-water protection standard is to protect the ground-water resource near Yucca Mountain. The NAS advised using present knowledge and cautious but reasonable assumptions to describe the exposure scenarios to be used in performance assessment (NAS Report, p. 100). We believe it similarly appropriate to use present knowledge and cautious, but reasonable, assumptions in determining potential ground water usage. EPA has used this approach in defining where the ground-water resource might be accessed, considering such factors

as depth to ground water, present and potential access points for ground water usage, the types of activities supported by the ground water resource, and the characteristics of the local land and terrain as far as suitability for agricultural pursuits or residential development (see the responses to Issues H and I herein, and Section III.B.4.f of the preamble, "Where Will Compliance With the Ground Water Standards be Assessed?"). As explained above, when these factors are considered, we did not select the repository footprint as a point of compliance for the Yucca Mountain repository.

Issue I: Other alternatives for ground water point of compliance beyond the site boundary

1. The point of compliance should be at or less than 1 km from the site boundary. (442)

2. The point of compliance for ground water should be at 5 km (Alternative 1). (56, 84, 85, 308, 343, 498)

3. The point of compliance for ground water should be at 20 km (Alternative 2). (175, 565)

4. The point of compliance for ground water should be closer than 30 km. (85,137)

5. The point of compliance for ground water should be at 30 km (Alternative 3). (217, 640)

6. The point of compliance for ground water should be no closer than the RMEI (proposed at 20 km, corresponding to Alternative 2). (175, 238, 773)

7. None of the proposed points of compliance offers sufficient protection. (410)

8. 5 km is too close for ground water compliance, and 18 or 20 km are indistinguishable. (562)

9. The proposed alternatives for ground water compliance are not reflective of the resource. (599)

10. Technical Edit: Revise preamble to reflect available data regarding ground water flow from Yucca Mountain to the town of Amargosa Valley. (657)

Response to Issue I:

A number of comments suggested that EPA locate the point of compliance at varying distances from the repository footprint, ranging from less than 1 km to 30 km. One commenter suggested that the proposed alternative points of compliance are not reflective of the resource. One comment suggested that we revise the preamble to reflect available data regarding ground-water flow away from the repository. As discussed above, we chose to retain the concept of a controlled area, limited to no more than 300 km^2, while limiting its extent in any direction to 5 kilometers, except that in the direction of ground water migration, the controlled area may extend no farther than any point on a line described by 36 degrees, 40 minutes, 13.6661 seconds north latitude. This latter distance is roughly 18 km from the repository footprint.

One comment supported a compliance point less than 1 km from the site boundary (442). Numerous comments supported a compliance point at 5 km from the site boundary, partly as a matter of consistency with our generic standards at 40 CFR part 191 (Comments 56, 84, 308, 343, 498). As indicated above in the Response to Issue H, we acknowledge this approach and find it particularly well-suited for a generally applicable standard. The present rule, however, is mandated by EPA's new authority under the Energy Policy Act of 1992 and calls for a site-specific public health and safety standard for Yucca Mountain. According to Section 801(a)(1) of this Act, our standards are to be "based upon and consistent with" the findings and recommendations of the Yucca Mountain NAS panel. We have considerable site-specific information and the recommendations of the Yucca Mountain NAS panel, which advised using present knowledge and cautious but reasonable assumptions to define who is protected. None of the information we have reviewed suggests it likely or reasonable that year-round residents will locate at or within the site boundary of the proposed repository. We believe this is also true at a distance of 5 km from the site boundary. Placing the point of compliance at 5 km violates our requirement that assumptions on future states not be overly speculative. We believe that the point of compliance should reflect current land use, or reasonable projections of future land use, in terms of the volume of water used and its location. As discussed in Chapter 8 of the BID, it would be extremely difficult to farm that close to Yucca Mountain, partly because of poor soil conditions (Section 8.2.3.3 of BID) and because extracting ground water at that location would be technically challenging and prohibitively expensive for an individual or small group (Section 8.2.3.2 of BID). Our understanding of projections of future land use do not indicate significant population growth much farther north of Lathrop Wells (see Appendix I, BID), which is approximately 20 km distant, although there are plans for development between Lathrop Wells and the NTS boundary (Docket A-95-12, Items V-A-14, 15, 16, 19). Given present and planned population patterns and the extreme difficulty in accessing ground water at 5 km, we think it unreasonable that a year-round resident will locate there. Therefore, we have not chosen a point of compliance at points less than 5 km from the repository footprint for the site-specific standards at Yucca Mountain.

As one goes farther away from Yucca Mountain in the direction of ground water flow, it is easier to drill for ground water as the water table is closer to the ground surface. Additionally, the soil characteristics improve such that agricultural pursuits become more feasible and this is evidenced by the considerable agricultural activity in the Amargosa Valley some 30 km from Yucca Mountain, which was suggested as a compliance point by a few comments (217, 640). However, to select a distance of 30 km would ignore farming that occurs as close as 23 km (Chapter 8, BID). Also, much greater dilution of the affected ground water occurs at 30 km and existing uses of ground water closer than 30 km would not be adequately protected. For these reasons, EPA did not select 30 km as the compliance point for ground-water protection purposes.

Distances approximating 20 km appear more reasonable to consider. Two commenters recommended the 20 km distance (comments 175, 565) and two thought it should be no closer than the 20 km distance applicable to the RMEI (comments 238, 773). EPA has decided to require compliance with the ground-water and individual-protection standards at the same location, i.e., in the accessible environment where the highest concentration in the plume of contamination is located. This distance can be no farther south than the southern boundary of

NTS (about 18 km from the repository footprint). We believe that the RMEI could use the same ground-water resources for domestic and agricultural practices and hence be exposed to a greater number of exposure pathways. Since the RMEI may be exposed to a greater number of pathways, some of which may not be due to direct ingestion of ground water, the individual-protection standard will be used to judge the acceptability of the RMEI exposures.

According to Chapter 8 of the BID, no farming occurs closer than about 23 km south of the proposed repository footprint. There are approximately ten residents at 20 km and hundreds of persons at a distance of 30 km. Current projections of population growth indicate increases in the area of the 20 and 30 km distances. Although one comment (562) portrayed the 18 and 20 km distances as indistinguishable, we believe there are merits to limiting the maximum distance in the direction of ground-water flow to less than 20 km. We have adopted a controlled area, limited to 300 km^2, that may extend no farther in the direction of ground-water flow than the distance from the repository footprint to any point on a line described by 36 degrees, 40 minutes, 13.6661 seconds north latitude. The southwesternmost corner of the NTS and its southern boundary correspond to this latitude designation (Docket A-95-12, Item V-A-29), which is roughly 18 km from the repository footprint. It is expected that some population growth may occur north of the 20 km location, Lathrop Wells. This would be a small group of residents who could use ground water for domestic and some limited agricultural purposes. As shown in Appendix III of the BID, the same gravelly, sandy loam that supports agriculture between 20 and 30 km from Yucca Mountain also extends north of Lathrop Wells to the NTS boundary at 18 km. A distance of 18 km provides a degree of conservatism, as compared to a 20 km location, in that the expected concentrations of radionuclides in the representative volume of ground water would be slightly higher at 18 km. At distances closer than 18 km, the depth to the water table increases dramatically, as shown by Table 8-5 and Figure 8-9 in the BID. While it becomes more difficult to drill for water, soil conditions also become less favorable for agriculture. Also, access to NTS is restricted by the Federal government. We believe, based upon the site-specific information now available, and using cautious, but reasonable, assumptions, that a point on a line described by 36 degrees, 40 minutes, 13.6661 seconds north latitude would be the closest location for a small group of individuals to be accessing the ground-water resources near Yucca Mountain and is, therefore, protective of the ground-water resources reasonably anticipated in the vicinity of the Yucca Mountain repository. Again, DOE and NRC must determines where the highest concentrations of radionuclides in the accessible environment will occur, and assess compliance at that location. This is to assure that the compliance point for ground water is positioned to be certain that the analyses take into account the highest concentration in the accessible environment and will be cautiously, but reasonably, conservative in nature.

Finally, one comment (657) indicated that the description of the ground water system beneath the site was not accurate and should be revised to reflect information published in the DOE Viability Assessment document and supporting information. We have revised the preamble and the supporting Background Information Document to reflect the most current information available about the ground water flow system around the repository.

Section 7 Performance Assessment[1]

Comment Issues Page #

Issue A: Is EPA's requirement that NRC use the mean or median of the highest results for compliance determinations appropriate?

1. While EPA's reasoning is sound, the choice of mean or median is an implementation detail that should be left to NRC. (229, 236, 616)

2. I fear that by using the mean that an RMEI by an individual of the CG may be diluted by assuming a large population of lesser exposed RMEI's. NO don't use the mean. Do like is common in current EIS practice and prepare for the worst case exposures. (168)

3. The EPA should use an approach of specifying that the dose limit to the critical group limit should be the 99 percent upper confidence bound, based on those parameters that can be quantified. (288)

4. [R]eliance on the mean of the distribution of highest dose is not justified. The performance assessment must address the dose to the maximally exposed individual(s), including the conditions

[1] All acronyms are defined in Appendix B.

of age and physical conditions of the dose recipients. The doses to other members of the exposed population must also be incorporated into the standards. (370)

5. This appears to be a reasonable approach that has more basis in scientific precedent than the "expected dose" used by DOE. (386) Given the uncertainties inherent in performance assessment, compliance should be based on consideration of the full range of values. Either the mean or median of the distribution of the highest doses from various exposure scenarios should adequately address uncertainties associated with performance-assessment results, depending on the degree of skewness. (570)

6. The ICRP approach is to favor a presentation of the results as ranges of numbers or bounding estimates and to emphasize the inherent judgement necessary in evaluating whether there is compliance with the constraints in compliment to the compliance with technical managerial principles. (515)

7. DOE believes that using the mean or median is an acceptable and conservative measure... DOE believes that the uncertainties in performance assessment are best addressed by consideration of the full range of values during the licensing process. The implementing regulator should be allowed to decide, considering this full range, whether there is sufficient confidence that the mean or expected value meets the standard. (629)

8. We support EPA's choice of the mean of the distribution of the highest doses resulting from the performance assessment as the appropriate comparison with the all-pathways, individual-protection radiation standard. However, we consider that any confidence limits and uncertainties applied to this approach should be left to the NRC to determine through implementation of the EPA's standard. (777)

Response to Issue A:

EPA has specified a compliance measure we believe is reasonable but still conservative, i.e., the mean of the distribution of projected doses from DOE's performance assessments. We believe that specifying this compliance measure is necessary to provide the appropriate context for implementation of the standard. Supplying context for understanding the intent of the standard is necessary to constrain and direct the otherwise unbounded range of approaches to demonstrating compliance that could be justified in the absence of such context. For example, if only an exposure limit was specified in the standard, rather than the mean of a distribution of calculated dose assessments, it is possible that a small number of assessments could be used to demonstrate compliance. In such a case, the full range of relevant site conditions and processes would not be considered and the uncertainties in projecting long-term performance would not be captured by the analyses and the regulatory decision making. At the other extreme, without a defined performance measure, endless and exhaustive site characterization studies and analyses could be required, driven by a perceived need to identify the most extreme "worst-case" scenarios. We believe that a thorough assessment of repository performance expectations should examine the full range of reasonably foreseeable site conditions and relevant processes expected during the

regulatory time frame. In making quantitative estimates of repository performance, we believe that unrealistic or extreme situations or assumptions should not dominate estimates of expected performance. With these considerations in mind, we believe that specifying a performance measure is necessary to supply a requisite context for implementing the rule in the regulatory process as well as providing the applicant (DOE) a focus for its efforts to build the compliance arguments and supporting calculations.

EPA believes that a probabilistic approach to repository performance assessments would appropriately capture the range of anticipated site conditions and relevant features, events, and processes. Probabilistic analytical methods are well established in the repository performance assessment field [DEIS (DOE/EIS-0250D) and Viability Assessment (DOE/RW-0508), Docket A-95-12, Items V-A-4 and V-A-5)] and we believe they will be used to project repository performance over the long time frames involved to assess the range of variations in dose that can be expected. We have been reluctant to explicitly specify that a probabilistic approach must be used because such statements could be interpreted to bar the use of deterministic analyses in any sense, which is also not our intent. We recognize that deterministic analyses can be useful for carefully constructed bounding analyses and sensitivity studies and we do not intend to restrain such constructive applications. However, we do require that DOE demonstrate compliance with the individual-protection standard by means of performance assessment, and we have revised the definition of performance assessment to incorporate probabilistic considerations. In addition, by specifying the mean as the performance measure, we are unmistakably implying that a sufficiently large number of performance projections should be made for the repository to consider the full range of conditions and processes, and also are implying that a probabilistic approach should be used to give a relative weighting to the results of these assessments. Given a large number of performance projections, the mean of the distribution will less likely be overwhelmed by unlikely, extreme results.

In line with EPA's use of the term "reasonable expectation," the fundamental compliance measure consistent with a literal interpretation of this term would be the mean value of the distribution of calculated doses. As the only alternative for a compliance measure, the mean may be interpreted too restrictively, however. In actuality, some situations may result in very high dose estimates for situations that have low probabilities and simply averaging these "outliers" into the distribution of calculated dose estimates can bias the mean to perhaps unrealistically high levels. Although this is certainly a conservative approach, which is desirable, the effects can be overly conservative resulting in driving regulatory decision making on the basis of very low probability and potentially unrealistic situations. Another interpretation of the "expected" situation would involve using the median of the expected range of calculated values. The median (reflecting a value exceeded half of the time) may be more representative of actual conditions, since it is reasonable to expect that at least some of the variables involved in the performance calculations have skewed distributions and the resulting distributions for all the situations assessed would show a non-uniform distribution. If the parameter value distributions for those variables that strongly influence the repository performance are skewed, either toward higher or lower values, the median of the distribution of calculated doses could be either higher or lower than the arithmetic mean. Although we proposed using the higher of the mean or median, after further consideration we

believe that the mean alone will be an appropriate measure of compliance. We believe this approach is sufficiently conservative in that it leans toward giving greater weight to calculations that result in higher exposures, without being overly influenced by "worst-case" and possibly extreme low-probability situations.

Many comments supported the mean or median selection (229, 236, 386, 570, 616, 629, 777), particularly in consideration of the uncertainties involved in projecting repository performance (570, 629). As some comments stated explicitly, the full range of possible parameter values should be examined in repository performance assessments and in the licensing process (570, 629). EPA agrees with these comments for the reasons explained in the preceding text.

A number of commenters stated that while they agreed with the selection of performance measures, the choice should be left as an implementation detail for NRC (229, 236, 616, 777), while some comments (629, 777) stated that measures of confidence should be left to the implementing authority. With respect to whether this constitutes an implementation function that should be left to NRC, EPA believes that specifying the fundamental compliance measure is necessary as a means to supply the appropriate context for understanding the intent of the rule and for implementation guidance. We do not believe that setting the fundamental compliance measure intrudes on the implementation function. The primary task for the regulatory authority is to examine the performance case put forward by DOE to determine "how much is enough" in terms of the information and analyses presented, i.e., how will the regulatory authority determine when the performance case has been demonstrated with an acceptable level of confidence? We have proposed no specific measures in our standard for that judgement. We have not specified any confidence measures for such judgements or numerical analyses, neither have we prescribed analytical methods that must be used for performance assessments, quality assurance measures that must be applied, statistical measures that define the number or complexity of analyses that should be performed, nor have we proposed any assurance measures in addition to the numerical limits in the standard. We have specified only that the mean of the dose assessments must meet the exposure limit, without specifying any statistical measures for the level of confidence necessary for compliance, such as a 95 or 99% confidence level for the mean. We believe setting a confidence level is clearly an implementation function that should be left to NRC and we have made no requirements in the standard to foreclose NRC's flexibility in setting appropriate confidence measures. In the WIPP certification criteria, where we were also the implementing agency, we did set a confidence measure [§194. 55 (d) and (f)] in addition to the basic performance measure, as was our responsibility. In addition, for the WIPP certification standard we included implementation requirements, including analytical approaches [§194.55(b)] along with quality assurance requirements (§194.22), other assurance requirements (§194.41), requirements for modeling techniques and assumptions (§194.23 and 25), use of peer review and expert judgement (§194.26 and 27). These requirements go well beyond the simple statement of a compliance measure. We have not incorporated a similar level of detail in the Yucca Mountain standard because we believe we must specify only what is necessary to provide the appropriate context for NRC's implementation. We therefore disagree that this choice is an intrusion into the implementation responsibilities of NRC.

Some comments advocated alternative dose limits (168, 288), more specifically that "worst-case" or 99th percentile values of the calculated dose distribution should be used. As explained above EPA believes that the mean will reflect the effects of high dose situations sufficiently and we do not feel the alternatives proposed are compatible with our approach. As we have explained in the response to comments on our "reasonable expectation" approach, the intent of reasonable expectation is to fully understand and appreciate the inherent uncertainties involved in projecting repository performance to engage in regulatory decision making with a full understanding of all the uncertainties. We believe that under this approach, high dose situations will be identified and described, particularly their probabilities, and such situations will be carefully examined in the licensing process to determine their underlying assumptions so that decisions are not driven by unrealistic, or very low probability situations. We believe that the reasonable expectation approach, in combination with the performance measures we have specified and the necessary implementation by NRC, will assure that the full range of potential repository performance will be evaluated appropriately.

One comment (370) stated that the dose to the maximally exposed individual (further qualified by age and other physical conditions) should be the performance measure and that doses to other individuals should be incorporated into the standard. EPA believes our selection of dose receptor (the reasonably maximally exposed individual) is a conservative but reasonable approach consistent with our approach to regulatory decisions in general. In the standard we have specified that certain characteristics of the dose receptor should be based on characteristics of the current population (§197.21) so that the receptor is representative of the exposed population (which will weigh the extreme physical conditions in proportion to their actual occurrence in the population). We believe that postulating receptors with maximum "worst-case" characteristics is an arbitrary and fundamentally speculative approach that makes regulatory decision making difficult because the choices cannot be clearly justified, i.e., one speculative choice is no more defensible than another in terms of decision making. In this regard we are consistent with the position of NAS, which stated that it would be reasonable to "protect the vast majority of members of the public" rather than focusing on "the risks imposed on a very small number with unusual habits or sensitivities" (NAS Report, p. 51-52).

One comment described the ICRP approach as an alternative to EPA's selection of performance measures (515). We believe that the applicant's compliance case will document the full range of performance projections and consequent dose assessments consistent with the intent of the comment. As we have explained in our discussions of the "reasonable expectation" approach, the full range of uncertainties should be identified and taken into consideration in regulatory decision making. We believe our general approach and performance measures will provide the information and insight advocated by this comment.

EPA notes that for the WIPP certification, the compliance measure that we used for the individual protection standard was the higher of the mean or median of the calculated distributions of doses from releases [§194.55(f)]. We proposed the same performance measure as appropriate for the Yucca Mountain repository so that an equivalent measure would be applied in both geologic repository situations. We have reviewed information and assessments done for the Yucca

Mountain site [such as those in the DEIS (DOE/EIS-0250D) and Viability Assessment (DOE/RW-0508), Docket A-95-12, Items V-A-4 and V-A-5] and have not found evidence that uncertainties and technical difficulties in assessing performance for the site are dramatically greater than at the WIPP site – to the extent that a very different compliance measure is justified, although the respective sites have their unique differences and uncertainties. However, in our final rule we are specifying the mean alone as the basic compliance measure. Projecting repository performance at either site presents technical difficulties and uncertainties that require detailed site characterization studies and encourage the use of probabilistic approaches to dose assessments. In the BID for the WIPP rule (EPA 402-R-96-002, Docket A-95-12, Item V-A-23), the use of the mean as a conservative but reasonable measure of repository performance is discussed in detail. The WIPP BID contains a more statistically oriented discussion of compliance measures and confidence measures. The mean or median are both reasonably conservative measures because they are influenced by high exposure estimates found when analyzing the full range of site conditions and relevant processes, without being geared to exclusively reflect high-end results, as would be the case if a high-end percentile of the distribution were selected as the measure. As noted in the WIPP BID, the mean and median values of the distribution of calculated doses are the same if the distribution of calculated doses is symmetrically distributed around the mean value, but will differ if the input data used in the calculations shows a prominent skewness either to generally high or low values. Because it is possible to observe skewed parameter distributions, a non-uniform dose distribution is not unexpected. Nevertheless, we believe that use of the mean alone will adequately address these questions.

Issue B: Is EPA's limitation on low-probability features, events, and processes (proposed as §197.40) appropriate?

1. If our interpretation is correct, events with lower than one chance in 10,000 chance of occurring within 10,000 years means an annual occurrence rate of less than one in 100 million (10-8) per year. No rationale for this choice is presented. This is another implementation area that should be left to NRC. (328)

2. EPA should examine unplanned release scenarios of low probability to determine if the Yucca Mountain Repository should operate. (416) EPA should propose a "design standard" for the Yucca Mountain Repository. (414)

3. It is unclear: (1) Whether performance assessments for ground water protection (and human intrusion) exclude additional natural events and processes compared to that for the individual protection standard, and (2) What the extent of the additional exclusion is. DOE recommends that EPA clarify the exclusion of unlikely or very unlikely events and processes. (650)

4. We support EPA's position on allowing the exclusion of unlikely natural events from both the ground water and human-intrusion scenarios. (767)

5. DOE agrees with EPA's conclusion that the geologic record is best preserved in the relatively recent past. DOE believes that probabilities of processes and events for the 10,000 year period of

compliance should be calculated based on this record because this record is likely to be representative of processes and events for the next 10,000 years. (649)

6. The Quaternary has long been accepted as the appropriate period in the geologic record to use and requires no further action from EPA. (572)

Response to Issue B:

Comment 328 asks for an explanation of the probability cut-off EPA proposed in §197.40 of the standard (§197.36 of the final rule) as it relates to framing performance assessment scenarios for projecting repository releases. The purpose of a performance assessment is to evaluate the performance of the repository under expected conditions, within reasonable variations (please see additional discussions in this document and the preamble to the final standard concerning our "reasonable expectation" approach and performance measures for pertinent information related to this question also). This means that extremely unlikely or speculative features, events, and processes should not play a prominent role in the assessment. There is a certain amount of judgment involved in selecting a specific probability level below which features, events, and processes are considered so "unlikely" that they should not be evaluated. We see the level we selected as the threshold for these "very unlikely" features, events, and processes (a 1 in 10,000 chance of occurring within 10,000 years after disposal, sometimes represented as an annual probability of 10^{-8}) as providing sufficient room for many features, events, and processes that might be considered unlikely but could have a significant impact on the results of the assessment. It is not intended to represent the probability of an event occurring in any particular year (which, as the comment points out, would be vanishingly small), but must be viewed in the context of the probability of a feature, event, or process being active at the site during the next 10,000 years. This level also translates to a 1 in 100 (i.e., 1%) chance of occurrence over 1 million years, the length of time NAS identified as the period of geologic stability, so that DOE's projections beyond 10,000 years may include these less likely features, events, and processes. Nor should it be interpreted to mean that any feature, event, or process that has taken place at the site during the last hundred million years should be included in the repository performance assessments. The repository block tuffs are in the range of 11.4 - 15.2 million years old (BID, Chapter 7). Extending the time frame for examining site conditions back that far brings into consideration features, events, and processes associated with the original deposition of the repository host rocks and some of the surrounding rocks. The inclusion of such features, events, and processes are not likely to be repeated in the next 10,000 years unless convincing arguments can be made for the reoccurrence of the type of volcanic activity that created the repository tuff deposits initially. In contrast, studies of the volcanic history around the site area point to the occurrence of a different type of volcanic activity in the relatively recent geologic past, with some events occurring less than 10,000 years ago. This type of volcanism (basaltic volcanism, exemplified by the Lathrop Wells lava cone and other features in the repository area) appears to be the type that has some probability of occurring within the next ten thousand years (BID, Chapter 7).

Comments 649 and 572 expressed agreement with our assertion that the Quaternary Period is the appropriate portion of the geologic record to use in estimating probabilities for natural features,

events, and processes that may occur at the site over the next 10,000 years. EPA agrees with these comments for the reasons stated above and in the comments. The Quaternary Period contains the best preserved evidence of features, events, and processes that have taken place at the site thereby allowing the most reliable means of estimating their probabilities. It also covers the past glacial periods (in the Pleistocene) where precipitation rates would be higher than today, thereby offering a means of realistically estimating future changes in precipitation rates for use in repository performance assessments. Such variations in climatic and geologic conditions are required (§197.15) so that the repository performance projections will address possible variations in site conditions during the regulatory period (10,000 years) and beyond that time. Climatic changes over the very long-term [the one million year period of "geologic stability" described by NAS (NAS Report, pp. 6 and 91-2)] can produce significant changes in site conditions that would strongly affect repository performance projections by changing important performance factors from precipitation rates over Yucca Mountain to shifts in population downgradient from the repository, as noted in the NAS Report (pp. 91-92).

Comment 416 stated that EPA should examine low probability unplanned release scenarios to determine if the repository "should operate." This comment appears to be assuming that EPA is the regulatory authority with approval responsibilities for the repository. We are charged with framing the standard, but NRC is responsible for the final review and approval process for the repository, i.e., determining if it "should operate." In reviewing the data for site conditions (see Chapters 7 and 8 of the BID) and DOE's most recent assessments of the site's performance in the DEIS and DOE/VA (Docket A-95-12, Items V-A-4 and V-A-5), EPA did not find evidence that low probability features, events, and processes, that could have a potential to result in releases likely to exceed the standard, would be excluded from DOE's assessments of repository performance. For example, the potential for disruption of the repository by volcanic events will be considered since the probability estimates are above the cut-off limits in the standard (Viability Assessment, vol. 3). The effects of seismic activity and the potential for nuclear criticality, the other two important disruptive processes, are also being evaluated by DOE (Viability Assessment, vol. 3). In implementing our standards, NRC has the flexibility to consider features, events and processes with probabilities below our cut-off value (i.e., lower than 10^{-8} probability) if it deems them important to its decision making responsibilities, though not specifically in determining compliance with our standards. We believe our probability cut-off levels will not artificially eliminate important features, events, and processes from the repository assessment efforts and that the final determination of whether the repository should operate, as this comment states, is the responsibility of NRC.

A closely related comment (414) stated that EPA should establish a "design standard" for the repository. The EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository. The EnPA does not authorize or require us to promulgate a standard tied to a specific repository design. Therefore, we have not taken an approach that would establish requirements for design, or anticipated performance of specific aspects of the repository design. Moreover, a design standard is not practical for a number of reasons. Establishing overarching health-based requirements in the standard allows the repository developers flexibility in developing repository

designs that are capable of meeting the standard's requirements, and to optimize the designs as ongoing site characterization studies reveal more detail about the repository site's natural system. Allowing the repository design to be modified to increase confidence in its projected performance as site information becomes more reliable, up until the time the actual repository license application is submitted, is clearly a desirable approach. Establishing design requirements in advance in the standard seriously limits the flexibility to evolve the repository design to optimize its performance and the confidence that can be placed in performance projections. Prejudging the repository design (i.e., the various components of the engineered barrier system) and the containment and waste isolation functions of elements in the design is not a prudent course, since it could seriously limit design optimization efforts, misdirect attention from the overarching goal of health protection to potentially exposed individuals, and add considerable uncertainty in the licensing process by establishing performance standards that are not directly measures of health protection. In carrying out its implementation responsibilities, if NRC determines that requirements for specific aspects of the repository design are necessary, it can impose such requirements. We believe consideration of design requirements are implementation concerns more properly addressed by NRC (see also the response to comment 486 for a discussion of subsystem performance requirements).

Two comments dealt with the inclusion of unlikely and very unlikely features, events, and processes from the performance assessments to be done for the human intrusion and ground-water protection standards (650 and 767). Comment 650 asked for clarification on the inclusion or exclusion of unlikely features, events, and processes in the ground-water protection and human intrusion standards. Unlikely natural features, events, and processes are excluded from the human intrusion assessment [§197.26(f) and §197.36]. The stylized intrusion scenario is intended to test the repository performance by an assumed by-passing of the engineered barrier and part of the natural barrier (the unsaturated zone below the repository). Combining unlikely features, events, and processes with the stylized intrusion scenario is not reasonable from two perspectives. As discussed in the NAS Report (Chapter 4), the intent of the analysis is to test repository performance under expected conditions, with the hope that the repository will be "resilient" to a limited human intrusion event. EPA agrees with this recommendation, as discussed elsewhere in this document and in the preamble. The inclusion of unlikely features, events, and processes would be counter to that intention of testing the expected "resilience" of the repository, and therefore we have not included in the standard requirements to do so in the performance assessments. NAS also concluded in its report that there was no scientific way to make supportable predictions for the probability of human intrusion to breach the repository barriers. In the light of this conclusion, NAS recommended that an intrusion be assumed to occur and be assessed (NAS Report, Chapter 4). As some comments on human intrusion pointed out (see comment responses on human intrusion in Section 5 of this document), drilling for water from the top of Yucca Mountain rather than in the adjacent valleys is very unlikely and we agree that the actual probability of that event is very low. If we were to combine additional unlikely features, events, and processes with the stylized intrusion scenario (which in reality has a low probability although difficult to define reliably), we would in reality be requiring compliance be met for very unlikely situations (the probability of such situations would be the product of the low probability for the drilling event itself multiplied by the low probability of the added unlikely features, events,

and processes). Such a position is inconsistent with our position on the probability limits for features, events, and processes to be included in repository assessments for the individual protection standard (§197.36).

Regarding the use of low probability unplanned release scenarios, relying on the worst conceivable event without regard to probability would be neither economically nor technically justifiable. In addition, EPA's role is not to "determine if the repository should operate," but to establish a standard that protects human health and the environment in the Yucca Mountain region. The NRC's role is to approve or disapprove the license application. As part of that determination, NRC will evaluate compliance with the EPA standard. The NRC's licensing of nuclear facilities typically requires analysis of accident or "off-normal" events to ensure that the facility's design basis is appropriately identified. The NRC may take into account lower probability events in the broad context of licensing, but not for determining compliance with the EPA standard.

The human intrusion and ground-water standards should apply the same restriction on low-probability ("unlikely") features, events, and processes. EPA has left it to NRC to define the level of probability that constitutes an "unlikely" feature, event, or process. The human intrusion standard assumes that a single borehole penetrates the repository. No probability has been assigned to such an event, which is consistent with the NAS recommendation.

Issue C: Is EPA's requirement for repository performance projections for periods beyond 10,000 years appropriate?

1. Requiring projections for 10,000 and 100,000 years could be confusing to the public and the licensing authority. How should long-term projections be evaluated if they are well above the 10,000 year standard? (473)

2. Even 10,000 year projections involve methodologies that become more difficult to prove with increasing time. (272) Requiring projections beyond 10,000 years invites calculations of increasingly greater uncertainty. (567)

3. A better approach would be to require periodic updates of the performance assessment using better data. This would serve as a check of the original assumptions and increase confidence in the understanding of repository conditions. (557)

4. If EPA is not going to extend the compliance period beyond 10,000 years, there needs to be technically feasible backup licensing criteria that addresses the longer-term waste isolation characteristics of the proposed site after the engineered barriers fail. (486)

5. The text in the preamble (page 46993) should be changed to state that "NRC is not required" to use additional analysis in determining compliance with proposed 197.20. NRC should not be constrained from using post-10K year calculations if it deems such use appropriate. (593)

6. DOE agrees on the statements for the use of the 10K and 100 K performance assessments. (646) If the post-10,000 year assessments are to be used for regulatory insight, it is appropriate, but this should be left up to NRC to consider what weight should be given to such speculation, and EPA should make no requirement. (236)

7. Given that the proposed EPA standard requires that the performance of the disposal system be examined after 10,000 years if the peak dose is calculated to occur then, there may be little practical difference between the TYMS report's recommendations and the proposed EPA standards. The major issue is that EPA provides no guidance on how analyses should be done for the period of geologic stability beyond 10,000 years and gives no indication of how the results should be used in judging acceptability. (398)

Response to Issue C:

This issue relates directly to Question 16 in the preamble in the proposed standard. Although EPA asked for comment on the appropriate use of projections after the regulatory time period, the thinking on this issue depends to a significant extent on our decision to set the regulatory time period at 10,000 years. We have addressed comments specifically on the 10,000 year regulatory period in more detail in Section 3 of this document. Reflecting the discussion of our basis for the 10,000 years regulatory time frame, we concur on the comments (272, 567) that calculations into far distant time frames (like 100,000 years or more into the future) entail greater amounts of uncertainty as the time frame stretches outward. Recognizing these inherent uncertainties, we believe, however, that there is a useful purpose for requiring that long-term assessments be made. Using the 10,000 years time line as a measure for regulatory decision making about compliance is largely a policy-based decision, so that the time limit is not left to subjective debates over the exact time frame appropriate for any particular site (as a function of site-specific conditions like ground water travel time estimates). The projections of releases from the repository are also a function of the engineered barrier design [for the Yucca Mountain repository this is largely concerned with the waste package design and the use of drip shields (Chapter 7 of the BID)]. The repository design can be changed at any time until a license application for the repository is submitted, and therefore basing a regulatory limit on the expected performance of a specific design feature is not appropriate since it would be predicated on an assumed design and not on more fundamental considerations relating more directly to health protection, i.e., the degree of confidence that can be placed on long-term performance projections.

From a purely scientific perspective, there is no basis for assuming that performance calculations up to the 10,000 year point are inherently reliable whereas projections beyond that date are not. Therefore, EPA believes that the performance projections should be continued well beyond the 10,000 year period to examine the projected performance of the disposal system at the extremes of our confidence in these assessments. Since the confidence that can be placed in performance projections does not change between year 10,000 and 10,001 of the performance analyses, it appears prudent to extend the analyses into a longer time frame for the purpose of getting a more comprehensive picture of the site's anticipated performance. In requiring these long-term projections, we are asking whether, based on our understanding of the natural and engineered

barriers, a dramatic deterioration of the disposal system performance is to be expected, and if so when should it be expected. By extending repository performance projections into very long time frames, on the order of hundreds of thousands of years, the assessments should examine whether the total waste isolation system changes in a gradual manner or can degrade abruptly resulting in dramatic releases.

The NAS recommends that performance assessments be carried out to the time of estimated peak dose (NAS Report, p. 55), and EPA has incorporated this recommendation into the standard (§197.35). We note that DOE has performed assessments over a time frame of one million years (Viability Assessment, DOE/RW-0508, Docket A-95-12, Item V-A-5) – the time period that NAS estimates the geologic regime at the site is "geologically stable" – and we would expect that assessments over this time frame could be performed to support the licensing case to be presented by DOE. In addition, the newest repository design proposed by DOE, called EDA II (see Chapter 7 of the BID), features a very highly corrosion resistant waste package complemented by a drip shield to result in resistance to breaching from corrosion processes for tens of thousands of years (Yucca Mountain Economic Impact Analysis, Docket A-95-12, Item V-B-2). To assess the behavior of this design, performance assessments would have to be conducted on time frames of hundreds of thousands of years to assess potential releases from anticipated degradation processes.

Several comments (236, 398, 473, 593) focused specifically on the use of these post-10,000 year projections in the licensing process. One comment (593) states that EPA is inappropriately limiting NRC by stating that it "is not to use the additional analyses in determining compliance with proposed §197.20." This comment suggests that NRC should be permitted to use the post-10,000 year analyses in assessing compliance with the 10,000 year individual-protection standard if it believes such use to be appropriate. Other comments (473, 398) object that we have not provided sufficient guidance on the evaluation or use of these projections for licensing purposes. Still another comment (486) argues that the EPA standard must include additional licensing criteria to completely address the hazardous lifetime of the radionuclides beyond the 10,000 year regulatory period.

Specifically with respect to comments 236, 398, 473 and 593, the question of how to treat the performance projections in a licensing process, where a compliance decision has to be made, involves some additional considerations beyond just simply getting a more comprehensive picture of anticipated performance. As mentioned previously, the characteristics of the disposal site will change over long time periods in response to the natural processes active at the site, like seismicity in the area around Yucca Mountain that can affect ground water flow and structural integrity of the repository, or climatic variations that will affect the hydrologic setting at the site. The effects of these changes may be to improve performance of the repository, decrease performance, or the net effect of the changes might leave the performance essentially the same as that anticipated from current conditions. Different performance scenarios can be proposed with little concrete evidence favoring one over the other, and consequently, scientific consensus in a licensing process could be difficult to impossible to achieve. EPA has used language in the standard that establishes the requirement that very long-term performance projections be made for

the repository, and that they be reported in documents that will be included in the licensing process, and will be available for public review and comment (in the EIS that must accompany the license application). However, we have not specified how or whether the regulatory authority should use the information for licensing decision making. We anticipate that if these very long-range performance projections indicate that repository performance would degrade dramatically 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). EPA has 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 believe 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. As a result, while the post-10,000 year projections will not be used specifically to determine compliance with the 10,000 year individual-protection standard, they will constitute part of the full record available in the much broader context of facility licensing.

Another comment (557) suggests that requiring periodic updates of the performance assessment using more recent data would be more as a check on the original assumptions for the repository assessments. This approach is somewhat similar to that taken for WIPP, where DOE is required to demonstrate continued compliance every five years. As stated in NRC's proposed regulations (10 CFR part 63), the license application submitted in 2002 must be updated a number of times until the time when the application is made to amend the license to permit permanent closure of the repository. At these times the performance projections for the repository would presumably be re-evaluated using additional information and analyses made with newly obtained data (see proposed 10 CFR 63.22, 63.24, 63.33, 63.45, 63.51). In this way the performance projections will be re-evaluated over the period when the repository is constructed, wastes are emplaced and the repository is actively monitored prior to closure. It will be up to NRC to define the specifics of these periodic license amendments including the necessary updates of technical analyses, and what will constitute a satisfactory update. We believe the decisions of when and how to re-evaluate DOE's repository performance assessments within the execution of the licensing process is an implementation question that should be decided by NRC and therefore we must disagree with the suggestion that we establish within our standard explicit requirements for periodic updating of the repository performance projections. EPA believes that the standards we are establishing must be met for satisfactory compliance, but the process through which compliance is demonstrated is the responsibility of the implementing authority.

Comment 486 expresses the need for licensing criteria that address the longer-term waste isolation characteristics of the site after the engineered barrier system is assumed to have failed in its containment function. The criteria apparently being advocated are essentially subsystem performance criteria that would be applied as performance expectations for the natural barrier system. EPA notes that subsystem performance objectives, similar in intent to what the comment

proposed, are part of NRC's existing regulation for geologic disposal (10 CFR part 60). However, NAS did not recommend that subsystem performance requirements should be a part of our standard, and in commenting on NRC's 10 CFR part 60 it urged caution over the use of subsystem performance requirements. The NAS believes that subsystem requirements could lead to "suboptimal repository design" (NAS Report, p. 125). EPA believes that a total systems approach for assessing repository performance is the appropriate means to determine compliance with our standard and we agree with the NAS caution. We believe that subsystem requirements could serve as assurance measures to complement the total system limits contained in our standard; however, assurance measures are the responsibility of NRC to impose as part of its implementation responsibilities. We believe the question of subsystem performance requirements should be addressed by NRC in developing its implementing regulations for Yucca Mountain.

Issue D: Is it appropriate to require a consideration of changes in climate, geologic and hydrologic conditions over time in repository performance assessments?

1. It is appropriate to consider climate changes. Climate changes are very possible and exposure scenarios would change significantly.(15)

2. Seismic activity can cause changes in ground water pathways and the area is seismically active, and some recent events have occurred on faults previously considered inactive. (58, 106)

3. It is reasonable to vary natural conditions within reasonable bounds. (648)

4. We can be certain that there will be changes in climate, which may make the biosphere more temperate than today's dry regime. (164, 380) Such changes and conditions have been observed over the past 10,000 years and should be assumed to happen again. (366) Statements cited from the NAS report concerning future climate states being "Glacial states" are either too strong or not correct, and recent research by Ku, et. al. (1998) indicates that the majority of past climate in the Great Basin was not spent in the pluvial state. (581)

Response to Issue D:

Comments favored consideration of potential future variations in climatic and geologic conditions within reasonable bounds. Making projections of repository behavior over time periods of thousands of years involves addressing the subject of changing climatic and geologic conditions, since these conditions determine the geologic setting for the site over the regulatory time period and must be used in assessing how the repository's waste containment and isolation capabilities will perform. There are uncertainties in how these conditions will change over the long-term and some degree of speculation is inherent in estimating their potential variation. The NAS considered this subject and recommended that the effects of natural processes such as climate change, seismic and volcanic events could be reasonably bounded in performance assessments of the site (NAS Report, p. 9). EPA agrees with NAS, and we have required that the assessments used to project repository performance include the effects of these processes on the performance projections. In §197.36 of the final rule, we have given a probability limit for features, events,

and processes, or sequences of features, events, and processes, that would have to be included in the performance evaluations. This limit is intended to bound the range of the features, events, and processes to be included in order to eliminate highly speculative effects.

Most of the concern over potential climatic changes centered on the possibility that the region surrounding Yucca Mountain might become significantly cooler and wetter than it is today. Such a climate is generally considered less desirable for a geologic repository than a warm and dry environment because more water would be available to infiltrate the repository. One comment (380) suggests that DOE can bound the uncertainties to some extent by modeling a "hypothetical biosphere" that would provide more variation than assuming current conditions with "some constrained climate variation." Another comment (581) suggests that predictions of wetter future climates based on previous climate conditions may be incorrect since some recent research indicates past climates were not dominated by wetter conditions. The responsibility for projecting the bounds of future climatic variations and defending the projections in the licensing process belongs to DOE. EPA believes that it has addressed this situation by stating that DOE "must vary" climatic, geologic, and hydrologic assumptions to incorporate "reasonable scientific predictions" of changes over 10,000 years (§197.15). This assessment should also account for potential seismic activity. DOE's assessments of the Yucca Mountain repository performance in the DEIS and DOE/VA (Docket A-95-12, Items V-A-4 and V-A-5) have in fact considered a wide range of ground-water infiltration rates corresponding to a wetter climate.

Issue E: Is it appropriate to select and keep constant today's biosphere characteristics for assessing public health effects?

1. Changes in demographics, life styles, and technology observed historically make the assumption of fixed present conditions troubling. (31) Nevada has undergone extensive population increases that could affect water supplies if these continue in the future, as seems likely. (122, 132)

2. The possible increase in population density in areas adjacent to YM should be considered in framing biosphere characteristics. (71) The critical group cannot be defined independently from the biosphere - you need to assume either current site-specific attributes or a more stylized approach based on general characteristics. (511)

3. Equally troubling is the apparent inconsistency that exists between the way EPA treats the uncertainties of future human activities and those associated with future climatic and geologic conditions. Confronted with the uncertainties of future human activities in the area around Yucca Mountain, EPA concludes that current activities constitute the least arbitrary scenario to use in calculating potential human exposures. . . . When confronted with a similar type of uncertainty in the modeling of climatic and geologic conditions, EPA concludes that at a certain point the uncertainties of the analysis eliminate its credibility altogether, but fails to state why 10,000 years is the magic dividing line. (439)

4. Prohibiting consideration of societal changes for such long time periods leads to too strict a standard. (477)

5. It is reasonable to hold today's attributes constant. (463) Speculative data on future biosphere characteristics should be avoided. (569) It is speculative to suggest the manner of possible changes. (262, 648) The NAS recommended this position. (330)

6. Holding biosphere attributes constant will protect others (besides the RMEI, which should be defined as an age-weighted subsistence farmer at the edge of the repository) except for an intruder or people active at Franklin Lake Playa (a largely evaporative surface discharge area) in the far distant future. (381)

7. Can't use today's biosphere and cannot predict future populations near the site. (547)

8. NRC agrees in principle to fixing the biosphere characteristics, but specifying the biosphere characteristics is an NRC implementation function. (612)

Response to Issue E:

Comments on this subject varied widely. Some felt that the dynamic population growth in the Las Vegas and surrounding areas would argue against the use of static current conditions as unrealistic.
In support, another comment (547) asserted that future populations around the site could not be predicted and the current biosphere conditions could not be assumed for the standard. Some comments stated that technological advancements and societal changes should be given consideration, otherwise the standard would be too strict. Other comments reflected a belief that fixing biosphere parameters to current conditions is a reasonable approach in principle.

The NAS examined the question of the scientific feasibility of predicting future land uses, living styles and population distributions and concluded that there is no scientific basis to support making projections over the long-term (NAS Report, p. 10). Over a regulatory time period of 10,000 years, projections of population distribution and lifestyles are highly speculative and the use of such speculative assumptions for dose assessment calculations would only result in unresolvable controversy when used to make compliance decisions. EPA agrees with the NAS conclusion and has adopted a position in this standard that avoids speculative assumptions about biosphere changes over the compliance period by assuming current conditions – which can be defined reliably. While it is certain the current conditions will change, EPA cannot, with certainty, project the nature or character of such changes. Thus, any speculative assumptions concerning possible future states differing from current conditions would be arbitrary.

By developing a standard that assumes current biosphere conditions, including such aspects as current risk estimates for health effects due to radiation exposure, EPA has built in a measure of conservatism. If our standard provides an acceptable level of protection today, it is not unreasonable to presume that future advances in medical diagnosis and treatment would reduce

risks to future, potentially exposed individuals. One comment (477) suggests exactly this possibility to support a position that our standard is too strict. However, this comment then goes on to say, "Should, on the other hand, there be an intervening collapse of historical and technological continuity, doses of 15 mrem would be irrelevantly unimportant compared to the disasters that caused the collapse." The fact that the comment offers no basis for supporting either of these extremes precisely illustrates the dilemma in forecasting the characteristics of future societies and the necessity to assume present conditions will persist into the future. Any other assumption leads to potentially unlimited speculative scenarios to be put forward in a licensing process.

Another comment (439) accuses EPA of inconsistency in its handling of uncertainties related to human activities and those related to climatic and geologic conditions. In the commenter's view, holding human activity at current levels is reasonable, if not optimal. According to this comment, however, EPA provides insufficient justification for stating that at a certain point, uncertainties in climatic and geologic changes overwhelm the ability to project exposures. More specifically, the comment objects to our drawing a "magic dividing line" at 10,000 years, rather than requiring compliance to the time of peak dose. It is suggested that we should define a bounding scenario for these uncertainties, and that this approach would be consistent with the NAS recommendation.

In assessing the NAS recommendation, EPA has considered a number of factors, including policy issues not specifically addressed by NAS. NAS acknowledged that policy considerations would play a legitimate role in setting a compliance period. Section 3 of this document describes in detail the reasoning we have used to set the regulatory time frame at 10,000 years. Contrary to the comment's assertion, we do not assign a "magic" significance to 10,000 years. Performance calculations are not highly reliable slightly before the 10,000 year period and become highly unreliable slightly thereafter. Clearly we believe that calculations beyond 10,000 years have value, or we would not have required DOE to include them in its EIS. However, we also believe that over the very long time periods leading up to the peak dose and beyond, 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).

One comment from NRC (612) agreed in principle with fixing biosphere characteristics, but stated that it should be NRC's responsibility. EPA has not in fact fixed all of the relevant characteristics of the biosphere in the standard, leaving considerable flexibility to DOE and NRC to more specifically define the biosphere characteristics that will control dose assessment evaluations. We have affirmed the principle that present day conditions should be assumed, and we have only specified a few details of the biosphere in the context of defining the RMEI in sufficient detail that biosphere analyses resulting in dose projections can be framed as we intend in the standard. EPA has specified a fixed amount of drinking water consumption and that lifestyle and dietary patterns for the RMEI be representative of the population in the Amargosa Valley area (see Section 4 of

this document for more discussion of the RMEI). The details on these aspects are left to DOE and NRC to define during the licensing process. We feel that we have been only specific enough to provide a context for implementation. The task of precisely defining all the relevant biosphere characteristics for use in dose assessments and assessing dose estimates as a function of the variation in these characteristics is, we believe, the responsibility of DOE and NRC to resolve in the licensing process.

Issue F: Is it appropriate to expect that the risks to future generations should be no greater than risks judged acceptable today?

1. Risks should be limited to what is acceptable today. (225) The risks should be communicated to future generations. (170) This idea is embodied in the Nuclear Waste Policy Act. (268) Radiological criteria should be considered as indicators of health detriment rather than measurements. (517) Expected risk calculations should recognize that technological advances will in reality lower future risks. (527) Risk estimates should be re-assessable on a scale of 50-300 yrs. (571) It makes sense to rely on dose/risk projections only for compliance periods within which the assumptions used to generate those projections remain reasonable. (618)

2. Compliance assessments will incorporate conservatisms to compensate for uncertainties, which will effectively lower actual risks to future populations. (231)

3. Yes. However, future risk research will suggests that the effects of low-dose radiation are lower than current projections.(331)

4. Dose conversion factors used to calculate risk to future generations should reflect the greater uncertainty in dose projections compared to calculating current risk. (388) Dose/risk conversion factors may be different than what's assumed today. (468)

5. Has a war scenario or sabotage/terrorism been considered? (539)

6. Inter-generational equity is appropriate, but the individual protection standard is adequate protection. (654)

7. The standard should be the most conservative considering the great uncertainties over 10,000 years, not less conservative because of the uncertainty. (10)

8. The "risks judged acceptable today" by the nuclear power industry and the DOE and EPA are not acceptable to many of those who are, even currently, at the highest risk. (372)

Response to Issue F:

Comments on the issue of potential risk to future generations considered a wide range of relevant factors. Some comments stressed the need to communicate risks to future generations and periodically reassess the risks, while others stress that risks will in reality decrease in the future as a result of technological advancement or increased understanding of radiation effects. Some comments recommended that risk/dose conversion factors consider uncertainty and may be different in the future. Other comments expressed opinions that the assessments performed contained enough compensating factors to make up for uncertainties, that inter-generational equity is appropriate, that risks should be limited to today's acceptable levels, and that the individual protection standard was sufficient for the purpose. One comment inquired about whether war, sabotage or terrorism scenarios had been considered.

The intent behind geologic disposal of nuclear wastes is that the generation enjoying the benefits of nuclear energy should bear the burden of disposal efforts for the waste products and not pass on the liabilities to future generations. Consistent with this aim, EPA believes it is appropriate that the risks from nuclear waste disposal should not be greater to future generations than the level considered acceptable today. Section 111 (a)(7) of the NWPA embodies this principle: "...appropriate precautions must be taken to ensure that such waste and spent fuel do not adversely affect the public health and safety and the environment for this and future generations," (NWPA, Pub. L. No. 97-425, 96 U.S. Stat. 2201, 2207). This position is also a foundation of international practice, as stated by the IAEA in its "Principles of Radioactive Waste Management" (IAEA Safety Series No. 111-F, 1995, Docket A-95-12, Item V-A-10).

EPA's standard addresses this issue by requiring the projected performance of the geologic repository to meet exposure limits considered acceptably low, for a period of at least 10,000 years. The 15 mrem/yr dose limit set in the generic standard for land disposal of the types of waste intended for the Yucca Mountain repository, in 40 CFR part 191, reflects a societal decision on acceptable risk, resulting from the public rulemaking process used to establish that standard (although, as comment 372 points out, "societal decisions" may not be to the liking of each individual member of that society). This limit was also used in the certification of the WIPP geologic disposal facility in New Mexico. EPA sees no reason to believe that the same level of protection, or alternatively stated, the same level of risk, should not be applied to the Yucca Mountain geologic repository. Through the public rulemaking process we are establishing an acceptable risk level for the Yucca Mountain repository performance requirements. This standard establishes the same level of protection as our previous rulemakings for deep geologic disposal – an individual exposure limit of 15 mrem/yr to the RMEI at the compliance point for a period of 10,000 years. Our final rule also includes standards to protect ground water resources downgradient from the repository from unacceptable contamination for the same time period. The standards will be implemented by the NRC through a licensing process in which DOE will have to demonstrate that the geologic disposal facility at Yucca Mountain will provide the performance necessary to comply with those standards.

In addition, the NAS recommendations on technical bases for the Yucca Mountain standard proposed an exposure level between 2 and 20 mrem/yr as the range of potentially acceptable exposures (NAS Report, p. 5). The exposure level EPA set in this standard falls within that range and is consistent with the existing regulations and the WIPP disposal facility application of the 40 CFR part 191 standard.

A theme frequently repeated in the NAS recommendations is that speculation about societal conditions, technological advancement, or human actions cannot be defended scientifically and therefore considerable caution is needed in making projections into the distant future. EPA assumes that if the disposal facility can demonstrate compliance with the level of confidence considered adequate today, future generations will also be protected. We believe that a 10,000 year regulatory compliance period is sufficiently long to assure inter-generational equity for the potential risks from a geologic repository (see other comment responses dealing with the regulatory time period in Section 3 of this document). Improvements in technology, particularly medical diagnosis and treatment, indicate that future risks should be lower than current risk estimates ("likely to reduce the consequences of exposure to radiation"). One comment (331) stated that further research will show that the risks of low-doses of radiation have been over-estimated. If this suggestion is eventually confirmed, our standard would still be protective, although perhaps more conservatively than currently thought.

Comments 388 and 468 expressed concern that uncertainties in long-term future dose projections should be reflected in the dose conversion factors used for performance assessments, and that these conversion factors may be different in the future than the values assumed today. Comment 618 cautioned that EPA's standard should be viewed as an indicator of repository performance, rather than having a specific correlation to expected health effects, because such correlations are unreliable after a few hundred years. Other comments reflected somewhat differing viewpoints on the effects of uncertainties (apart from dose conversion factors). Comment 231 suggested that future generations would actually be more protected than our standard requires because DOE would introduce considerable conservatism into its long-term projections to account for uncertainty. Comment 10 took the position that our individual-protection standard should be more stringent (i.e., lower) precisely because of the uncertainties involved in projecting long-term exposures. Consideration of uncertainties is an integral part of the decision that the site does or does not meet the compliance requirements, and it is the responsibility of the implementing authority to determine if the uncertainties have been adequately assessed. We have not specified the details of how the uncertainty assessments will be done, preferring rather to include a concept first put forward in our generic standard – the concept of reasonable expectation (see 40 CFR 191.15). Section 197.14 of our final rule also describes the intent of the reasonable expectation as recognizing that absolute proof, in the ordinary sense of the word, is not attainable for repository performance projections over the long time periods considered. Inherent in this approach is a burden on the implementing authority to consider the uncertainties inherent in the features, events, and processes involved. It is the responsibility of the implementing authority (in this case NRC) to develop the detailed requirements for examining the uncertainties involved in projecting repository performance. A more detailed discussion of reasonable expectation is located in Section 2 of this document.

Comment 571 suggested that the repository risk estimates be reassessed on a scale of 50-300 years, essentially saying that the compliance decision be reassessed periodically in some formalized way (analogous to DOE's WIPP certification, which must be re-evaluated every five years). Our standard puts forth the exposure limits and ground-water contamination limits considered acceptable; however, the mechanisms for making the final compliance decision and approving the disposal site for operation lie with the implementing authority (the NRC). Currently, DOE's plans for the operation of the repository indicate that it will be actively monitored for a period of about one hundred years after operations begin, at which time a license amendment would be filed with NRC to allow permanent closure of the repository. This long monitoring period would allow the risks from the projected repository performance to be reassessed at least once in the context of the licensing process before the repository is closed. Any decisions about future reassessments beyond that time would be an implementation decision that we would defer to NRC's discretion. We note that NRC has proposed a performance confirmation program to verify the data, assumptions, and analyses used to demonstrate compliance with our standard until permanent closure of the repository [proposed 10 CFR 63.102(m)].

Comment 539 asked if EPA had considered war, terrorism or sabotage scenarios in developing the protection requirements. In the context of making its recommendations, NAS concluded that there was no scientific basis for predicting the probability of deliberate intrusion into the repository for malicious purposes (NAS Report, p. 106). We agree with that opinion and have not considered these scenarios in developing the standards, which focus on the ability of the repository to isolate the waste from the environment (see also the comments on the human intrusion standard in Section 5 of this document).

On the question of communicating risks to future generations, the generic 40 CFR part 191 standard requires that institutional controls be required as an assurance measure to achieve that purpose. Institutional controls are of two types: active controls which require a deliberate dedication of resources to limit access to the repository site for a period of time, such as erecting and maintaining fences; and passive controls designed to convey the nature and risks of the repository contents to future generations, such as erecting monuments, establishing records in public archives, etc. EPA has not included requirements for these kinds of institutional controls because the text of our generic regulation states that these measures are not necessary if the implementing agency (NRC), includes them in its regulations. We anticipate that requirements for institutional controls will be incorporated into the implementing regulations developed by NRC for the Yucca Mountain repository (10 CFR part 63), as they are included in NRC's proposed rule. It then would become the responsibility of NRC to judge the effectiveness of DOE's proposed institutional controls for communicating the risks of the repository to future generations.

Issue G: The fragility of arid land should be considered in this standard.

1. I don't think – particularly for people in the east – that arid lands are wastelands that can well be sacrificed to this damaging or potentially damaging, if you prefer, utilization.. Arid lands are along with cold lands of the world, really the most fragile of all ecosystems. (37)

Response to Issue G:

The performance standards in this rule are not based on climate conditions. The limits are based on protective levels of radiation exposure and ground-water contamination that would be appropriate for geologic disposal in any climatic regime.

Issue H: Insufficient site characterization has been completed for Yucca Mountain.

1. We are still concerned about the lack of rigor that is currently being applied in the site characterization program for Yucca Mountain. The Yucca Mountain site is extremely complex geologically and hydrographically. There has been too much emphasis however placed on models and expert elicitation processes rather than the development of comprehensive information and data. (114)

Response to Issue H:

EPA agrees that Yucca Mountain is a very complex site. For this reason, we have included requirements and direction in the rule that deal with the questions of the features, events, and processes to be considered in assessing the site's projected performance (§197.15 and §197.36), and for the level of understanding necessary for presenting an acceptable demonstration of compliance in licensing, i.e., our explanation of the "reasonable expectation" term used in our standard (§197.14). It is the responsibility of DOE to characterize the site to a degree adequate to support the performance case presented in the license application to NRC. It is NRC's responsibility to evaluate DOE's performance case and the data base and understanding underlying it, including the uncertainty involved in characterizing the site and in projecting the performance of the site's natural and engineered barriers. The degree to which elicited information from experts and data collected in field studies are used in making performance projections for the site is an implementation issue that we believe is the responsibility of NRC to exercise in the course of its licensing efforts.

Issue I: Yucca Mountain is a geologically uncertain location for radioactive waste.

1. The cinder cones visible from the top of Yucca Mountain makes it clear that Yucca Mountain is indeed a geologically uncertain location for radioactive waste. (34)

2. This hill was not supposed to have water in it. It was one of the original criteria. Well, the guys who are working on the site characterization project found water in the hill. This was supposed to be a nice solid hill, no faults. They found faults. There seems to be a continual changing of the requirements of successful characterization to fit the hill. That doesn't sit well.

And this area is characterized as rarely having earthquakes. Well, we had a good one the other day. (65)

Response to Issue I:

EPA recognizes that uncertainties in projecting the site's performance are important components in evaluating the site's potential performance, and we have reflected this understanding by the requirements and direction given in Sections 197.15 and 197.36 of the standards. The standards require the assessment of features, events, and processes expected to be active and to have effects on the performance of the natural and engineered barriers during the regulatory period (§197.36). To identify potentially important features, events, and processes, the geologic record at the site is a prime source of information for determining the probabilities of relevant features, events, and processes, and potentially disruptive events such as the volcanic events and earthquakes mentioned in the comments. The potential for these features, events, and processes and their effects on waste containment and isolation are to be included in the performance projections used in the license application to demonstrate that the site will meet the requirements of the standards. The DOE is responsible for developing the information to support the performance assessments used in licensing, including the estimates of uncertainty in that information and its evaluation. The NRC is responsible for determining the acceptability of the information and assessments presented by DOE and for making the final decision on the site's compliance with the standards.

As explained in discussions on the rationales for the standards in the preamble to the rule and this comment response document, EPA's standards address the total system performance of the Yucca Mountain disposal system – not specific characteristics of the site such as seismicity or hydrology. The individual exposure and ground-water protection limits are not based on characteristics of the site. Our direction and responsibility for developing the Yucca Mountain standard is to establish protective standards for the Yucca Mountain disposal system in total. It is the responsibility of DOE to adequately characterize the site, develop an engineered barrier system for the site, and present a performance case for licensing. It is NRC's responsibility to evaluate the performance projections and their uncertainty, and make the final decision on compliance with the standards. The characteristics of the site mentioned in this comment will be part of the uncertainty considerations NRC will have to evaluate during licensing.

Issue J: Disagree with EPA that the corrosion rates of the canister components may be quantified with a higher degree of accuracy and precision. (289, 544, 582)

Response to Issue J:

These comments express disagreement with the conditional statement in the preamble to the proposed rule indicating that corrosion rates may be highly quantified. This statement was made in the context of discussions on the meaning of reasonable expectation and the framing of performance scenarios. The comments focus on the extrapolation of laboratory corrosion testing data for performance estimates of the waste container over the regulatory time frame. It was not EPA's intention to imply that there is no uncertainty in the extrapolation of laboratory-measured

corrosion rates to long time frames. We agree there is uncertainty in such extrapolations, but this was not the context of the statement in the preamble text. Rather, the context of the text was the comparison of data and assumptions used to construct and analyze performance scenarios. Some parameters, such as corrosion rates of metal components, would be derived from data bases of laboratory experiments, which can be conducted repeatedly and with a high degree of precision and accuracy for the system being measured, i.e., short-term corrosion rates under laboratory conditions. Other parameters used in repository performance assessments would be based on less easily obtained data, such as the rates of ground water flow into waste emplacement drifts. Water inflow data, in contrast to well-defined laboratory studies, are derived from measurements of other parameters that are uncertain, making the estimates of ground water seepage a function of the uncertainty in the measured parameters and models used to estimate it. The intent of the preamble discussion was to illustrate that the data used in performance assessments can have varying degrees of uncertainty inherent in them and that these uncertainties should be recognized and considered in the assessments, rather than omitted from the assessments or assumed to be at their most extreme values merely to simplify the analyses.

Comment 582 also mentioned that natural system behavior can be based on evidence in the geologic record as opposed to engineered barrier projections based on laboratory testing. The contrast illustrates an important point about uncertainty and repository performance projections. The geologic record provides evidence for the operation of features, events, and processes and their effects over very long time frames – tens, to hundreds of thousands, to millions of years. Extrapolating data from the geologic record to annual rates used in repository assessments involves the uncertainty of going from the long time frame to the small. The extrapolation of short-term laboratory data to the thousands to tens of thousands of years necessary for compliance assessments involves the reverse process; going from short times (months to years) to comparatively long time frames. Both extrapolations are inherently uncertain, and these uncertainties should be fully understood and evaluated, as we point out in our discussions on the reasonable expectation concept (see Section 2 of this document).

Issue K: It is not necessary for EPA to establish assurance requirements. (313, 605)

1. This is an implementation issue that should be left up to NRC. (248, 652)

2. Assurance requirements are more appropriate to implementation than standard setting and are already included in NRC's proposed Part 63 and DOE's proposed 963. (576)

Issue L: EPA's standard should include assurance requirements.

1. We support the use of qualitative *assurance requirements* to maximize confidence in the quantitative standards. We are also in favor of these to increase confidence in the performance of the repository. (349)

Response to Issues K through L:

In the preamble to our proposed standards (64 *FR* 46998), EPA requested comment on whether it is appropriate for EPA to establish assurance requirements in this final rule and if so, what those requirements should be. We recognize that, because of the highly extended regulatory time frame applicable to Yucca Mountain, it is desirable to consider qualitative elements that may reduce some of the uncertainties associated with projecting the effects from releases from radioactive wastes over long periods.

Our generally applicable standards for the disposal of SNF, HLW, and TRU wastes (40 CFR part 191, 58 *FR* 66402, December 20, 1993; 50 *FR* 38073 and 38078, September 19, 1985) require the consideration of assurance requirements. The assurance requirements in 40 CFR part 191, however, do not apply to facilities that NRC regulates, like Yucca Mountain. However, because the EnPA mandates that EPA set site-specific standards for Yucca Mountain, we believe that we have the authority to include assurance requirements in this rule. Based on the public comments on the proposal and the fact that NRC's proposed licensing criteria (see proposed 10 CFR 63.102, 63.111, and 63.113; 64 *FR* 8640, 8674-8677, February 22, 1999) contain requirements for multiple barriers, institutional controls, monitoring, and the retrievability of waste from Yucca Mountain, we believe that it is not necessary for us to include similar requirements in this rule. We encourage NRC to include the assurance requirements, or requirements similar to those in 40 CFR part 191, in its final licensing criteria for Yucca Mountain.

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Public Comments on Yucca Mountain Proposed Standards

Comment ID Number	EPA Docket Number*	Commenter
1-2	IV-F-1 D-1	Steven Kraft
3-16	D-2	Kevin Kamps
17-21	D-3	Brian O'Connell
22	D-4	Paul Farron
23-26	D-5	Charles Higley
27-38	D-6	Judith Johnsrud
39-50	IV-F-2 A-1	Sally Devlin
51-56	A-2	Steve Frishman
57-59	A-3	Judy Treichel
60-61	A-4	Lavonne Selbach
62-66	A-5	Ralph McCracken
67-72	A-6	Engelbrecht von Tiesenhausen
73-75	A-7	Bill Dewitt
76-86	A-8	Mal Murphy
87-93	A-9	Grant Hudow
94-95	A-10	Geoff Jennings
96-97	A-11	Ken Garey
98-102	IV-F-3 L-1	Dr. Jacob Paz
103-106	L-2	Judy Treichel
107-113	L-3	Ian Zabarte
114-123	L-4	Dennis Bechtel
124-130	L-5	Bob Loux
131-133	L-6	Andrew Remus

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Comment ID Number	EPA Docket Number*	Commenter
134-139	L-7	Rich Nielsen
140-141	L-8	Peter Cummings
142-146	L-9	John Hadder
147-155	IV-F-4 K-1	Kay Drey
156	K-2	Melissa Blakley
157	IV-D-1	Bruce Schmalz
158-175	IV-D-2	Frank Bergwall
176-181	IV-D-3	Public Citizen
182-183	IV-D-4	Wisconsin Electric
184	IV-D-5	D.E. Fields
185-186	IV-D-6	Bob Brister
187-188	IV-D-7	A.B. Curie
189-190	IV-D-8	Carolina Power and Light Company
191-199	IV-D-9	Nuclear Projects Office, Mineral County
200-203	IV-D-10	Virginia Power
204-205	IV-D-11	City of Las Vegas
206-209	IV-D-12	Committee to Bridge the Gap
210	IV-D-13	Heather Young
211-212	IV-D-14	Pacific Gas and Electric Company.
213-219	IV-D-15	Department of the Navy
220	IV-D-16	H.E. Gonzales

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Comment ID Number	EPA Docket Number*	Commenter
221-251	IV-D-17	Nuclear Energy Institute
252-272	IV-D-18	National Association of Regulatory Utility Commissioners
273-279	IV-D-19	Southern Nuclear Operating Company
280-297	IV-D-20	Institute for Energy and Environmental Research
298-299	IV-D-21	Tennessee Valley Authority
300-313	IV-D-22	Nye County Department of Natural Resources Federal Facilities
314-316	IV-D-23	Ely Shoshone Tribe
317	IV-D-24	U.S. Geological Survey
318-332	IV-D-25	American Nuclear Society
333-338	IV-D-26	Alliance for Nuclear Accountability
339-349	IV-D-27	Clark County Department of Comprehensive Planning
350	IV-D-28	Kevin Kamps
351-373	IV-D-29	Judith Johnsrud
374-390	IV-D-30	Nevada Office of the Governor
391-399	IV-D-31	The National Academies
400-403	IV-D-32	Northern States Power Company
404-407	IV-D-33	North American Water Office
408-411	IV-D-34	Gladys Schmitz, et. al
412	IV-D-35	L.D. Saint

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Comment ID Number	EPA Docket Number*	Commenter
622-753	IV-D-36	U.S. Department of Energy
413-418	IV-D-37	Jim Hardin Associates
419-422	IV-D-38	Health Physics Society
423-425	IV-D-39	Judith Saum
426-435	IV-D-40	Nuclear Information and Resource Service (NIRS)
436-446	IV-D-41	Natural Resources Defense Council
447-449	IV-D-42	Entergy
450-454	IV-D-43	Ruth Niswander
455-457	IV-D-44	League of Women Voters of Nevada
458-473	IV-D-45	Beverly Hartline
474-480	IV-D-46	David Bodansky
481-484	IV-D-47	NIRS-2
485	IV-D-48	Sally Devlin
486	IV-D-49	Mifflin and Associates
487-491	IV-D-50	Inyo County Board of Supervisors
492-495	IV-D-51	Florida Department of Health
496-504	IV-D-52	Churchill and Lander Counties, NV
505-506	IV-D-53	Nancy and Lee Louden
507-517	IV-D-54	International Commission on Radiological Protection

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Comment ID Number	EPA Docket Number*	Commenter
518-527	IV-D-55	Joint City/County Impact Alleviation Committee
528-529	IV-D-56	Eureka County
530-532	IV-D-57	Florida Power and Light Company
533-548	IV-D-58	Faun Shilleiala
549-552	IV-D-59	Duke Energy Corporation
553-589	IV-D-60	U.S. Geological Survey
590-591	IV-D-61	NIRS-3
754-757	IV-D-62	Elko Band Council
758-760	IV-D-63	Diana Cahall
761-779	IV-D-64	ComEd
780-783	IV-D-65	Shoshone-Paiute Tribes
784-786	IV-D-66	Timbisha Shoshone Tribes
787-795	IV-D-67	Washoe Tribe of Nevada and California
796-798	IV-D-68	National Association of Regulatory Utility Commissioners
593-621	II-D-92	Nuclear Regulatory Commission

* Commenters listed under docket numbers IV-F-1 through IV-F-4 testified at public hearings held in Washington, D.C., October 13, 1999 (D); Amargosa Valley, NV, October 19, 1999 (A); Las Vegas, NV, October 20, 1999 (L); and Kansas City, MO, October 27, 1999 (K).

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Appendix B
List of Acronyms and Abbreviations

AEA-Atomic Energy Act

ALARA-as low as reasonably achievable

BEIR-biological effects of ionizing radiation

BID-background information document

CAA-Clean Air Act

CED-committed effect of dose

CEDE-committed effective dose equivalent

CG-critical group

DEIS-Draft Environmental Impact Statement

DOE-U.S. Department of Energy

DOE/VA-DOE's Viability Assessment

EIA-Economic Impact Assessment

EIS-Environmental Impact Statement

EnPA-Energy Policy Act of 1992

EO-Executive Order

EPA-U.S. Environmental Protection Agency

FEPS-features, events and processes

GCD-greater confinement disposal

HLW-high-level radioactive waste

HWIR-hazardous waste identification rule

IAEA-International Atomic Energy Agency

ICRP-International Commission on Radiological Protection

IPS-individual protection standard

LET-linear energy transfer

LLW-low-level radioactive waste

LNT-linear-non threshold

MCL-maximum contaminant level

MCLG-maximum contaminant level goal

MTHM-metric tons of heavy metal

NAS-National Academy of Sciences

NCRP-National Council on Radiation Protection and Measurements

NEPA-National Environmental Policy Act

NESHAPs-National Emission Standards for Hazardous Air Pollutants

NID-negligible incremental dose

NIR-negligible incremental risk

NPRM-notice of proposed rulemaking

NRC-U.S. Nuclear Regulatory Commission

NRDC-Natural Resources Defense Council

NTS-Nevada Test Site

NWPA-Nuclear Waste Policy Act of 1982

NWPAA-Nuclear Waste Policy Amendments Act of 1987

OMB-Office of Management and Budget

OSTP-Office of Science and Technology Policy

RCRA-Resource Conservation and Recovery Act

RME-reasonable maximum exposure

RMEI-reasonably maximally exposed individual

SAB-Science Advisory Board

SDWA-Safe Drinking Water Act

SNF-spent nuclear fuel

TDS-total dissolved solids

TEDE-total effective dose equivalent

TRU-transuranic

TYMS-Technical Bases for Yucca Mountain Standards (The NAS report)

UIC-underground injection control

UNSCEAR-United Nations Scientific Committee on the Effects of Atomic Radiation

USDW-underground source of drinking water

WIPP LWA-Waste Isolation Pilot Plant Land Withdrawal Act of 1992

YMR-Yucca Mountain Repository

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