RESPONSE TO COMMENTS

Amendments to the Public Health and Environmental
Radiation Protection Standards for Yucca Mountain, Nevada

40 CFR Part 197
Final Rule

September 2008

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

Introduction

The Environmental Protection Agency (EPA) has promulgated amendments to its public health and safety standards for radioactive material stored or disposed of in the potential repository at Yucca Mountain, Nevada (40 CFR Part 197). Section 801 of the Energy Policy Act of 1992 [(EnPA, Public Law 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 No. EPA-HQ-OAR-2005-0083-0076).

"Public comments reproduced in this document were taken from submittals to Docket No. EPA-HQ-OAR-2005-0083 (in Regulations.gov) and records from public hearings. EPA is solely responsible for the identification and categorization of comments. While we have attempted to preserve original comments, in some cases, we may have combined or paraphrased comments. However, we have not revised or corrected any quoted comments for readability or other reasons. Also, in reproducing oral testimony from public hearings, EPA has relied upon the official transcript and has not changed any text. Where words appear to have been transcribed incorrectly, EPA has consulted the whole of the testimony to discern the intended meaning."

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 based upon the license application it submitted to NRC on June , 2008. The NRC will use its licensing regulations to determine whether DOE has demonstrated compliance with standards prior to issuing the necessary authorization and license 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 for disposal 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 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.

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 that has the potential to supply many people in the surrounding area.

Background

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, Public Law 97-425) formalized the current Federal program for the disposal of SNF and HLW by:

(1) directing EPA to set generally applicable environmental radiation protection standards based upon authority established under other laws;

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

(3). making DOE responsible for siting, building, and operating an underground geologic repository for the disposal of SNF and HLW.

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 (at the time) 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, Public Law 100-203) amended the NWPA by, among other actions, selecting Yucca Mountain, Nevada, as the only potential site that DOE should characterize for a long-term geologic repository. EPA issued the amended 40 CFR Part 191 disposal standards, which addressed the judicial remand, on December 20, 1993 (58 FR 66398).

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

The EnPA gave EPA new authority described in the first paragraph of this document, but continued the general Federal agency responsibilities laid out in the NWPA. Thus, NRC will issue implementing regulations for our amendments to the standards. The NRC then will determine whether DOE, based upon its license application, has complied with the standards and whether to issue a construction authorization and 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 June 2001, we issued the public health and safety radiation standards for Yucca Mountain, 40 CFR Part 197. The State of Nevada, the Natural Resources Defense Council (NRDC), and several other environmental and public interest groups challenged several aspects of our final standards in the Court of Appeals for District of Columbia Circuit on the grounds that they were insufficiently protective and had not been adequately justified. In July 2004, the U.S. Court of Appeals for the District of Columbia Circuit ruled that the 10,000-year compliance period was not consistent with the NAS recommendation "that the compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by long-term stability of the geologic environment (NAS Report p. 7). The amendments that are the subject of comments in this document are mainly in response to the Court ruling. In response to the Court's ruling, we proposed amendments to the standards in August 2005. We have finalized these amendments based, in part, upon the consideration of the public comments included in this document.

Response to Comments

We held a 90-day public comment period for the proposed amendments to 40 CFR Part 197 from August 22, 2005 through November 21, 2005. Overall, we received about 2550 sets of comments that amounted to about 3000 pages of comments and 1100 pages of attachments. The large majority of these were in mass mailings, so counting each of the mass mailing campaigns as one "submittal," there were about 300 individual submittals. In addition, we received comment during oral testimony in public hearings in Amargosa Valley, NV; Las Vegas, NV; and Washington, DC. Comments received on the proposal were categorized according to topics. 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. While we have attempted to preserve original comments, in some cases, we may have combined or paraphrased comments.

This document addresses comments received on the 2005 proposed amendments to the radiation protection standards for Yucca Mountain by summarizing the views expressed by commenters 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 21, 2005. However, these comments were still considered. We have addressed all substantive 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.

Copies of all comments submitted to EPA regarding the proposed certification decision can be found in the official docket, designated EPA-HQ-OAR-2005-0083, at www.regulations.gov. Each comment is identified by a unique number. Appendix A of this document correlates these identification numbers to the docket numbers and name(s) of the commenter. Appendix A also identifies the people who testified at the public hearings and the corresponding comment numbers. A list of acronyms and the terms they represent are in Appendix B.

The docket, EPA-HQ-OAR-2005-0083, is located in the Docket public reading room, which is located in the EPA Docket Center, Room 3334 (202-566-1742) in the EPA West Building, located at 1301 Constitution Ave., NW, Washington, D.C. The Docket is open to the public on all federal government work days from 8:30 a.m. to 4:30 p.m.. 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 Documents 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) or go to http://library.nevada.edu/about/hours.html.

You may also inspect the informational docket at the Public Library in Amargosa Valley, Nevada (phone 775-372-5340) or go to http://www.avnv.net/library.html. As of this date, the hours are M-W-F (9:00 a.m. – 5:00 p.m.) and Tuesday and Thursday (9:00 a.m. – 7:00 p.m.), and Saturday (9:00 a.m. – 1:00 p.m.).

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Docket Number	Commenter
0088	Gene Douglas
0089	Fred deSousa
0090	Stephen Hans
0091	Jeremiah (no other name)
0093	David Ottley
0094	Frank Albini
0095	K. Halac
0099	Nickolaus Leggett
0100	R.G. Dodge
0101	Manuel Bettencourt
0102	Bill Lawless
0103	Anonymous
0104	Alan Trunkey
0105	Faun Shillinglaw
0107	Alliance for Nuclear Accountability
0109	E. Spence
0110	R. Glenn Vawter
0111	Aviv Goldsmith
0112	K. Halac
0113	Faun Shillinglaw
0114	Louis H. Garner
0115	Melody Polson
0117	Robert Patterson-Rogers
0118	Tamara Downs-Schwei
0119	Nancy Ann Surma
0120	P. Christi
0121	Ann Collins
0122	Elizabeth Rogers
0123	Richard Lyons
0124	Shawn Wozniak
0125	Anonymous
0126	Bob Sutter (sample of mass mailing)
0127	John and Denise Madonna (sample of mass mailing)
0128	M. Lee
0129	Dennis F. Nester
0130	Ryan Kaplan
0131	Lou deBottari
0132	Unreadable (sample of mass mailing)

0133	Stephen Schrems
0134	Anonymous
0135	Anonymous
0136	Anonymous
0137	Art Hanson
0138	Deborah Hunter
0139	Ezequiel Orona
0140	Marisa Dobson
0141	W.D. and Namsuk Mindock
0142	Stacy A. Miller
0143	Albert G. Cohen
0144	Robert Lincoln
0145	Anonymous
0146	Franklin J. Harte
0147	Joseph P. Mahon
0148	Anonymous
0149	Richard Zuckerman
0150	Edward Mainland (sample of mass mailing)
0151	Rosalie Bertell
0152	Cheryl Erb
0153	Donna Detweiler
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0158	Thomas Baldino
0159	Michael Moats
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0161	Anonymous
0162	Michael L. Cook
0163	Tammy (no last name)
0164	Valerie Heinonen
0165	Dot Sulock
0166	Janet Greenwald, Citizens for Alternatives to Radioactive Dumping
0167	Susanne and Robert Vandenbosch
0168	Madonna Soctomah
0169	Nina Keller
0170	Ronald Kuhler
0171	Joy Reese
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0173	Frank Perna
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0175	Rene Vivo

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0179	Ravi Grover
0180	Anonymous
0181	S.J. Gordon
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0187	Anonymous
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0191	Deborah Baker
0192	Anonymous
0193	Daniel Walker, Californians for Safe, Clean, Efficient Nuclear Power
0194	Nadine Hudes
0195	Tony Guzman
0196	J.E. Holmgren
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0221	Jeff Odendahl
0222	Robert R. Loux, Executive Director, Agency for Nuclear

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0330	Steven P. Nesbit, Duke Power
0331	Judith H. Johnsrud, Radiation Committee, Sierra Club
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APPENDIX B
Acronyms and Abbreviations

BEIR	Biological Effects of Ionizing Radiation
BID	background information document
CED	committed effective dose
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOE/VA	DOE's Yucca Mountain Viability Assessment
EIS	Environmental Impact Statement
EnPA	Energy Policy Act of 1992
EPA	U.S. Environmental Protection Agency
FEIS	Final Environmental Impact Statement
FEPs	features, events, and processes
FR	Federal Register
GCD	greater confinement disposal
HLW	high-level radioactive waste
HSK	Swiss Federal Nuclear Safety Inspectorate
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
KASAM	Swedish National Council for Nuclear Waste
LLW	low-level radioactive waste
MCL	maximum contaminant level
mrem/yr	millirem per year
mSv/yr	millisievert per year
MTHM	metric tons of heavy metal
NAPA	National Academy of Public Administration
NAS	National Academy of Sciences
NCRP	National Council on Radiation Protection and Measurements
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NRDC	Natural Resources Defense Council
NTS	Nevada Test Site
NTTAA	National Technology Transfer and Advancement Act
NWPA	Nuclear Waste Policy Act of 1982
NWPAA	Nuclear Waste Policy Amendments Act of 1987
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
RMEI	reasonably maximally exposed individual
SSI	Swedish Radiation Protection Authority
SNF	spent nuclear fuel
SR	site recommendation
TRU	transuranic
TSPA	total system performance assessment

UK	United Kingdom
U.S.C.	United States Code
WIPP LWA	Waste Isolation Pilot Plant Land Withdrawal Act of 1992

Section 1 General Comments

ISSUE A: The post-10,000-year limit was written to be sure that Yucca Mountain can be licensed.

1. If the Mountain can't meet the standards, the EPA should not be changing the rules so the site can meet them. That is wrong. People there should not receive extra radiation. (Comment 0105-4)

2. If EPA wouldn't allow 350 mrem/yr in Superfund, I see no reason to allow it at Yucca Mt. just so NRC can license it. It is pretty obvious that there is no way you could use your initial standard of 15 mrem/yr. beyond 10,000 years, so you found another way to let NRC license the repository by changing the use of the average (or mean) and using the median instead….Someday in the far future, somebody is going to look back at your decision here and just sit and wonder why this was done. EPA will have to take the blame. I feel you are collapsing under political pressure here, because the nuclear industry is so strong. The only way new plants can be built is if the waste goes into a repository. But don't you see, what they see as the answer to the waste problem, is a green light to build new plants and create more radioactive waste. And how much more exposure will EPA allow?….You can say that all that is to be considered in this rulemaking is the new standard you propose – but the total picture of all the ramifications of this must be considered – for if this standard is accepted, it will allow the licensing of the repository – you know that. This is the turning point. Make this decision with all the gravity it deserves. (Comment 0113-8)

3. When EPA began to write its new rule for Yucca Mountain, the Agency was faced with a choice – to pass or fail the repository project. One option would have been to write a rule that would provide protection to the public and the environment, as is the Agency's charge. However, EPA chose to provide the means for the site to be approved and licensed and the repository to be built. Instead of joining the "save the dump" political effort, EPA must abandon this proposal and release a new draft for comment that provides real protection for public health and the environment for the dangerous lifetime of the waste. (Comment 0130-4, 0195-4, and 0257-1)

4. When EPA's proposed dose criterion at times beyond 10,000 years and the proposal to use the median, rather than the mean, to assess compliance with that dose criterion, are considered together, it is difficult not to conclude that EPA has developed a standard that is intended to ensure that the Yucca Mountain facility will comply with the standard, i.e., that EPA's proposed standards beyond 10,000 years were based in large part on projected doses beyond 10,000 years. Indeed, this conclusion seems almost inescapable when EPA's decision not to extend groundwater protection requirements in § 197.30 beyond 10,000 years, which is based on a weak argument with no technical merit, is considered . …there

is nothing inherently wrong with developing a standard for Yucca Mountain that is reasonably achievable. EPA has often taken this approach in developing other radiation standards including, for example, standards for releases from uranium fuel-cycle facilities (40 CFR Part 190), standards for management and disposal of uranium or thorium mill tailings (40 CFR Part 192), standards for radioactivity in drinking water (40 CFR Part 141), and standards for airborne emissions of radionuclides (40 CFR Part 61) . The uranium fuel-cycle and drinking water standards probably are the best examples, because they were based almost entirely on EPA's evaluations of what was reasonably achievable, rather than *a priori* judgments about acceptable exposures, doses, or health risks to the public … (Comment 0186-13)

5. What criteria was used for research and for what length of time & where was this done and how were these values selected to arrive at your numbers? (Comment 0198-2)

6. It's my opinion that the EPA's attempt to massage and change the standard is not an effort to protect the public but to give to the federal government what they want. (Comment 0209.4-1)

7. We believe that EPA has created a standard at the behest of and in collusion with the Department of Energy to fit DOE site-specific needs for licensing. (Comment 0209.6-6)

8. It's no coincidence that EPA's proposed standard for the proposed 10,000 years -- 10,000-year period allows radiation doses ten times higher than during the initial period at a level far beyond what EPA, in its previous rule-making, said, quote, No regulatory body will ever consider acceptable. The only possible reason for the use of the convoluted, bifurcated standard is EPA's commitment to promulgate a standard that will make DOE's life easier in the NRC licensing process.

When the Court vacated EPA's original Yucca Mountain rule in 2004 for, among other things, limiting the period of compliance for just 10,000 years. The simplest and most logical thing for EPA to do was to extend the same allowable dose for the first 10,000 years for the entire life of the repository. Yet EPA rejected that solution out of hand. Why? As these varied EPA representatives have themselves acknowledged in the meeting with Nevada officials earlier this year, to do that would disqualify Yucca Mountain. And EPA has been directed to assure that does not happen. Instead, EPA has produced a collusion with DOE, a standard that just coincidentally allows exposure slightly higher than DOE's most optimistic estimates of where the maximum releases for Yucca Mountain will be after 10,000 years. EPA has manufactured a standard tailored to fit the site, not to protect public health and safety.

EPA's proposed rules are unacceptable in all counts. It flaunted the intent of the Court, which was to ensure that Yucca Mountain be judged using credible science based on the maximum expected risk to the human health and safety. Instead, EPA is transparently and unethically acting to facilitate the Yucca Mountain licensing by literally stacking the deck with unprecedented, irresponsible breaks from established regulatory and ethical principles. In developing the proposed Yucca Mountain health and safety standards, EPA is turning the standard-setting process on its head. Instead of designing a regulation to protect the current and future generations by ensuring the proposed repository site is, in fact, capable of isolating the waste, EPA has worked hand in glove with DOE to design a standard with a single objective in mind: That it will not disqualify the site. (Comment 0209.7-5)

9. The EPA has obviously conformed the standard to meet the ability of the DOE to achieve them. The ploy is so transparent it's laughable. The watchdog has lost his bite. Indeed, he has lost his bark. (Comment 0209.12-3)

10. Many experts and scientists argued that the EPA could not realistically develop a plan that could ensure public safety past 10,000 years. Unfortunately, many underestimated the extreme measures the proponents of this protect would take to ensure that the scientifically flawed project continues. Instead of playing by the rules of the game, rules intended to protect public safety, the DOE and the EPA have decided to simply change the game.

In its most shockingly disturbing ruling yet, the EPA decided that it was scientifically reasonable to increase its radiation standard after 10,000 years from 15 millirems to 350 millirems. This means the EPA has determined that once the clock hits 10,000 and one day, it is completely reasonable for the radiation exposure to increase 23-fold. I and my fellow Nevadans emphatically disagree.

The EPA has an obligation to protect public safety today, tomorrow, and in a million years. It should not speculate that a standard which is not deemed safe today could miraculously become a safe standard in the future. This decision was not based on any measure of public safety and instead just continues to highlight the means the DOE will go to in order to ensure that the Yucca Mountain Project continues. This recent rule just reinforces the idea that when you don't like the rules, you change the game. (Comment 0209.15-1)

11. Neither EPA's 40 C.F.R. Part 197 rulemaking (published in 2001) nor its current, revised proposal are the product of its independent judgment about the health and safety of the citizens of the United States. Like its predecessor, the proposed rule reflects the wholesale adoption of standards pushed on EPA by DOE and its industry allies as representing merely the standards *that could be met* by a repository at Yucca, not the standards that would protect the public health and safety in fulfillment of EPA's statutory responsibilities. As a result, the current proposal is not the product of reasoned decisionmaking and does not constitute a public health-based standard, as required by the Energy Policy Act of 1992. (Comment 0226-7)

12. Changing the rules as you have apparently done by greatly increasing the dose limit does nothing but convince people that the dump site is bad and that the government is just playing games to make it seem like it is good. You can't with a straight face allow much higher doses and pretend that you are being protective and meeting your responsibilities. (Comment 262-1)

13. The Environmental Protection Agency has a difficult and vital role in our country delineated in its mission statement. It must turn away from political pressures inside and outside the administration to develop rules for protection based on our best understanding of the risks involved. While Citizen Alert would like to see more stringent standards, at the

very least, [15 mrem/yr and ground-water protection] should be upheld through the period of peak risk; otherwise, the integrity of the EPA will be undermined. How are we to know when the EPA is developing a sound scientifically protective standard or just bending to special interests. Relaxing the standard to accommodate greater uncertainties is not justifiable, and outside of the responsibility of the EPA. The preamble contends that since the results of performance assessment past 10,000 years are highly uncertain and that a higher allowed dose limit is necessary to satisfy a "reasonable expectation" of the goals of the standard. The REASONABLE EXPECTATION is that the EPA will act as an independent agency and advance protection standards that do just that, "...protect human health and the environment." It is not the role of the EPA to cater to the "needs" of the Dept. of Energy (DOE) to have a standard that will a priori allow Yucca Mountain to be licensed. (Comment 0268-11)

14. Citizen Alert sees this proposed rule as a collusion with the DOE and the NRC as well to write a standard that superficially complies with the Court of Appeals ruling, and tailored to be within the DOE's calculated expected doses. Thus, in effect, the Environmental Protection Agency is working on behalf of the DOE and nuclear industry, and abandoning its charge "...to protect human health and the environment." (Comment 0268-13)

15. EPA has cast sound science aside in favor of political expediency in the myopic pursuit of Yucca Mountain. (Comment 0293-1)

16. [C]ontrary to the original intent of the Nuclear Waste Policy Act, this project has been driven by commercial and political interests rather than sound science. Rather than abandon a site that has failed to meet even minimal public health and safety requirements, the Department of Energy (DOE) and other government agencies involved in the Yucca Mountain Project have repeatedly bent or changed rules and fabricated data to forge ahead with a project that is a grave threat to public health and the environment. The new public health and environmental radiation protection standards perpetuate gross violations of scientific, ethical and public health principles that consistently characterize the government's conduct with respect to the Yucca Mountain Project. (Comment 0301-1)

17. Rather than setting a stringent health-based standard that the Yucca Mountain site should meet to be licensed, the EPA appears to be creating a "two-tiered standard," which is intended to help get the repository approved and open for business. DOE has publicly estimated radiation doses of 250 millirem/year at 200,000 to 300,000 years in the future, so EPA now proposes a standard above that level. Such blatant disregard for scientific objectivity and public health is very disturbing. (Comment 0301-4)

18. As an affected resident, I found many of the arguments for the original 15 millirem standard to be flawed and misleading. If a site-specific standard was being created, site-specific needs of those other than the DOE should have been addressed. (Comment 0306-3)

19. According to the DOE's own estimates, the maximum dose from the Yucca Mountain site would be between 200 to 300 millirem per year several hundred thousand years from now. With this rule, the EPA appears to be pandering to current political interests that wish to see Yucca Mt. stuffed full of radionuclides no matter what the environmental cost, at the expense of future generations. (Comment 0306-12)
20. The EPA's original requirements for the final disposal of spent nuclear fuel and high-level nuclear waste, specified in 40 CFR Part 191, called for a deep geological repository which would contain the radioactive waste via geology alone. Since then the standards have been altered to compensate for various geologic weaknesses as have been found in the planned Yucca Mountain repository. The latest proposed rule change is just another example of dealing with Yucca Mountain's weaknesses by fudging the containment standards. The EPA should choose to back out of this dark hole and reset its course so as to extend the present radiation protection standards for 100 times the presently specified 10,000 year period for any and all future SNF and high-level nuclear waste repositories. (Comment 0309-6)

21. EPA has proposed a rule that will allow the site to be licensed when instead the Agency should be proposing standards that rely on the geology of the site. The federal government submits that the engineered barriers will never leak during the first 10,000 years, and the rest of the time the standards allow an unprecedented dose for which the models can demonstrate compliance. (Comment 0311.1-1)

22. EPA's proposal is a shoehorn designed to weaken the standards so that the geologically unsuitable site can still be licensed, rather than requiring the site to meet public health and environmental protection standards. If the Yucca Mountain site cannot meet basic, long-established public health and environmental protection standards, as it clearly cannot, then the dump should never be opened. DOE has publicly predicted doses of 200 to 300 mrem/year at 200,000 to 300,000 years after burial of the waste, so now EPA proposes weakening the standards just enough so that Yucca could still be licensed .
EPA's proposal represents raw politics, is antithetical to science-based public health and environmental protection, and would doom residents near Yucca to cancer and death at horribly high rates. All this, just so the nuclear establishment can maintain the illusion of a solution for the high-level radioactive waste dilemma, so that building new reactors and keeping the old ones running can be "justified." It must be pointed out that electricity is but the fleeting byproduct of nuclear reactors. The actual product is forever deadly radioactive waste. (Comment 0324-7)

23. The rush to open Yucca despite its fatal scientific flaws is all the more outrageous in that much of the motivation comes from the effort by the nuclear establishment in industry and government to maintain the illusion that the high-level radioactive waste dilemma is not only solvable, but solved. This effort is being pushed largely through pressure to avert lawsuits against DOE (and thus, American taxpayers) by the nuclear utilities for breach of contract (DOE failing to begin taking title to irradiated fuel by Jan. 31, 1998), but also through pressure to build the first new nuclear reactors in the U.S. in over 30 years. The federal government's attempts to live up to an impossible deadline, and the industry's desire for a public relations victory on the nuclear waste front, are poor excuses for dooming

future generations downstream from Yucca to horrendous rates of cancer and cancer death when the dump leaks massively at some point in the future. EPA should take no part in such ghoulish games, but should fulfill its congressional mandate to protect public health and the environment without bowing down to political or economic pressures. (Comments 0324-17 and 0324-32)

24. The EPA's decision to choose the median rather than the mean is flawed and appears to be based on the fact that Yucca would not meet a standard based on the mean. (Comment 0341-6)

25. Another major concern is that EPA's proposal is designed to weaken the standards so that Yucca Mountain, which is a geologically unsuitable site, can be licensed. (Comment 349-6)

26. We believe that the revised proposed standard for releases between 10,000 years and a million years was written to ensure that the Yucca Mountain site will meet the standard. It's not the first time in the Yucca Mountain nuclear waste repository program that the rules were made to fit the site, to ensure that it will not be disqualified from consideration. (Comments 0353-2 and 361-2)

27. I believe -- let me just put it more politely and say these numbers certainly raise a question as to whether they are coincident by appeal to natural radiation or whether they are a more transparent attempt to accommodate the industry in what I believe is the worst site that has been investigated in this country for a nuclear waste repository. (Comment 0368.3-9)

28. I really question the number that EPA has come up with a 350 millirem median and a two rem 95 percentile which is indicated by the data from the DOE in that these are the very numbers that would allow the DOE to license this repository according to the contractor calculations that have been public for quite a long time. (Comment 0368.3-10)

29. Unfortunately, EPA's second attempt at drafting a radiation standard …is yet another example of setting regulations to guarantee that the site will be licensed rather than setting health-based regulations that the site must meet in order to get licensed. (Comment 0368.6-1)

30. Instead of setting a new and very dangerous precedent for the storage of radioactive waste throughout the country in order to simply satisfy political pressures to license Yucca Mountain, the Environmental Protection Agency should fulfill its mission to protect human health and the environment. We ask you to withdraw the standard immediately and to propose a standard that is truly protective of public health and the environment for this generation and generations to come. (Comment 0368.7-4)

31. Instead these standards appear made to order. By setting a 350 millirem per year standard for dosages based on a median measure, the EPA is consciously providing a standard made to fit the limitation of the site. (Comment 0368.9-1)

32. In working to set a standard that would enable Yucca Mountain to be licensed, the EPA has abandoned its real priority. Contrary to EPA's assertion, the proposed standard will not protect public health for one million years. While the EPA may have set a standard in place for a million years, that standard is 14 to 23 times weaker than the accepted standard of protection. In fact, in establishing this new standard, the EPA has relied on questionable logic and science. … the uneven application of the concept of uncertainty suggests again that the EPA is less interested in protecting the public and more focused on licensing Yucca Mountain and that instead of a consistent logic being applied throughout, the EPA is more interested in bending the rules to fit their end goal.
(Comment 0368.10-1)

33. EPA's use of a 350 millirem per year median dose limit is thus a transparent attempt to keep Yucca licensable despite its clearly unsuitable geology. This median of 350 millirem per year results in doses of 2,000 millirem per year or two rem per year to the five percent of people most exposed downstream. EPA's proposal is a shoehorn designed to weaken the standards so that the geologically unsuitable site can still be licensed rather than requiring the site to meet public health and environmental protection standards.
(Comment 0368.13-3)

34. DOE expects Yucca Mountain to release 250 millirem of nuclear radiation every year, so EPA is lowering its safety standards so DOE can meet them. To simply change these to weaken public health standards so we can hastily approve Yucca Mountain as a nuclear waste repository is both dangerous and irresponsible. These standards are designed to protect the energy and nuclear industries at the expense of public health and safety.
(Comment 0368.14-2)

Response to Issue A:

As set forth in the Energy Policy Act of 1992 (EnPA, Public Law 102-486, 42 U.S.C. 10141 n. (1994)), the role of the Environmental Protection Agency (EPA) regarding Yucca Mountain is to develop public health and safety standards that are based upon and consistent with findings and recommendations of the National Academy of Sciences (NAS). The Agency believes the amendments we are finalizing in this rulemaking are consistent with the NAS recommendations and are protective of public health and the environment. The standards were developed based upon our re-examination of the findings and recommendations of the NAS, consideration of the guidance of the International Atomic Energy Agency, the Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD), the International Commission on Radiological Protection (ICRP), and review of international regulatory programs. The final dose standard of 1 mSv (100 mrem/yr) applicable for the period from 10,000 up to 1 million years is consistent with current national and international recommendations to protect public health. These recommendations provide a clear basis to conclude that this standard will also protect public health in the far future.

The standards were not developed based upon the performance assessment in the Department of Energy's (DOE's) license application for Yucca Mountain. Of course, we were aware of publicly available preliminary performance projections such as those in the final environmental impact statement (FEIS) for the Yucca Mountain disposal system, but as commenters have pointed out, those preliminary projections could change for use in the license application; and, as we have now seen in the license application, they did. However, we did not use either the FEIS or license application projections as a basis for the standards in any case. We did use a simplified performance assessment code, but it was not designed to make performance projections of the actual Yucca Mountain disposal system. Instead, as explained later in Section 6 of this document, we used it to address comments related to the relative effects of uncertainty on the projections of performance as time proceeded beyond 10,000 years (this study is in the docket as EPA-HQ-OAR-2005-0083-0386).

The requirement to set a peak dose standard within the period of geologic stability (on the order of 1 million years (NAS Report p. 9) is unprecedented in United States regulations. Therefore, one of the approaches we used was to look to the international community for guidance on a reasonable approach. Our selected approach for the period between 10,000 years and the time of peak dose out to 1 million years is consistent with most international recommendations and programs. In general, dose projections for these long periods are considered to become more qualitative as time goes on because of increasing uncertainty, i.e., they are looked at as more of an indicator of performance rather than a highly reliable forecast of performance. Many countries do not impose explicit dose limits for such periods, but, rather, require only qualitative evaluation of performance. In other cases, dose limits are specified but are treated as "targets" or "objectives," and strict compliance with the limit is not required. (Please see Section III.A.2 of the preamble to the final standards and Section 2 of this document for further discussion of this issue.)

Therefore, all of these considerations, together with international recommendations citing 1 mSv (100 mrem)/yr as a protective public health limit, led us to the chosen dose limit. The results of the Yucca Mountain Total System Performance Assessment were not a basis for the standard. In addition, we cannot anticipate whether the Nuclear Regulatory Commission (NRC) will issue a license even if it is eventually determined that DOE's performance assessment shows compliance with our standard.

As regards the Superfund criteria (Comment 0113-8), they either do not include or have a different perspective on factors relevant to Yucca Mountain, for example, the performance period and intent of the action. Comparing Superfund sites to the Yucca Mountain site is inappropriate because both the circumstances and the applicable statutory constructs are vastly different. Superfund addresses current contamination that could expose the public. EPA developed these standards specifically for the Yucca Mountain site and, by law, they cannot be applied to Superfund or any other sites.

Comments 0186-13, 0341-6, and 0368.9-1 indicate that the mean of the dose rate projections should be used rather than the median. We have reconsidered the decision in the proposed rule to use the median of projected doses and we agree with these comments. Therefore, we require that the mean of the projections be used for the entire compliance period. This issue is discussed more fully in Section 7 of this document.

There are also comments (0209.15-1 and 0368.10-1) that point out the difference in the proposed dose rate limits before and after 10,000 years and that our use of uncertainty implies that we are more interested in seeing the Yucca Mountain disposal system licensed than protecting the public (0301-4 and 0368.10-1). The difference in the pre-10,000 year and post-10,000 year dose-rate limits has now been reduced since we have responded to comments and lowered the annual limit after 10,000 years to 1 mSv (100 mrem)/yr - which has long been recognized internationally as a dose rate limit that is protective of public health. (Please see Section III.A.2. of the preamble to the final standards for further discussion) The NAS specifically recommended that EPA's dose rate limit apply at the time of peak risk (dose); we are implementing this recommendation by considering both the protection of human health and the environment and the ability of science and technology to project performance over 1 million years. Therefore, with the irreducible uncertainties in projections over this unprecedented regulatory period, we believe that a somewhat higher limit after 10,000 years, 1 mSv (100 mrem)/yr, is both protective and reasonable. The issue of the two-tiered standard is also discussed in Section 4 of this document.

In response to Comment 0309-6, 40 CFR Part 191 (the generic standards for spent nuclear fuel and high-level radioactive waste disposal) did not call for containment of radioactive waste via geology alone. In 1985, EPA defined "disposal system" as "any combination of engineered and natural barriers that isolated spent nuclear fuel or radioactive waste after disposal." This is not only in keeping with the Nuclear Waste Policy Act at 42 U.S.C. 10141(b)(1)(B), it demonstrates EPA's expectations that both manmade and geologic barriers would play a part in making a successful disposal system. To emphasize that point, EPA defined "barrier" as "any material or structure that prevents or substantially delays movement of water or radionuclides toward the accessible environment. For example, a barrier may be a geologic structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around waste, provided that the material or structure substantially delays movement of water or radionuclides.

Section 1 General Comments

Issue B: Opposed to the standards or the repository in general

1. This facility at Yucca Mountain is built on probable earthquake faults. Radioactive material should not be stored there in the first place. Money should be spent to solve the problem at the local site that has nuclear waste as the result of production of electricity or experimentation. There are 2.5 million people plus potentially sitting in harms way. Every effort must be taken to protect the residents of Nevada. We are not an uninhabited desert in which to dump dangerious mateirials. SOLVE THE PROBLEM ANOTHER WAY! I VOTE!! (Comment 0117-1)

2. I stand in solidarity with the people of Nevada in opposition to the Yucca Mountain Project. It is a desaster for earth and our country. I find the radiation standard is inadequate and that alone makes the who project unacceptable. Do the right thing for people and the earth - stop this project now. (Comment 0120-1)

3. I respectfully request that you revise your standards to truly protect the public health as regards the yucca mountain project - yucca mountains nevada. i stand united with navadans and with all caring and compassionate americans in making this request. (Comment 0121-1)

4. I am writing to oppose the Yucca Mountain Project. The standard that you envision for the consequent radiation is unacceptable. I urge you to revise your standards in order to protect public health. This plan is an injustice to the people of Nevada and any other people who, in the future, will suffer the results of unsafe burial of radioactive materials. (Comment 0122-1)

5. The EPA is committing a terrible injustice to not only Nevadans and the Native American people of Nevada, but ALL Americans. I stand united with Nevadans in opposition to the Yucca Mountain Project and the unacceptable radiation standard. I demand that you once again revise your standard to truly protect the public's health. (Comment 0124-1)

6. How can you allow a standard of a high cancer rate in the Yucca Mt. Region where there is a proposed high level nuclear waste dump planned? Not only is the area unsuitable, geologically and the land belongs to the Shoshone who don't want the dump, but it will endanger people along the waste transport routes in the US and increase the threat of terrorism. No. You would not want cancer. It is an awful thing. Please do not allow it. (Comments 0127-3 and 0172-1)

7. We don't want any more radiation. Tighten the waste regulations and stop building more nuclear plants. (Comment 0138-1)

8. Whatever it takes, stop so that people including children don't get cancer. (Comment 0152-1)

9. We urge that the current health and safety standards for radiation exposure be strengthened not weakened. (Comment 0164-7)

10. Please rescind your support for standards that would allow high cancer rates in the populations surrounding Yucca Mountain in the future. (Comment 0166-1)

11. Please stop the EPA's Carcinogenic Yucca Radiation Rule. (Comment 0168-1)

12. For humanity's sake please do not change the Irradiation standards of exposure to human beings...For whose benefit is this???? Do you want this level Of radiation in your and your families bodies? Noone will be immune to these generational effects. Listen To your consciences if such still exists.. (Comment 0171-1)

13. Withdraw this standard and propose a standard that is protective of public and environmental health. (Comment 0179-1)

14. Your cancer-causing Yucca Mountain radiation regulations are outrageous. No one deserves cancer, especially not children. (Comment 0184-1)

15. Finally, we urge you to personally attend the hearing so that you can hear and see the depth of Nevadan's opposition to a weak radiation standard that does not meet the National Academy of Sciences guidelines, thus needlessly exposing them to public health risks. Because of the enormity, time span and risk of the proposed project, any standard must err on the side of caution in order to guarantee the protection of public health and the environment for hundreds of thousands of years. (Comment 0205-1)

16. Looking at this document, it says, public health and environmental standard. And what we're hearing is a radiation standard of 350 millirem. And that's what we're being sold tonight, and your job, as the Environmental Protection Agency, should be that: To protect the environment and to listen to the champions of the environment that are here tonight and not to shove a new standard that's been invented down our throats. (Comment 0209.2-3)

17. I've been opposed to this issue since Yucca Mountain was talked about. My children were small at the time, and we had no say in it. It went forward despite many, many, many, people not wanting it. So I've lost faith and trust in the process and in the people that are trying to make these changes and push Yucca Mountain through. (Comment 0209.4-3)

18. The Nevada Department of Justice, in close partnership with the Nevada Agency for Nuclear Projects, has been at the forefront of Nevada's 20-plus-year struggle to stop development of the proposed high-level nuclear waste down at Yucca Mountain. And we will, as the State, be submitting formal extensive comments on this rule. The proposed Yucca Mountain high-level nuclear waste repository presents great health and safety risks to Nevadans and is wholly unacceptable to Nevada's leadership. (Comment 0209.6-1)

19. EPA's revised proposal will advertise it's the most rigorous rule ever because it seeks to extend health and safety regulations out one million years. Is actually an unprecedented example of obstination, federal agency collusion, and morally bankrupt standard setting. (Comment 0209.7-2)

20. I'm strictly against Yucca Mountain. I live approximately 45 miles away, and I don't think it's good. I don't like the low-level waste that we have coming through Pahrump, Nevada, and I think it's dangerous. (Comment 0211.6-2)

21. Rather than propose a rule that is in keeping with the recommendations of the NAS, EPA has on two occasions now, put forward radiation standards which fail to offer sufficient levels of protection, and that fall far short of the requirement under the law that they be based upon the work of the National Academy of Sciences. (Comment 0271-1)

22. Please withdraw the proposed standard and set a responsible limit. Do not plan to leave a mess which will only cost more to cleanup in the future. (Comment 0274-2)

23. In reactor communities, the NRC has licensed onsite high-level radioactive waste facilities and employed the term “temporary” which evidently does not have a definition in the NRC’s dictionary. A4NR does not support the opening of the Yucca storage site with its suspicious science (ex. Geology), and its inadequately tested barriers. (Comment 0294-1)

24. EPA's proposed standard is inconsistent with the recommendations of the National Academy of Sciences (as required by the Energy Policy Act of 1993) and the July 9, 2004 ruling of the U.S. Circuit Court of Appeals for the District of Columbia. The proposed rule violates and contradicts EPA's historical approach to public health and environmental protection in which standards were progressively toughened. In addition, the proposal sets a disturbing and dangerous precedent for future regulation of radiological and hazardous materials. (Comment 0309-1)

25. I conclude that EPA has no alternative but to withdraw the proposed rule and reissue a new draft standard that abandons the arbitrary and scientifically unjustified radiation exposure limits; that continues strict groundwater protection requirements through the period of maximum exposure; that eliminates statistical gerrymandering through the use of median vs. mean calculations; that removes inappropriate and illegal intrusions into the NRC regulatory arena; and that returns to EPA's historical approach to radiation and environmental protection. (Comment 0309-2)

26. Please! No! Do not weaken the radiation regulations for Yucca Mts. People before greed. (Comment 0332-1)

27. Yucca Mtn. is an integral part of the U.S.A. – Do we desecrate even any spot of our land we now hold dear? (Comment 0333-1)

28. I object to the new radiation standard for Yucca Mountain. Please don’t endanger our lives. (Comment 0335-1)

29. I object to the new standards fro the Yucca Mountain. It will endanger many lives. (Comment 0337-1)

30. I strongly object to the weakening of the radiation regulation for Yucca Mountain. (Comment 0339-1)

31. Those who are elected to make decisions for the good of our people and country need to consider better radiation standards for the Yucca Mountains. It will endanger many lives. (Comment 0343-1)

32. I object to the new radiation standard for Yucca Mountain. It will endanger many lives. (Comment 0344-1)

33. I object to the new radiation standards for Yucca Mountain. It will endanger many lives. (Comment 0347-1)

34. I do not think that Yucca Mountain is a safe storage facility for nuclear waste. Nor do I think the methods of transportation are safe enough get the waste there. (Comment 0366-1)

35. We find this proposal, … to be totally unacceptable to protect public health and safety. And that is indeed EPA's mission or so we wish to believe. … I should hope that EPA in its reconsideration of this unacceptable rule will be begin to take into account the problems of the future. (Comment 0368.4-2)

36. I strongly OPPOSE the EPA’s revised radiation protection standard for Yucca Mountain. This proposal does not come close to protecting public health and does meet comply with federal law. (Comment 0371-1)

Response to Issue B:

The commenters generally object to EPA’s proposed standards, the dose rate levels they see as insufficiently protective, or the Yucca Mountain project. As discussed in greater detail in the preamble to the final rule, and in Section 2 of this document, EPA has, after considering a variety of factors including public comment on the proposed rule, established the public health and safety standard at Yucca Mountain applicable after 10,000 years as 1 mSv (100 mrem)/yr. This post-10,000-year standard protects the public health and safety and is appropriate given all the relevant factors considered by the Agency when projecting exposures very far into the future. In addition, by applying over the entire period of geologic stability beyond 10,000 years (up to 1 million years), it will capture the peak dose during that period. By doing so, our final rule is consistent with the NAS recommendation to have a standard with compliance measured “at the time of peak risk, whenever it occurs within the limits imposed by the long-term stability of the geologic environment, which is on the order of one million years.” (NAS Report p. 2) See the discussion of geologic stability in Section 10 of this document.

Relative to the comments regarding transportation, the Agency has not issued standards for the transportation of the waste to Yucca Mountain since it was not given the authority under the Energy Policy Act of 1992 to do so. It is the responsibility of the Department of Transportation and the Nuclear Regulatory Commission to regulate that transportation.

Section 1 General Comments

Issue C: Use of the standards as a precedent for other sites

1. There is a big reason not to set a standard of 350 mrem per yr. It will be used as a precedent for other regulations. My State of Wisconsin is high on the "hit list" for a second repository in granite in the Wolf River baolith and then, will we need a 3rd repository or what? Are you thinking of the future use of your standard?? This is not a site-specific standard for Yucca Mt. when you use allowable "natural" doses elsewhere in the U.S. for your measurements. (Comment 0113-9)

2. We are on the brink of final decisionmaking now. And your decision will be used by the rest of the world as a reference for their repositories. (Comment 0113-11)

3. These proposed regulations allowing 350 millirem per year radiation doses are completely unacceptable and must not be allowed to set a precedent to be applied at other radioactively contaminated sites across the country because they represent a large-scale weakening of environmental and public health protection standards. (Comments 0126-2, 0127-2, 0130-3, 0133-5, 0135-5, 0137-5, 0144-4, 0146-5, 0147-5, 0148-5, 0150-4, 0159-5, 0163-5, 0164-4, 0175-4, 0177-4, 0182-3, 0189-3, 0190-4, 0302-20, 0310-4, and 0324-2)

4. This proposed rule may establish a dangerous precedent as it is inconsistent with internationally accepted radiation protection standards and could seriously impact locations around the country with radioactive contamination. (Comments 0132-3, 0149-1, and 0195-3)

5. The new EPA standard for the second period, 10,000 to one million years, is worse, as it could set a new precedent for the world. No other organization has suggested setting any environmental protection standard beyond 10,000 years. We simply have no historical record upon which to base this kind of policy, no international body of radiation protection scientists nor nuclear engineers participated in the establishment of this precedent-setting standard. This precedent should not be set without major international participation, careful science policy studies and much discussion. (Comment 0209.9-4)

6. This proposed standard will set a terrible precedent because it is contrary to internationally-effected radiation protection standards and lowers the bar on radiation protection at other contaminated sites across the country. I find little comfort in the fact that you're not just putting Nevadans in harm's way. (Comment 0209.13-4)

7. The EPA proposed standard is not only unacceptable for Yucca Mountain, but also unacceptable for any other potential geologic repository site. The EPA proposed rule would likely set a dangerous precedent that would apply to any other site or sites that might be considered if Yucca Mountain is found unacceptable. In the event that Yucca Mountain should be licensed and constructed under the EPA proposed rule, a dangerous and unacceptable precedent would apply to any other sites that might be considered for a second or subsequent repository. We believe that the 15 millirem per year maximum

exposure threshold, coupled with the 4 millirem groundwater protection standard, would provide a safe and equitable standard for Yucca Mountain and for any other site or sites which might be considered for repository development. As residents of Wisconsin, we are concerned that the EPA proposed rule might set a precedent for future licensing of repository candidate sites in granite. DOE seriously studied potential candidate sites in Eastern and Midwestern granite formations, including many formations in Wisconsin, between 1976 and 1986. EPA must assess the potential implications of the proposed rule for other geologic repository sites before taking any final action in this docket. (Comment 0275-3)

8. If approved, the new EPA standards for Yucca, which drastically relax current regulatory standards for radiation protection, would have consequences far beyond the Yucca Mountain Repository. The proposed rule would also set a dangerous precedent for relaxation of all radiation protection standards at DOE sites everywhere. (Comment 0301-10)

9. The EPA proposed standard is not only unacceptable for Yucca Mountain, but also unacceptable for any other potential geologic repository site. The EPA proposed rule would likely set a dangerous precedent that would apply to any other site or sites that might be considered if Yucca Mountain is found unacceptable. In the event that Yucca Mountain should be licensed and constructed under the EPA proposed rule, a dangerous and unacceptable precedent would apply to any other sites that might be considered for a second or subsequent repository. There are several credible scenarios under which DOE might consider other repository sites in addition to Yucca Mountain, or in place of Yucca Mountain…As residents of Wisconsin, we are concerned that the EPA proposed rule might set a precedent for future licensing of repository candidate sites in granite…EPA must assess the potential implications of the proposed rule for other geologic repository sites before taking any final action in this docket. (Comments 0303-2. 0325-2, and 0325-3)

10. EPA's proposal would set a very dangerous precedent that could be applied across the U.S., not just at Yucca Mountain. EPA has for decades declared any radiation dose above 15 to 25 mrem/yr to be "non-protective of public health." Its general policy has been to regulate exposures to limit cancer rates to l in. 10,000 persons exposed, or even to 1 in 1 million persons exposed. For example, EPA limits radioactivity in drinking water to 4 mrem/yr, air emissions at 10 mrem/yr, and Superfund cleanups to the equivalent of roughly 0.03 to 3 mrem/yr. EPA has gone on record, again and again, that radiation doses of 100 mrem/yr produce unacceptable levels of risk, But EPA's 350 mrem/yr proposed standard for Yucca would be a 23-fold increase in "allowable" radiation over the 15 mrem/yr standard, and would more than triple the amount of radiation exposure EPA has repeatedly stated produces unacceptable levels of risk . If EPA gets away with this, it could set a precedent to rollback cleanup efforts at other radioactively contaminated sites across the country, including other radioactive waste dumps, nuclear power plant sites, and nuclear fuel chain facilities. There is the added danger that EPA could attempt to apply such inter-generational double standards to other polluted sites suffering nonradioactive, toxic and hazardous material contamination, allowing for much higher cancer rates (and other disease rates) to future generations. (Comments 0324-6, 0324-12, and 0324-21)

11. Warning! Please don't put future generations at risk for lowering the bar on radiation protection for all nuclear sites. Please. (Comment 338-1)

12. The new radiation standards for Yucca Mountain lower the bar for radiation protection for all nuclear sites in the United States. (Comments 0318-1, 0319-1, 0320-1, 0321-1, 0323-1, and 0343-2)

13. The new radiation standard for Yucca Mountain lowers the bar on radiation protection for all nuclear sites in the U.S. The EPA is endangering future generations. (Comment 0345-1)

14. Allowing a 350 millirem per year radiation dose has the potential to set a precedent to be applied at other radioactively contaminated sites across the country, including standards for cleanup efforts and other radioactive waste dumps, nuclear power plant sites and nuclear fuel chain facilities. (Comment 0349-2)

15. The proposed standard is contrary to internationally accepted radiation protection standards and lowers the bar on radiation protection at other contaminated Department of Energy (DOE) sites around the country, including those in New Mexico. (Comment 0354-4)

16. These proposed regulations allowing 350 millirem per year radiation doses are completely unacceptable and must not be allowed to set a precedent to be applied at other radioactively contaminated sites across the country because they represent a large-scale weakening of environmental and public health protection standards-the worst such standards, by far, in the Western world-in violation of international norms. This inter-generational immorality must also not be applied to other EPA jurisdictions, such as non-radioactive, toxic and hazardous chemical contaminated sites. (Comment 0355-3)

17. EPA has said that doses of over 100 millirems/year produce "unacceptable risk" so a dose of 350 is unacceptable to the public. (Comment 0367.2-13)

18. They must not be allowed to set a precedent because they represent a large-scale weakening of the environmental and public health protection standards. (Comment 0368.1-2)

19. We also do believe that these standards unfortunately, if they go forward, would set a dangerous precedent. And now suddenly I should hope that EPA in its reconsideration of this unacceptable rule will be begin to take into account the problems of the future. (Comment 0368.2-5)

20. By throwing away decades of precedent, the EPA is setting a new and very dangerous precedent for the storage of radioactive waste throughout the country, if not overseas as well. ANA is concerned about the potential of this precedent for other DOE cleanup sites, but it could also roll back cleanup efforts at other radioactively contaminated sites across the country, including nuclear power plant sites, other radioactive waste dumps, and other nuclear facilities. (Comments 0368.9-3 and 0368.12-2)

21. EPA's proposal would set a very dangerous precedent that could be applied across the U.S., not just at Yucca Mountain. EPA has for decades declared any radiation dose above 15 to 25 millirem per year to be nonprotective. Its general policy has been to regulate exposures, to limit cancer rates to one in 10,000 persons exposed or even to one in one million persons exposed. There is the added danger that this precedent could be applied to other polluted sites suffering from nonradioactive but toxic and hazardous chemical contamination allowing for much higher cancer rates and other disease rates to future generations. (Comment 0368.13- 2)

Response to Issue C:

The Energy Policy Act of 1992 (EnPA, Public Law 102-486, 42 U.S.C. 10141 n. (1994)) gave authority to EPA to set site-specific standards applicable only to Yucca Mountain. The EnPA also prescribed that EPA's standards must be "based upon and consistent" with recommendations of the National Academy of Sciences (NAS). The NAS specifically recommended that the site-specific standards applicable to the Yucca Mountain repository apply at the time of peak dose within the period of geologic stability (which the NAS defined in the context of Yucca Mountain to extend to as long as about 1 million years). It is unreasonable to compare this action to standards developed in other regulatory contexts that apply for much shorter periods. Like the portion of the standard that applies for 10,000 years, traditional EPA rulemakings and Superfund cleanups continue to rely upon the risk range and limit incremental risk. The Agency recognizes the uniqueness of a peak dose standard within the period of geologic stability of the Yucca Mountain region in United States regulations and the need for a higher dose limit to maintain the same level of certainty as for shorter times. No other United States waste disposal program, either radioactive or non-radioactive, intends to extend its compliance period to 1 million years.

In response to Comments 0113-9, 0126-2, 0127-2, 0130-3, 0133-5, 0135-5, 0137-5, 0144-4, 0146-5, 0147-5, 0148-5, 0150-4, 0159-5, 0163-5, 0164-4, 0175-4, 0177-4, 0182-3, 0189-3, 0190-4, 0302-20, 0310-4, 0324-2, 0324-12, 0324-21, 0349-2, 0355-3, and 0367.2-13 in which commenters stated that a 3.5 mSv (350 mrem)/yr standard is unacceptable, we have reconsidered our position for this action. As a result, we have established 1 mSv (100 mrem)/yr as the dose rate limit after 10,000 years. This is discussed further in Section 2, Issue D.

In response to Comments 0113-11, 0132-3, 0149-1, 0195-3, 0209.9-4, 0209.13-4, 0275-3, 0301-10, 0303-2, 0324-6, 0324-12, 0324-21, 0325-2, 0325-3, 0338-1, 0354-4, 0355-3, 0349-2, 0345-1, 0368.1-2, 0368.2-5, 0368.9-3, and 0368.12-2: Just as we have consulted international sources, we recognize that actions taken by the United States will likely be referenced internationally, but that does not mean they will be adopted elsewhere. In fact, in establishing a compliance period of 1 million years, we have responded to the decision of the U.S. Court of Appeals for the D.C. Circuit and have established a standard applying at peak dose. The international sources that we have consulted have provided a basis for identifying a standard for the far future that is protective of pubic health and safety. Similarly, in the end, other countries and agencies will establish standards based upon their individual situations, not based upon the actions of EPA.

Therefore, while we conclude that our standards will protect public health to the time of peak dose within 1 million years, there is no basis for assuming that this same standard will necessarily be applied to any other waste site in the United States or internationally.

Section 1 General Comments

Issue D: Generally supports the proposed amendments

1. I would like to thank the EPA for having the political courage to (finally) propose reasonable radiation standards for the Yucca Mtn. project. Even with the amended standards, Yucca Mtn. is being held to the most stringent environmental standards ever imposed on any industry or project, let alone on any other energy source. (Comment 0201-1)

2. We believe that there are fundamental flaws in the approach that forms the basis of the proposed rule. However, we realize that there are practical considerations that require that the proposed rule should be adopted in essentially its current form. (Comment 0215-1)

3. NARUC supports this latest EPA revision as both reasonable and justifiable. We generally agree with most elements of the proposed revision, including the specified compliance period and dose limits. (Comment 0217-1a)

4. The proposed standards for the Yucca Mountain Project are fully supported by myself. …..The hydrology and geology of the site is well characterized and the models are both sound and conservative. The 10,000 year standard (15 mrem) for such a human endeavor is both conservative and practical. …The 1,000,000 year standard (350 mrem) is both sound and conservative. These standards are based on sound science and conservative modeling beyond which we venture into incredible and impractical territories. – (Comment 0220-1, 0212-1)

5. If it is not feasible to safely predict the behavior of the planet over that period of time, let alone a huge tightly packed body of the deadliest toxins known to man, let us acknowledge that to each other, and proceed responsibly (Comment 0306-2).

6. With respect to the specific questions posed by EPA on elements of the proposed standard (*e.g.*, median vs. mean; treatment of features, events, and processes; Reasonably Maximally Exposed Individual) Duke endorses the comments provided by NEI on the behalf of the nuclear industry. (Comment 340-4)

7. The SRS CAB has analyzed the issues and concluded that the public health standards proposed by the EPA for Yucca Mountain are fair, adequate, and consistent with the standards prescribed for similar endeavors. Simply put, the proposed EPA standards are fair, technically adequate, and responsive to the legitimate needs of the citizens of both Nevada and the other 49 states in our country. (Comment 0368.11-1)

Response to Issue D:

The standards we have established are protective of public health and the environment, responsive to the DC Circuit ruling, and provide clear and adequate measures for DOE to follow and NRC to implement. Based upon public comments and further deliberations, the Agency has determined that the compliance measure will not be the proposed median, but rather the arithmetic mean in the post-10,000-year standard and the post-10,000- year dose rate limit is 1 mSv (100 mrem)/yr. The reasons for that are discussed in more detail in the preamble to the final standards and Section 2 of this document.

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Section 2 Dose Limits

Issue A: Definition of Reasonably Maximally Exposed Individual

1. The EPA calculated this proposed standard using what is known as a Reasonably Maximally Exposed Individual (RMEI). RMEI is defined as a "standard man." The EPA is willingly ignoring the potential impacts to children, women, mothers, the elderly, and others who may in fact be more vulnerable to radiation exposure. (Comments 0131-1 and 0195-7)

2. I am aware of the "standard man" calculation which totally ignores the existence of children, women, mothers, and the elderly and the radiation's potential impacts on their well being. Children are not "negligible"! (Comments 0130-6, 0132-2, and 0140-3)

3. Your agency has willingly ignored the potential effects that this project may have on children, women, and the Native American people of Nevada. This is an unjust and irresponsible policy. (Comment 0354-3)

4. … EPA has written the regulations for Yucca Mountain in such a way that the biosphere and human behaviors essentially are fixed by rule and are assumed not to change much at future times. This is a reasonable approach, in my view, because by fixing the biosphere and human behaviors by rule, performance assessments and compliance demonstrations can focus on the capabilities of natural and engineered barriers in limiting releases to the accessible environment, which is the important concern in disposal of long-lived radioactive wastes, and largely meaningless speculation about how exposure pathways and doses might change at far future times is removed from consideration. (Comment 0186-16)

5. We're going to treat everybody the same over a period of time. And I think those receptors are individuals differ, and their exposure to hazards -- the lifestyle, what they eat, the rabbits and trees. They're not just numbers, those are part of who we are, the land that fits our identity and how we construct threats and risks and hazards in our community. (Comment 0209.5-3)

6. During this (10,000 years) time period, the concept of protecting a Reasonably Maximally Exposed Individual (RMEI) has some validity. Real people live in locations near the facility... The nature of a potentially exposed individual 100,000 years in the future is somewhat different. These are hypothetical people. … should be treated probabilistically with regards to their lifestyle, consumption of food, and consumption of water as it affects radiation exposure. They should also be treated probabilistically with regards to location within the affected region. For these hypothetical people the protection of a maximally exposed individual is an overly conservative regulatory approach. (Comment 0215-4)

7. We believe that the RMEI approach is not an appropriate basis for …. regulatory limits … and that the proposed limits are inappropriately conservative. However, we are not proposing a change to the proposed rule. We do see value, however, in the interpretation of the RMEI criterion as a conservative bound to the achievement of a probabilistic safety goal. The prescriptive guidelines provided by EPA for the analysis of RMEI should be adopted as they are presented. (Comment 0215–6)

8. Under the Individual Protection Standard the term "reasonably maximally exposed individual" is used, which is too ambiguous; later, loosely defined as having ". . . a diet and living style representative of the people who now reside in the town of Amargosa Valley, NV." This is a disturbing departure of the usual practice of the "subsistence farmer" scenario to assess maximum exposure. To be sure, such a lifestyle does actually exist in Amargosa Valley. The point is to define a "critical group", which according to the International Commission on Radiological Protection explicitly states that a critical group "represents an extreme" of radiation exposure "to insure that no individual doses are unacceptably high."(ICRP Publication No. 46, 1985, p.9) This reasoning is in the best interest of the public health of future generations unlike the definition in the current proposed rule. (Comment 0268-6)

9. The NAS directed the use of the average member of the critical group for the receptor. The EPA used the reasonably maximally exposed individual (RMEI). The pre-10,000 years RMEI lives in Amargosa Valley. Will EPA justify using the same RMEI post-10,000 years when released contamination will start at the mountain and extend all the way to Death Valley? Could some other individual at another location be the maximally exposed individual for the new time period? DOE should have to determine and justify the parameters defining the new RMEI and use this possibly time varying definition post 10,000 years. (Comment 0273-1)

10. We agree with EPA's decision to maintain its choice of the RMEI as presently defined and not attempt to redefine any characteristics of the RMEI for the beyond 10,000 year analysis. As EPA correctly observes, the present day RMEI is a conservative approximation of how future individuals will live. The present-day RMEI lives a rural-residential lifestyle in a very dry climate, hence, heavily uses groundwater. Such an individual would be more vulnerable to groundwater contamination than would be an individual living under wetter climate conditions where rainfall and surface water would be more plentiful. A constant and conservative definition of the RMEI is a prudent and appropriate choice for any long-term repository safety analysis. (Comment 0298-19)

11. Both agencies use of the "standard man" as their model "dose receptor" ignores the higher vulnerability to radiation of fetuses, children, women, subsistence farmers, the elderly, those with weakened immune systems, and Native Americans living a traditional lifestyle. These populations must be fully protected against radiation leaking into the environment. (Comment 0310-3)

12. Re: EPA's comment on page 49019, column 3, that "The standard described above applies, for a period of 10,000 years after disposal, and is to be measured against exposures to the RMEI at a location outside the controlled area (in the "accessible environment")." How does the federal government propose to control the "controlled area" for 10,000 years, or for a million years? Will institutional controls last that long?
What is to prevent humans from moving into the "controlled area" and growing crops or livestock, and drilling wells into the severely contaminated groundwater table for drinking and irrigation water? (Comment 0324-19)

13. Under the Individual Protection Standard the term "reasonably maximally exposed individual" is used, which is too ambiguous; later, loosely defined as having ". . . a diet and living style representative of the people who now reside in the town of Amargosa Valley, NV." This is a disturbing departure of the usual practice of the "subsistence farmer" scenario to assess maximum exposure. To be sure, such a lifestyle does actually exist in Amargosa Valley. The point is to define a "critical group", which according to the International Commission on Radiological Protection explicitly states that a critical group "represents an extreme" of radiation exposure "to insure that no individual doses are unacceptably high."(ICRP Publication No. 46, 1985, p .9) This reasoning is in the best interest of the public health of future generations unlike the definition in the current proposed rule. (Comment 0328-5)

Response to Issue A:

As EPA stated in the preamble to the proposed amendments, the RMEI is not a subject of the current rulemaking: "Comments on the definition of the controlled area and specification of the RMEI are outside the scope of today's proposal. We will not consider or respond to comments on these topics." (70 FR 49023) For further discussion of this subject, please see the 2001 Response to Comments document. (Docket No. EPA-HQ-OAR-2005-0083-0043)

Section 2 Dose Limits

Issue B: Support the use of 350 mrem CEDE/year after 10,000 years

1. The proposed standards for Yucca Mountain are more than adequate. 1. They apply to a hypothetical human living less than 15 miles from the site, where no one lives now. 2. They enforce a level of risk no greater than what millions of American live with every day because of natural radiation. 3. Americans, including Nevadans, have enjoyed the benefits of nuclear energy for decades. It's time to accept this minimal risk as the cost for reduced greenhouse gases, better homeland security, and less reliance on foreign oil and natural gas. We, as a nation, chose and accepted the risk of nuclear energy in exchange for its benefits. It's our responsibility to now minimize that risk by placing its byproducts in a safe, secure place rather than stacked up in temporary locations near large populations and water sources. (Comment 0089-1)

2. We are concerned by news articles we have read, where some people have characterized this new post-10,000-years standard as too lax, when in fact it sets the most protective long-term safety requirements ever established by EPA. Therefore, in the attached report we review EPA's current regulations for managing the long-term risks of other radioactive and non-radioactive materials. This review confirms that there are no cases where EPA regulates any type of risk past 10,000 years. The review also shows that the actual long-term risks from many activities that EPA could regulate are indeed significant. Therefore the proposed Yucca Mountain standard is not consistent with EPA's management of risks from its other hazardous non-radioactive and radioactive materials, but instead is more protective. (Comment 0174-1)

3. Support use of a dose limit until the time of peak dose, but it does not need to be the same as for the shorter compliance period. (Comments 0180-4; 0181-4)

4. The EPA has succeeded in creating a standard that allows a reasonable person to decide if a repository at Yucca Mountain is a good thing or a bad thing. The proposed rule avoids pretending we can determine a repository would impose radiation exposures equivalent to a few chest X-rays per year to local people in – take your pick – 200,000, 500,000, or 1,000,000 years. (Comment 0185-1)

5. I believe it is reasonable that the dose criterion (or criteria) used to define acceptable performance in the time period beyond 10,000 years can be less stringent than the dose criterion that applies over the first 10,000 years. (Comment 0186-1)

6. If the EPA is proposing to require Yucca Mountain to safely contain radiation, including through events such as earthquakes, volcanic activity, and heavy water events, at levels of no increased radiation to the environment beyond natural background levels for the next 10,000 years, and then for the next million years at levels not above the current amounts of environmental radiation, then I would very much support such standards. (Comment 0191-1)

7. It would be short sighted and even dangerous to demand radiation standards so extremely tight that they affectively ban beneficial uses of nuclear energy. Alternatives to nuclear energy also have risks to public health, such as oil spills/fires, coal mine collapses, acid rain, CO_2 exhaust, global warming, etc. Should be also ban life saving medical diagnostics and radiation cancer treatments because we have no place to safely store the medical waste with small amounts of radiation? (Comment 0193-3)

8. It is absurd to claim that EPA's proposed standards do not sufficiently protect the public. Public health risks that are literally millions of times higher are routinely and readily accepted all the time. (Comment 0201-3)

9. The claim of insufficient public health protection is also absurd given that, despite decades of thorough study, no correlation between dose rates (within the range of natural background) and cancer incidence has ever been detected. Even if one were to accept the linear-no-threshold (LNT) theory of cancer risk from radiation exposure, dose rate limits that are a tiny fraction of natural background are impossible to defend, due to their clear inconsistency. Such limits are, by definition, selectively applied. How can such small dose rates be declared unacceptable, but ONLY if their source has something to do with the nuclear power industry!! Meanwhile, natural exposures, or exposures from flying or medical exposures are perfectly fine. (Comment 0201-4)

10. I would also like to point out that it is scientifically invalid to employ the LNT theory (allowing exposures to be controlled at levels orders of magnitude under those for which any health effects are actually seen) but then establishing exposure limits in terms of dose, as opposed to person-dose. LNT clearly states that the overall health effects are directly proportional to person-dose. Individual "risk burden" is simply not a meaningful concept. If EPA wishes to use LNT, it should create pollutant release limits, based upon calculations of resulting collective exposure, as opposed to establishing individual exposure limits. (Comment 0201-5)

11. Individual exposure limits are only scientifically valid if the concept of a threshold is being invoked (which would justify a limit at or near the threshold). Of course, if a threshold for radiation exposure was accepted as the scientific basis, all of this would not even be an issue, as dose rates under 1000 mrem per year would not be regulated at all (since there is no evidence at all of health effects from annual exposures under 1000 mrem). Basically, Yucca Mtn. dose rate limits that are a tiny fraction of background (i.e., 15 mrem) are impossible to defend either way, i.e., whether or not LNT theory is accepted. (Comment 0201-6)

12. EPA needs to stick to its guns on the proposed Yucca Mtn. dose standards. Returning to the old standards would be completely inconsistent (w/ all other regulations), scientifically and logically indefensible, and very bad public policy. (Comment 0201-7)

13. The early-time standard will waste Americans', meaning consumers' and taxpayers', money because it is simply too low. The proposed EPA standard for Yucca Mountain will keep potential exposures far below any level that has ever been shown to cause any human health effects. This after thousands of studies of hundreds of thousands of exposed individuals as well as controls over the past 20, 50, and even 100 years. The official position of the Health Physics Society states in part: Below 10 rem, risks of health effects are either too small to be observed or are nonexistent. That was not 10 millirem, that was 10,000 millirem. If we can't see the effects on people of 10,000 millirem, on real people, why are we falsely attempting to protect Nevadans to 15 millirem per year? (Comment 0209.9-1)

14. I am a proponent of your standard. I think it will work. In terms of danger, as with commercial nuclear facilities, the individuals working at the station or at the mountain experience the highest dangers. The public, basically, experience no danger at all. (Comment 0211.7-2)

15. This comment pertains to the EPA's "proposed annual peak dose limit of 350 mrem applicable beyond 10,000 years." In brief, I believe it is an acceptable standard, although other similar standards would also be acceptable. Nonetheless, it would be unacceptable to create the potential for a major human disaster (i.e., "catastrophic consequences," in EPA's words) no matter how far into the future we are considering. In short, we must not "booby-trap" the Earth. As reflected in the EPA's stated rationale, meeting the proposed RMEI standard of 350 mrem/yr for Yucca Mountain would satisfy this demand, because the total doses are limited to levels that are now experienced by many people from natural radiation with no observed ill-effects. For these reasons, the EPA's proposal seems to me to be reasonable in its overall thrust and its numerical parameters. (Comment 0313-1)

16. Accordingly, we recommend that these proposed standards be approved and a final DOE rule be expeditiously established to guide subsequent DOE actions to license, construct, and operate the Repository. (Comment 0329-1)

17. Commenting specifically on the proposed annual dose limit, Duke agrees with EPA that the 15 mrem annual dose limit (currently applied for the first 10,000 years) should not be applied to the entire time frame of the proposed million year regulation. It would be inappropriate to impose such an extremely restrictive exposure limit on hypothetical far future populations. (Comment 340-5)

18. We, Coalition 21, a volunteer organization of about 50 members in southeastern Idaho, support the EPA radiation release standards for the planned Yucca Mountain disposal site, as extended beyond 10,000 years. The requirement that no one should receive more than 350 mr in addition to the present local background of about the same amount is certainly protective of human health. As the EPA points out, many Colorado residents receive this total amont of 700 mr per year already, without ill effects. Thus, even the 15 mr standard up to 10,000 is excessive. (Comment 350-1)

19. The proposed revisions to the EPA rule appropriately blend policy considerations and technical approaches in a manner that will enable evaluation of repository performance in comparison to a peak dose regulatory standard. Setting the level of protection is a policy decision, and EPA's recommended value of 350 mrem/yr (an annual risk level of approximately 2×10^{-4}) is not inconsistent with other routine risks that society accepts today. (Comment 0352-18)

20. It should be noted that the peak dose limit proposed by EPA is well below the doses in the range of several rem (thousands of millirem) that EPA and an earlier committee of the NAS calculated could be produced by consumption of groundwater near a repository. As EPA pointed out at the time of promulgation of the original standard for geologic repositories: "This possibility is inherent in collecting a very large amount of radioactivity

in a small area." These calculations were made at the time that the original standards for geologic repositories were under development, and the possibility of such doses was not viewed at the time as a reason for rejecting the concept of geologic disposal. A dose standard orders of magnitude lower than levels understood to be an inherent possibility of geologic repositories could well have the indirect effect of forcing a change in national policy concerning the acceptability of geologic disposal. Any such decision is appropriately one to be made by Congress and the President, not as the inadvertent result of a regulation developed pursuant to a law that was clearly intended to expedite the development of a repository. (Comment 0352-26)

21. We agree with the dose limit for the period after 10,000 years being set at a higher level since there is greater uncertainty in forecasting so far into the distant future. Selecting 350 millirems per year for that period for the reasonably maximally exposed individual is well reasoned and drawing that comparison to levels people in other Western States are routinely exposed to makes good sense. And we feel the public can relate to that better than trying to understand what a millirem is. (Comment 0368.5-2)

22. Let me conclude by saying that we believe the proposed revised rule meets the objectives laid out in the discussion accompanying the revision and that it is responsive to the court ruling, protective of public health, reflective of best science and cognizant of limits of long-term projections, implementable by NRC in its licensing process, and limited in scope and focused on aspects critical to the above goals. (Comment 0368.5-5)

Response to Issue B:

After considering public comments, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) as the individual-protection standard to apply for the period between 10,000 years and 1 million years. Instead, we are establishing 1 mSv/yr (100 mrem/yr) as the individual-protection standard applicable beyond 10,000 years. This level is widely accepted and recommended, both internationally and domestically, as a protective overall public dose limit for practices involving the use of radioactive material. We will, however, address the comments that indicated support for the proposed dose standard because much of their reasoning can also be applied to the 100 mrem/yr final dose standard, although we cannot state that the commenters would also support the stricter standard.

Commenters offered a variety of reasons for supporting the proposed limit of 350 mrem/year beyond 10,000 years. While Commenters 0191, 0313, 350, 0368.5 agreed that the use of background radiation is an appropriate point of reference at very long times (and to address uncertainties in projections at such times), others cited the potential consequences of setting standards that would hold the repository to unrealistically stringent performance requirements. Still others pointed to risks to individuals (as opposed to populations) from radiation at such levels as justification for a higher dose limit (although our 15 mrem/yr standard for the first 10,000 years was also criticized on this score).

Commenter 0193 cited the potential consequences to the country in terms of future use of nuclear energy, or increased use of fossil fuels, if the Yucca Mountain disposal system cannot be licensed, while Commenter 0089 also refers to the responsibility to manage waste generated from the historic use of nuclear power. These considerations are not a factor in the standards we have issued, although we have received numerous comments suggesting otherwise (see Section 22 of this document). Although the national policy is to pursue geologic disposal of spent fuel and high-level waste, our role in implementing that policy is limited to establishing standards to ensure the disposal system will adequately protect public health and safety and the environment.

Commenters 0201 and 0209.9 argue that the proposed dose limit of 350 mrem/yr is insignificant in terms of its demonstrated health impacts. These commenters point to studies and such organizations as the Health Physics Society to support their position that individual dose limits are not meaningful at such low levels (and may be counterproductive). Commenter 0201 further states that the appropriate measure of impact, if one assumes a linear dose-response relationship, would be person-dose, as radiation health effects can be estimated only with respect to populations, not individuals. Commenter 0201 suggests that an appropriate way to incorporate considerations of population exposures would be to formulate a standard in terms of cumulative releases over time of individual radionuclides, correlated to health effects, as we did in 40 CFR part 191. However, NAS did not recommend a release-limit approach, noting that "this form of the standard does not provide any information about how these releases affect public health…and so is incomplete unless coupled with a calculation of individual (or population) risk (or dose or health effects)." As a result, even if such calculations are provided, "such a requirement would [not] provide additional protection over that provided by the individual-risk limit." (NAS Report pp. 63 and 120, respectively) We also concluded that the conditions at Yucca Mountain did not lend themselves to exposures of wider populations than those in the direct pathway of potential contamination, e.g., through surface water or more widely connected ground-water systems, which was a primary consideration in formulating the generally applicable standards in 40 CFR part 191. We also note that NAS recommended a standard to limit exposures to individuals, and concluded that such a standard would also effectively protect populations. In fact, on page 120 of the NAS Report, there is this statement: "We conclude that there is no technical basis for establishing a collective population-risk standard that would limit risk to the nearby population of the proposed Yucca Mountain repository."
We agree with the comments in the sense that risk as an indication of health detriment, as recommended by NAS, is less useful over the time frames addressed by our regulation, and may be misleading. Estimates of risk for individuals, correlated to dose or intake, are available from various sources, including NAS and ICRP (and our Federal Guidance Report 13). ICRP cautions, however, that "Doses and risks, as measures of health detriment, cannot be forecast with any certainty for periods beyond around several hundreds of years into the future…Such estimates must not be regarded as predictions of future health detriment." (ICRP Publication 81, "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Radioactive Waste," Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraph 41) We have selected the 100 mrem/yr long-term dose standard based on the wide acceptance of that level as a protective public dose limit and

find that its associated risk will also protect public health and safety. Emphasizing that the questionable assumption that current risk estimates can be applied to the very far future calls for caution in such matters, we estimate the nominal annual risk of fatal cancer associated with 100 mrem/yr to be 5.75 x 10^{-5}, which is comparable to the range of risks represented by domestic and international regulations that NAS suggested EPA consider, and which NAS stated were "consistent with recommendations from authoritative radiation protection bodies". (NAS Report p. 49 and Tables 2-3 and 2-4) We do not believe it is appropriate to view this longer-term standard from within the Agency's traditional risk-management framework (which is typically applied to situations where results can be confirmed, modeling is utilized on a more limited scale, or institutional controls are more applicable).

We have, however, found it useful to relate the 10,000-year individual-dose standards in 40 CFR parts 191 and 197 to the Agency's risk range (and the NAS "starting point" for our Yucca Mountain standards), while remaining cognizant of the limitations of such comparisons. ICRP also suggests that it is not unreasonable for shorter-term assessments to relate dose or risk to health effects: "To evaluate the performance of waste disposal systems over long time scales, one approach is the consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years. This approach focuses on that period when the calculation of doses most directly relates to health detriment…" (ICRP Publication 81, Paragraph 71) See Section 2, Issue H, and Section 5 of this document for more discussion of the impacts of radiation.

Rather than as a direct measure of health impact, risk has been employed in long-term dose assessment primarily as a mechanism to explicitly evaluate the potential impacts of low-probability events and processes, which have the potential to contribute to exposures of greater significance. We believe this was the significance of the NAS recommendation to establish a risk standard. Our requirement for the probabilistic calculation of doses effectively incorporates the issue of risk as recommended by NAS.

Commenter 0174 points out that no other EPA regulations cover periods beyond 10,000 years, concluding that any level of regulation for longer periods is stricter than for any other activity or contaminant. Although they did not offer specific recommendations, Commenters 0186 and 0340 were in general agreement with our position that it is reasonable to set longer-term criteria that are higher than the level applied for 10,000 years. Commenters 0185, 0201, and 0352 note that 350 mrem/yr represents a lower risk than many activities routinely engaged in by the public. Commenter 0211.7 similarly suggests that public risks are insignificant compared to risks borne by workers at nuclear power plants or would be borne by workers at Yucca Mountain. While such comparisons can provide important perspective, their utility may be limited and complicated by questions of the voluntary nature of the exposure or whether compensation is offered for assuming greater risk (e.g., for workers).

Comment 0352-26 supports our proposal and notes that early studies of the geologic disposal concept (including EPA's original rulemaking for 40 CFR part 191) concluded that doses in the range of several rem per year would be possible in the event of consumption of ground water near the repository. The commenter points out that such a possibility did not disqualify the concept as a focus of national policy, and concludes that a long-term dose limit of 15 mrem/yr would in effect be changing the basis for national policy by discounting the inherent nature of the selected option. As the commenter suggests, in both our 1985 and 1993 rulemakings for 40 CFR part 191, we emphasized that the 10,000-year compliance period for both the containment requirements and individual-protection limit would lead to a combination of site characteristics and engineered barriers that would be capable of providing containment and isolation of the waste for these long periods of time. We did not, however, anticipate that such performance could be maintained indefinitely. Our generic technical analyses, in fact, suggested that significant releases and doses to individuals could result at later times, depending on the characteristics of the site in question and the presumed location of the receptor (to help mitigate such a possibility, we included the concept of a controlled area, which is considered part of the natural geologic barrier and inside which compliance with dose standards will not be assessed and need not be demonstrated). For example:

> The Agency examined potential doses to individuals, considering various times in the future, from waste disposal systems in several different geologic media. In most of the cases studied, radionuclide releases resulting in exposures to individuals did not occur until more than 1,000 years after disposal due to the containment capabilities of the engineered barrier systems. Beyond 1,000 years, but prior to 10,000 years, as the engineered barriers begin to degrade, releases resulting in doses on the order of a few rems per year appeared for some of the geologic media studied. For other, better geologic media, the Agency's generic analyses estimate no releases for 10,000 years. The Agency believes that selecting a 10,000-year time for the requirements, rather than a 1,000-year time frame, will encourage the selection of better sites and/or the design of more robust engineered barrier systems capable of significantly impeding radionuclide releases. These actions, in turn, will serve to reduce the individual risks associated with the disposal of radioactive waste.

58 FR 66401, December 20, 1993.

As the commenter noted, sites whose natural features did not provide total containment were not necessarily considered unsuitable, but we recognized that in those instances, the focus would have to be on "the design of more robust engineered barrier systems capable of significantly impeding radionuclide releases." We believe that it is unrealistic to assume that these sites would then exhibit better performance after the failure of those barriers than they would in the initial 10,000-year period. Consequently, we believe the potential for doses higher than 15 mrem/yr to individuals in the far future has always been implicit in the concept of geologic disposal. Over time, the initial static system consisting of intact waste packages and other engineered barriers in the natural geologic setting gives way to a more dynamic system in which episodic and gradual processes combine to transport radionuclides to the accessible environment. The sequence and timing of barrier failures strongly influence, and introduce considerable uncertainty into, the timing and magnitude of projected doses over the 1 million-year period. The range of projected doses widens considerably as the containment capability of the engineered barriers diminishes. Interpreting the safety of the disposal system for regulatory purposes, in our judgment, involves more than comparison of projected doses to a regulatory standard, and a standard applicable to the initial static system would not adequately capture the essential nature of a system that has evolved over 1 million years.

In further response to Comment 0352-26, our responsibility under the EnPA is to set public health and safety standards for the Yucca Mountain disposal system. We view this as neither expediting nor impeding the development of the disposal system. Moreover, we view such considerations as improper in the context of the regulatory scheme set forth in the EnPA. EPA's role is to promulgate, by rule, standards to protect public health and safety from releases from radioactive materials stored or disposed of in the repository at Yucca Mountain. Any consideration as to whether such standards are favorable or unfavorable in the context of the NRC licensing proceeding would be inappropriate.

Section 2 Dose Limits

Issue C: Extend 15 mrem CEDE/year to time of peak dose

1. The weaker standard would allow Nevadans to be exposed to approximately 25 times more radiation than the previous standard, and hundreds of times more radiation than people living next to a nuclear power plant. This is an unacceptable public health standard and would needlessly put Nevadans at risk. (Comment 0111-1)

2. I write to express my distress at the dangerous level of radiation allowed in the proposed standards for Yucca Mountain. I believe they do not adequately protect the health of humans in the area. This land is a resource that should be respected an treasured for the future. (Comment 0119-1)

3. EPA's recently revised standard, however, fails to comply with the court ruling and the intent of the NAS recommendations. Instead of extending the 15 mrem/yr limit through the time of peak risk, EPA has proposed a two part standard - 15 mrem/yr for 10,000 years, and then a 350mrem/yr standard thereafter (up to a million years). (Comments 0126-3 and 0127-3)

4. The only standard that will provide health and environmental protection is 15 mrem CEDE/yr until the time of peak dose. (Comments 0133-3, 0134-1, 0135-3, 0137-3, 0144-2, 0146-3 0147-3, 0148-3, 0149-2, 0150-2, 0159-3, 0160-2, 0163-3, 0164-2, 0165-1, 0182-1, 0188-1, 0189-1, 0190-2, 0192-1, 0257-7, 0260-2, 0262-2, and 0327-2)

5. I am disappointed in the proposal to allow 350 mrem/yr radiation in a mere 10,000 yrs at Nevada's Yucca site. (Comment 0153-1)

6. Current standards of 15 mrem per year from all pathways, and 4 mrem per year from drinking water, must be applied for the full regulatory period of peak radiation doses (hundreds of thousands of years into the future and beyond). (Comments 0175–3 and 0177-3)

7. I am puzzled and shocked at the rationale used to support the proposed dose limit of 350 millerems/yr as the dose limit for releases from the dump. If you can make decisions about what is safe at one point and say it is 15 and that is supposed to be ok, how can you then say 350 is ok at another time when you have no evidence that people will become less susceptible to radiation. What is acceptable should stay the acceptable limit regardless of time and that is 15. (Comment 0259-1)

8. EPA can exercise its profound mandate to serve as a "trustee to protect the interest of future generations" by adopting *a single standard that we and our grandchildren would be willing to live with.* The 15 mrem/yr standard is a laudable target. That would send this project where it belongs—back to the drawing board. Let's take the time, do the science, grow the technology, carry on the societal discussions, and do it right. (Comment 0267-9)

9. The 15 mrem/yr dose limit should be imposed through the period of peak risk, which is more like 300,000 years (according to DOE's calculations), and the Safe Drinking Water Standard should also extend through this period. (Comment 0268-2)

10. We urge EPA to adopt instead, a single, uniform protection standard for the entire projected life of the proposed repository, before and after 10,000 years: 15 millirem per year maximum exposure threshold. (Comment 0275-1)

11. The 15 mrem/yr dose limit should be imposed through the period of peak risk, which is more like 300,000 years (according to DOE?s calculations). (Comment 0289-3)

12. EPA's proposed rule exceeds the National Academy of Sciences' recommended acceptable range of risk of radiation exposure, which is 2 to 20 millirems per year, and the NRC's radiation health standard for low-level radioactive waste disposal sites, which is 25 millirems per year. (Comment 0293-10)

13. A4NR opposes all changes proposed in this rule for the post-10,000 year period. Like NNTFI, we "believe that the only radiation standard for Yucca Mountain that would provide health and environmental protection would be a rule that extends the existing allowable dose of 15 millirem/yr to the time of peak dose, whenever it occurs, and retains the groundwater protection standard of 4 millirem/yr." There is no justification for establishing a two-tiered standard or for allowing any greater risk to life in the future." (Comment 0294-4)

14. I urge EPA to adopt a consistent, protective rule that is not arbitrary and capricious. EPA has said 15 millirem per year is the appropriate standard; that should be the standard then throughout the lifetime of the proposed Yucca project. There is no sensible basis to require such a standard during the initial period, when the project appears able to meet the standard, and then a grossly more lax and unprotective standard thereafter, just because the project isn't safe enough to meet a consistently protective requirement. (Comment 0296-9)

15. EPA's proposed rules should be revised to keep radiation exposure limits to less than 15-25 millirem/year, as long as the stored nuclear waste remains toxic to human health. In addition, the EPA should enforce a separate groundwater protection standard of less than 4 millirem/year for the period beyond 10,000 years. (Comment 0301-12)

16. We urge EPA to adopt instead, a single, uniform protection standard for the entire projected life of the proposed repository, before and after 10,000 years: 15 millirem per year maximum exposure threshold, coupled with the 4 millirem groundwater protection standard. (Comment 0303-1)

17. I agree with the positions recommended by the State of Nevada and by the Nevada Nuclear Waste Task Force. The State of Nevada opposes the proposed EPA rule, and has recommended instead that EPA: "extend the 15 millirem per year maximum exposure threshold, together with the 4 millirem groundwater protection requirement, through the period of maximum projected releases for the Yucca Mountain facility." (Comment 0304-1)

18. The only scientifically and legally supportable way to bring EPA's Yucca Mountain rule into compliance with the Court's directives and the NAS recommendations is to extend the 15 millirem per year maximum exposure threshold, together with the 4 millirem groundwater protection requirement, through the period of maximum projected releases for the Yucca Mountain facility. (Comment 0309-3)

19. The period of compliance for the 15 mrem/yr and the 4 mrem/ ground-water standard must be continued through the time to peak dose. (Comment 0311.1-4)

20. There is no reason that EPA could not have required that a singular protective standard be required for the life of the repository, reliant on the modeling associated with the geologic conditions and stability. Indeed, that is precisely the action NAS recommended that EPA take in estimating maximum doses from releases of radionuclides. (Comment 0311.1-12)

21. EPA errs in setting a standard so high especially given the overlooked uncertainties associated with the decision. I urge the EPA to consider a more cautious approach and maintain the 15 mrem/year standard throughout the compliance period, a peak dose level that was also considered by the EPA (Section II.C.4.a.). The proposal states that "…a compliance standard on the order of 15 mrem/yr implies far more precision in projections for very long times than can be supported and, as such, is inconsistent with the "reasonable expectation" approach." However, the notion that "…rising uncertainties justify adopting a

different (higher) dose level" (Section II.C.2.b. paragraph 2) demands reconsideration. In addition, "reasonable expectations" ought to be more broadly defined to include blatant, presently-ignored-because-they-are-not-fully-understood uncertainties.
It appears EPA justifies the proposed standard of 350 mrem due to international guidance and speculated natural background levels, even though the NAS recommended the standard rely upon current conditions rather than speculation. Furthermore, the EPA states in Section II.C.1. that "no regulatory body that we are aware of considers doses of 150 mrem to be acceptable." Therefore, according to the Agency itself, 350 mrem is an unacceptable standard. It is more than three times the quantity allowed from nuclear facilities today by the Nuclear Regulatory Commission. (Comment 0312.5)

22. The annual dose limit for all pathways should be between 10 and 25 millirem and should remain constant in time over the period of geologic stability at the site. A separate sub-limit of 4 millirem per year to the most exposed organ from the drinking water pathway should be included over the entire period of geologic stability. (Comment 0314.1-8)

23. The far more generally applied level of "acceptable" risk of 10^{-5} to 10^{-6} should serve as the basis for determining whether future generations are being given at least the same level of protection as is considered acceptable for the present generation. This choice is consistent with the conclusions of both the International Commission on Radiological Protection and the International Atomic Energy Agency which have both recommended using a risk equivalent of 10^{-5} per year as a reference value in setting limits for the geologic disposal of high-level waste. (Comment 0314.1-12)

24. NIRS **again** submits on behalf of the 2,000 petition signers in the year 1999, as well as on behalf of its members across the U.S., that EPA's fullest protections must be applied not only for the first 10,000 years at Yucca, but through the period of peak dose (to live up to NAS recommendations) and beyond (to protect all future generations to the same standard as current generations, the only ethical and moral position to take). The 15 mrem/yr standard must be applied till peak dose hundreds of thousands of years into the future to meet the legal requirements, and should extend even beyond that to meet moral and ethical requirements. (Comments 0324-15, 0324-28, and 0324-29)

25. On behalf of my wife, my children, and myself, I am writing in opposition to the EPA proposed rule. We urge EPA to adopt instead, a single, uniform protection standard for the entire projected life of the proposed repository, before and after 10,000 years: 15 millirem per year maximum exposure threshold, coupled with the 4 millirem groundwater protection standard. (Comment 0325-1)

26. We recommend that the new EPA radiation protection standard should fall within this recommended exposure range limit of 10-30 millirems per year. EPA's radiation protection standard should be consistent with the NAS findings and recommendations. A radiation exposure limit should be set within the recommended range of 10 to 30 millirems per year, e.g., 15 millirems per year as recommended by EPA. (Comment 0326-2)

27. Citizen Alert also feels that it is necessary and important for the EPA to take a progressive step in applying maximum exposure limits that are less than those in the current rule, which stems from the following considerations:

- The U.S. government is embarking upon a project that has never been tried before, and we do not have the luxury of previous experience; only time will tell whether this grand experiment will achieve the intended goal of waste isolation.
- Given the current data it seems clear that groundwater contamination will occur at some point in the future (~200,000 - 300,000 years if the DOE calculations are reasonable), and is an irreversible process requiring hundreds of thousands if not millions of years to decay away.
- The shear scope of the Yucca Mountain Project in terms of the amount of waste, intensity of the radioactivity, and longevity affords special consideration. Otherwise, the small and possibly ignorable errors in design could be magnified resulting in potentially enormous impact.
- There are a number of other countries that have more stringent radiation protection standards than we do in the United States.

What do those countries know that we don't? Perhaps, they are looking ahead and predicting that as the body of information on the health effects of radiation expands, people will demand tighter standards. Certainly, the history of exposure standards in this country reveals a trend toward lower allowed exposure in nuclear facilities and the general public. For these reasons it is necessary to have that extra margin for error. What if we are wrong, and the models don't predict as expected? To be sure, we have been wrong before: the Titanic, Exxon Valdez, the Challenger, need we go on? Citizen Alert strongly urges the EPA to build in that extra "cushion" for the protection of all U.S. citizens. (Comments 0268-7 and 0328-6)

28. The City believes that the EPA should extend the 15 millirem per year standard through the period of maximum projected releases for the Yucca Mountain facility. (Comment 0341-1)

29. Eureka County believes that the radiation standard should be reasonable and protective in the near and far term, and that the proposed standard does not accomplish that goal. In order ensure that the radiation standard is protective, EPA should extend the 15 millirems per year maximum exposure threshold together with the 4 millirem groundwater protection requirement to apply throughout the period of maximum projected releases for the Yucca Mountain facility. EPA should withdraw the proposed rule and issue a draft standard that is protective through the period of maximum projected releases at Yucca Mountain. (Comments 0353-10 and 361-10)

30. The proposed 40 CFR 197 provides a level of protection for the first 10,000 years after the repository is closed, and less for those people who will be living after 10,000 years. In fact, the all pathway standard is weakened by a factor of approximately 24, and the groundwater standard is eliminated. The 15 millirem per year dose limit should be imposed through the period of peak risk, which, according to DOE's own calculations is more like 300,000 years. The Safe Drinking Water Standard should also extend through this period. (Comment 0354-5)

31. EPA's proposal to allow 350 millirem per year radiation doses to people living downstream from the leaking dump - the equivalent of 58 full chest x-rays per year - would not only cause cancer, but also birth defects, genetic damage, and other maladies, and at alarming rates, and must be withdrawn. Current standards of 15 millirem per year from all pathways, and 4 millirem per year from drinking water, must be applied for the full regulatory period at Yucca Mountain, extending to the period of peak radiation doses (hundreds of thousands of years into the future) and beyond. (Comments 0310-2 and 0355-2)

32. EPA should err on the side of caution ands use the present limit (15 millirems per year) as the standard for protecting the health and safety of people and the land now and in the future. (Comments 0360-4 and 0363-4)

33. Making this hard by fighting for the 15 mR – the burden of proof should be on DOE. (Comment 0367.1-20)

34. … we urge you to revise the proposed rules, to keep radiation exposure limits to less than 15 to 25 millirems per year. (Comment 0368.2-6)

35. …I'd like to be sympathetic to EPA …, although I think the EPA found a wrong solution for it, is how do you deal with the questions of hundreds of thousands of years from a technical point of view. And I would like to suggest that it's not in the relaxation of the standard. … let me recommend a specific alternative … for a standard which would be somewhere between 10 and 25 millirem for the effective dose equivalent per year from all pathways with a sublimit for four millirem per year from drinking water. (Comment 0368.3-2)

Response to Issue C:

After considering public comments, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) as the individual-protection standard to apply for the period between 10,000 years and 1 million years. Instead, we are establishing 1 mSv/yr (100 mrem/yr) as the individual-protection standard applicable beyond 10,000 years. This level is widely accepted and recommended, both internationally and domestically, as a protective overall public dose limit for practices involving the use of radioactive material. We will, however, address the comments that supported extending the 150 μSv/yr (15 mrem/yr) dose standard throughout the compliance period.

A significant number of commenters disagreed with our proposal and recommended simply extending the 15 mrem/yr standard at least through the time of peak dose. Many of these commenters also recommended extending the ground-water protection standards (we refer those commenters to Section 12 of this document). Commenters frequently cited the difference in protectiveness between the two levels as cause for concern. Some commenters argued that our proposal does not satisfy the Court ruling or the NAS recommendation. Commenters also touched on the issue of intergenerational equity, which we address in Section 9 of this document.

Comment 0259-1 questioned our reasoning that 350 mrem/yr is protective at very long times when we have not argued that humans will be less susceptible to radiation. It is true that we neither make this argument, nor do we consider that new information on radiation effects will result in tighter standards, as comment 0328-6 suggests. The RMEI is a hypothetical person representative of today's population in Amargosa Valley, and no changes in society, biology, or technology have been assumed. Our reasoning is that the increasing uncertainties in projecting releases over periods of several hundred thousand years justify modifying these numerical performance indicators to recognize this changing context. Comment 0355-2 states that "alarming rates" of health effects would result from our proposed standard. Our final long-term dose standard of 100 mrem/yr is protective of public health and safety (see Issue H of this section as well as Section 5 of this document for discussion of health risks from radiation). Our final standard is assessed against calculated doses to a person who is among the most highly exposed members of the population. Population patterns, lifestyles, and characteristics of potential contaminant pathways lead us to conclude that the majority of the population would be exposed at much lower levels than the RMEI, if at all.

We disagree with Comments 0126-3, 0127-3, 0293-10, 0296-9, 0309-3, 0311.1-12, 0324-15, 0324-28, 0324-29, and 0326-2, which claim that our approach is not consistent with either the D.C. Circuit decision or the NAS recommendation. As we noted in our proposal (70 FR 49021-49022), the Court ruled only that our standard was not consistent with the NAS recommendation to require compliance assessment at the time of peak dose. The Court vacated our standard "to the extent that it incorporates a 10,000-year compliance period." *Nuclear Energy Institute v. Environmental Protection Agency*, 373 F.3d 1251, 1315 (D.C. Circuit 2004). Therefore, in accordance with the recommendations of the National Academy of Sciences, we have established a peak dose standard together with a compliance period of 1 million years. We have addressed our original policy concerns regarding the use of very long-term projections as a licensing criterion by proposing a revised standard containing a higher compliance limit for very long times, as well as other requirements related to performance assessment and compliance determination. We believe we have addressed those policy concerns in a manner consistent with the findings and recommendations in the NAS Report. Our final standards are protective of public health and safety, meaningful, implementable, and provide a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation.

The NAS Report recognized the possible outcome of a rulemaking establishing a dose standard that changed over time; however, we believe this approach is consistent with the intent of the committee. The committee acknowledged the possibility of "some other" approach than "a health-based risk standard… specified to apply uniformly across time and generations" in its discussion of intergenerational equity. (NAS Report pp. 56-57) (See Section 9 of this document and the preamble to the final rule for more discussion of intergenerational equity.) The NAS committee recommended only that compliance be assessed at the time of peak risk, stating "that there is no scientific basis for limiting the time period of the individual risk standard to 10,000 years or any other value." (NAS Report p. 55) NAS did identify a range of risks represented by current national and international regulations, "all of which are consistent with recommendations from authoritative radiation protection bodies," for EPA to consider. (NAS Report p. 49 and Tables 2-3 and 2-4) Our 10,000-year dose rate limit of 15 mrem/yr is consistent with the range of risks identified by NAS, and we point out that none of the regulatory precedents considered by NAS applied for periods approaching 1 million years. (NAS Report p. 45) The NAS committee explicitly declined to recommend a risk or dose level, recognizing that as "not ultimately a question of science but of public policy." (NAS Report p. 5) Further, NAS noted that the final outcome of the rulemaking might diverge substantially from the starting point suggested by NAS: "Finally we have identified several instances where science cannot provide all of the guidance necessary to resolve an issue…In these cases, we have tried to suggest positions that could be used by the responsible agency in formulating a proposed rule. Other starting positions are possible, and of course *the final rule could differ markedly from any of them*." (NAS Report p. 3, emphasis added) Thus, we agree with NAS that the selection of a level for the peak dose standard is one of the regulatory policy issues left to EPA's discretion by the EnPA. The 100 mrem/yr peak dose standard is comparable to the range of risks suggested by NAS for EPA's consideration. The nominal annual risk of fatal cancer associated with 100 mrem/yr, 5.75×10^{-5}, is reasonable when significantly extended time frames are taken into account, and the considerable uncertainties in projecting performance for up to 1 million years are considered.

Further, we believe NAS understood that dose projections would effectively become increasingly stylized as the time period covered by the assessments increased, and that a compliance standard applicable for times approaching 1 million years might be different in some important respects from its recommendations. For example, NAS acknowledged that "it is obviously impossible to predict in detail either the nature or the timing of future climate change" (NAS Report p. 77), and the committee's frequent references to "bounding" and other approaches reflect its concern that effectively addressing long-term uncertainties would be critical in implementing compliance assessments over periods of this length. (e.g., NAS Report pp. 9, 19, 20, and 79) NAS's statement that "the final rule could differ markedly from" the starting point implicitly acknowledges that there might be valid reasons for departing from standards we (and others) had previously established for much shorter time frames. (NAS Report p. 49) Indeed, NAS noted a similar consideration in reaching its recommendation, stating that "selecting a time scale for analysis involves weighing how the scientific basis for analysis changes with time against the timing at which more numerous future health effects are likely to occur." (NAS Report pp. 30-31) We believe it is reasonable to consider not only how the scientific basis for the analysis changes, but also the demands of the regulatory process, in making the policy selection of a long-term peak dose standard applicable for times as long as 1 million years. More discussion on this point may be found in Issue G of this section.

We note that Mr. Robert Fri, who chaired the NAS committee, testified in his personal capacity before the Senate Environment and Public Works Committee on March 1, 2006 (oral testimony at Docket No. EPA-HQ-OAR-2005-0083-0380, pp. 54-58, prepared statement at Docket No. EPA-HQ-OAR-2005-0083-0402). His testimony, which paralleled presentations he has given in other venues, focused on the relationship between the time frame of regulation and the characteristics of the receptor identified in that regulation. Mr. Fri pointed out that the committee had recommended the use of a probabilistic critical group, which it felt would be less "deterministic" and conservative than the "any member of the public" standard in our generic regulations at 40 CFR part 191. We chose instead to identify the more conservative[1] reasonably maximally exposed individual (RMEI), which the committee commented in 1999 was "broadly consistent" with the goals of the probabilistic critical group (66 FR 32089, Docket No. EPA-HQ-OAR-2005-0083-0042). Mr. Fri testified that the combination of the RMEI (although in his view still "deterministic") and the 15 mrem/yr dose limit was a reasonable approach for the initial 10,000-year period. However, he cautioned that maintaining the RMEI as the receptor while extending the compliance period up to 1 million years put us in a position where "the Committee did not want to be" because it led to a level of conservatism with which the committee was not comfortable. He noted that one committee member had recommended such an approach, which was rejected by the committee (see pp. 100-103 and Appendix D of the NAS Report for this alternative view) as having the potential to "become just such an extreme case." (NAS Report p. 188) Mr. Fri's testimony stated that, while he could not say whether the 350 mrem/yr proposal would be consistent with the NAS recommendation, he believed it was intended to remove some of the conservatism (i.e., in his view it had the effect of moving us in the direction toward where the committee "wanted" us to go). This leads us to conclude that the approach we have taken in proposing a higher dose limit for longer times could be more consistent with the NAS recommendation than would be a 15 mrem/yr dose limit throughout the period of geologic stability.

Comments 0268-7 and 0328-6 raise a number of interesting points to conclude that the dose limit should remain at 15 mrem/yr beyond 10,000 years. Several of the points touch on the critical aspect of geologic disposal, which is the assumption that direct observation of the system will not be possible over the times when releases are most likely to occur.

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[1] In considering a proposed subsistence-farmer critical group as an alternative to its preferred probabilistic critical group, the committee noted that "it makes the most conservative assumption that wherever and whenever the maximum concentration of radionuclides occurs in a ground water plume accessible from the surface, a farmer will be there to access it." (NAS Report p. 102) The RMEI incorporates this "most conservative assumption."

The commenter suggests that "only time will tell whether this grand experiment will achieve the intended goal of waste isolation" – however, that must always be the case. Mathematical modeling is the only method available to project the overall system performance on geologic timescales, although other arguments need to be made to provide context and confidence in the approach taken to projections, and these other arguments may in fact become more important in decision-making as the time period covered by the assessment increases. As noted by NAS, the "results of compliance analysis should not, however, be interpreted as accurate predictions of the expected behavior of a geologic repository" over such times, and in fact must be viewed more as indicators of system performance. (NAS Report p. 71)

The commenter further states that the scale of Yucca Mountain means that "small and possibly ignorable errors in design could be magnified resulting in potentially enormous impact" and points to the Titanic, Exxon Valdez, and Challenger as justifying an "extra margin for error" if the models are not correct. However, our concerns regarding long-term modeling relate to the emphasis that such projections should be given in compliance decision-making, and are not tied specifically to DOE's ability to construct appropriate models. We do agree with the commenter regarding the propagation of error. Many commenters in later sections cited DOE's estimates of waste package performance as a critical factor that remains unproven. However, the effects of such design flaws or modeling errors are essentially unknowable, and in some cases might result in improved performance or overestimated releases. That is why we believe that judgments to be made by NRC prior to licensing regarding aspects of DOE's program such as quality assurance, performance confirmation testing, site characterization, and basic modeling assumptions may be as important, if not more important, than doses projected to occur several hundred thousand years after disposal. (See Docket No. EPA-HQ-OAR-2005-0083-0376, p. 45, for considerations in NRC's evaluation of "reasonable expectation.")

Finally, the commenter states that "there are a number of other countries that have more stringent radiation protection standards than we do in the United States." We presume this refers to our Yucca Mountain proposal for the peak dose standard beyond 10,000 years, and not to other radiation protection regulations, including the 15 mrem/yr standard applicable for the initial 10,000 years at Yucca Mountain. While we address this issue in more detail in Section 4 of this document, we note that the more typical approach internationally is to require compliance with quantitative performance assessment for only a limited period of time (in some cases, less than 10,000 years). Longer-term dose projections may be compared to dose or risk targets or reference levels, but are viewed more as qualitative indicators of performance, to be weighed in conjunction with other qualitative arguments for confidence in the overall safety of the facility.[2] Non-compliance

[2] The 2006 NEA document on "Consideration of Timescales in Post-Closure Safety of Geological Disposal of Radioactive Waste," which is based on surveys of NEA Member Countries, states "Calculated values of dose and risk are therefore viewed in regulations not as predictions but rather as indicators or measures of protection that are used to test the capability of the system to provide isolation of the waste and containment of radionuclides (the 'dose' that is being calculated is what radio-protectionists refer to as 'potential dose'). These indicators are to be evaluated on the basis of models that include certain stylized assumptions, in particular regarding the biosphere and human lifestyle or actions." (p. 38) NEA also notes: "There is agreement that calculations of dose and risk in the future are illustrations of possible system behaviour rather

with the dose or risk criteria in such cases is not necessarily cause for rejection of the safety case, unlike in our rule. The weight given to quantitative projections typically decreases as the time frame gets longer. Comment 0314.1-12 touches on the same issue in pointing out that an annual risk level of 10^{-5} to 10^{-6} "is consistent with the conclusions of both [ICRP] and [IAEA] which have both recommended using a risk equivalent of 10^{-5} per year as a reference value in setting limits for the geologic disposal of high-level waste." We believe the term "reference value" is instructive, as both organizations indicate that projected doses that would be unacceptably high in the initial period after disposal because they would exceed the regulatory standard (or "constraint") would not necessarily be unacceptable at longer times. ICRP states that "as the time frame increases, some allowance should be made for assessed dose or risk exceeding the dose or risk constraint. This must not be misinterpreted as a reduction in the protection of future generations and, hence, a contradiction with the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results" (Publication 81, "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste," Docket No. EPA-HQ-OAR-2005-0083-0417). Similarly, IAEA states: "In very long timeframes…uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases." ("Safety Requirements for Geological Disposal of Radioactive Waste," WS-R-4, Docket EPA-HQ-OAR-2005-0083-0383, paragraph A.7, p. 37) We attempted such an approach in our 2001 rulemaking, which gave NRC flexibility to consider longer-term dose projections as it thought appropriate within the licensing process (i.e., NRC would decide how much meaning or weight should be assigned to those projections).

Comment 0312.5 disagrees with our rationale for a higher standard, and expresses concern that "overlooked uncertainties" may be more important and should be included in the determination of "reasonable expectation." See Sections 6 and 17 of this document for more discussion of these aspects of our decision. The commenter also states that we appear to have relied upon "speculated natural background levels, even though the NAS recommended the standard rely upon current conditions rather than speculation." Our discussions of background radiation have been in the context of existing data, and we have not attempted to project background radiation through the period of geologic stability, as some comments suggested we should. Regardless, we have not used specific estimates of

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than predictions of outcomes, and there is consensus that, in the long term, numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than as absolute limits in a legal context." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, Docket No. EPA-HQ-OAR-2005-0083-0408, p. 24) Similarly, ICRP Publication 81 contrasts the approach of "consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years" with "consideration of quantitative calculations further into the future making increasing use of stylized approaches and considering the time periods when judging the calculated results. Qualitative arguments could provide additional information to this judgmental process." (Paragraph 71) The IAEA consensus document for geologic disposal ("Safety Requirements for Geological Disposal of Radioactive Waste," WS-R-4, 2006) states: "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Care needs to be exercised in using the criteria beyond the time when the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decisionmaking." (Paragraph 2.12) background radiation to derive our final peak dose standard. Finally, the commenter notes that the proposed peak dose limit is higher than that allowed from currently operating nuclear facilities. The final peak dose standard we are establishing, 100 mrem/yr, is the NRC's public dose limit applicable to individual licensed operations today (10 CFR 20.1301), although lower dose constraints apply to certain types of operations. However, we do not believe it is necessarily reasonable to compare the basis of regulatory limits for operating facilities, where active measures can be taken, with those established for a passive disposal system for which peak doses may occur at times approaching 1 million years into the future. Commenter 0293-10 makes a similar point in noting that the NRC standard for low-level radioactive waste disposal facilities in 10 CFR part 61 is 25 mrem/yr. However, the time frame of concern for these near-surface facilities is closer to the 10,000-year compliance period we originally established in our 2001 rulemaking. Limits on the concentrations of long-lived transuranic or other highly mobile radionuclides help to ensure that projected doses remain low. See also Issue G of this section for discussion of apportionment of potential doses among multiple sources.

Section 2 Dose Limits

Issue D: Reduce the dose limit below 15 mrem/yr

1. I urge you to reverse the decision to allow radioactivity from Yucca Mountain to come in contact with the environment and its people. Most recently the National Academy of Sciences came out with study results that indicated that no amount of radiation was good for people. The amounts that the EPA is willing to expose people to are far too high. (Comment 0158-1)

2. The EPA's dose limits for the 10,000 years after closure are within the range of most countries of 10-30 millirem per year is too high for the amount of radiation exposure we are encounter through a year. Exposure from living next a nuclear power plant is 1 millirem per year. With the increasing sources of natural and man-made produced radiation, the EPA should consider a lower threshold for the Yucca Mountain Project for the overall acceptable emission to 5-10 millirem per year for the first 10,000 years after the closure of the repository. (Comment 0265-1)

3. EPA should instead adopt a standard that limits exposure to less than the minimum exposure standard proposed by any body world wide. (Comment 0275-3)

4. Even a dose level of 15 millirem per year, which would be in addition to other sources, is impermissible if future public health is to be protected from high-level waste radiation damage. (Comment 0331-1)

5. Apart from the role of EPA in determining human exposure standards from the time of repository closure to 1,000,000 years, EPA indicates that much decision-making latitude will be permitted for DOE and NRC in a Yucca Mountain licensing process, if there is one. For that reason, it is imperative that EPA exercise its standards-setting responsibility with a maximum of precaution, revising downward toward zero exposure. (Comment 0331-8)

6. No risk is acceptable. No Nevada resident wants to live near a nuclear dump. (Comment 0367.2-16)

Response to Issue D:

Comments in this section generally expressed the opinion that our individual-protection standard should be lower than the 15 mrem/yr level established for the initial 10,000 years after disposal. Comment 0158-1 points to the BEIR VII study as concluding “that no amount of radiation was good for people.” (Docket No. EPA-HQ-2005-0083-0430) Comment 0331-1 similarly takes the position that 15 mrem/yr is insufficiently protective of public health. In response to the first comment, the BEIR VII study concluded that there is insufficient evidence to support the concept of a “threshold” below which radiation exposure conveys no risk, or that such risks are not proportional to the exposure (e.g., if the exposure doubles, the risk also doubles). EPA and other regulatory bodies continue to apply the “linear no threshold” approach in radiation protection. However, the BEIR VII committee did not conclude that radiation exposure conveys no benefits to consider against the potential risks. The 15 mrem/yr level is consistent with the Agency’s overall risk range, has been successfully implemented for periods of 10,000 years, and is protective of public health. See Issue H of this section, as well as Section 5, for more discussion of the health aspects of radiation in general and our standards in particular.

Several other comments supported a lower standard, but for other reasons. Comment 0265-1 suggests revising the standard to account for “increasing sources of natural and man-made produced radiation,” suggesting instead a level of 5 to 10 mrem/yr. Our mandate under the EnPA is to address releases of radionuclides from the Yucca Mountain disposal system. The standards we have established to address that specific source of radiation are protective of public health and the environment. We do not believe it is useful to speculate about the potential increase (or decrease) in radiation from other sources that may take place over the next several thousand years. See Issue N of this section for more discussion of other sources of radiation.

Comments 0275-3 and 0331-8 express skepticism about performance assessment modeling and the NRC licensing process. Commenter 0275 considers modeling to be unreliable and therefore recommends the standard be “less than the minimum exposure standard proposed by any body world wide,” as well as more stringent in other ways, such as comparing the 95th percentile value of projected doses to the dose standard. Commenter 0331 views NRC as having too much latitude in decision-making. A lower standard would indicate a “maximum of precaution” on our part. We do not believe the commenters’ suggestions are appropriate. Modeling is the primary tool available to estimate performance over very long time frames, and its capabilities must be considered along with its results. We agree that there are limitations to performance modeling, but do not agree that the emphasis should then be on extreme situations, which we believe would result from the first commenter's approach. Nor do we believe such an approach would be consistent with the intent of the NAS committee (see Issue C of this section and Section 7). Further, the limitations in providing "proof" of performance for periods of 10,000 years or longer have been widely recognized, leading to our adoption of the "reasonable expectation" principle. NRC does have latitude in reaching that determination, which it will have to defend in adjudicatory proceedings. Reasonable expectation also discourages reliance on extreme assumptions, whether conservative or optimistic. See Section 17 of this document.

Finally, Comment 0367.2-16 implies that the dose level should be zero, since "no risk is acceptable." We have never stated or believed that geologic disposal is expected to provide perfect containment for all times. It has always been assumed that releases, and subsequent exposures (assuming the presence of people whose characteristics would lead to exposures), will occur. Our responsibility is to establish standards for such releases that will protect public health. We do not interpret this responsibility as requiring that no person at any time will have the potential for exposure. Further, we do not regulate any other contaminant or activity to zero risk.

Section 2 Dose Limits

Issue E: Insufficient rationale to support the increase after 10,000 years

1. The Environmental Protection Agency says in its explanatory statement that "Given the increased uncertainty that is unavoidable in the capabilities of science and technology to project and affect outcomes over the next 1 million years, the concept of reasonable expectation underlying our standards implies that a dose limit for that very long period that is higher than the 15 mrem/yr limit that applies in the relatively "certain" pre-10,000-year compliance period could still provide a comparable judgement of overall safety." (Federal Register Vol. 70, p. 49029, 2005) This justification does not make sense. If one were designing a bridge whose steel and concrete performance became more uncertain with time, would one loosen or tighten the structural design standards if one realized that the bridge was going to have to provide safe transport for a longer period of time? The EPA has not provided an adequate justification for the large relaxation in stringency of the dose limit after 10,000 years. This comment does not address the question of whether the less-than-10,000-year standard is too restrictive or the greater-than-10,000-year standard is too lax. It only addresses the failure to provide a logical rationale for loosening the standard in the face of greater uncertainty. (Comment 0167-1)

2. Standards should not be "degraded" simply because a certain amount of time has elapsed. If a standard is set for a legitimate reason, it should remain intact until an equally legitimate reason is found to make an adjustment. The adjustment should be performance based and not simply because a time limit has passed. (Comment 0223-1)

3. With no valid explanation, EPA increased the radiation exposure limit to 350 millirems per year after 10,000 years. Needless to say, Yucca Mountain would then meet the new radiation standard. There is not enough evidence or a clear rational argument for not leaving the radiation standard the same after 10,000 years. There was no overriding rationale for lowering the standard for future generations. (Comments 0360-2 and 0363-2)

Response to Issue E:

The thrust of these comments is that uncertainty alone is not a sufficient rationale for departing from the 15 mrem/yr standard for the 10,000 year compliance period, and that EPA has not provided sufficient rationale for using increasing uncertainty as a justification for establishing the peak dose limit (Comments 0360-2, 0363-2,0223-1, and 0167-1). In response to these comments and others, the Agency performed some generalized site-specific modeling (uncertainty analysis) to: examine the effects of uncertainty in dose projections over the time to peak dose and gain some insight on the implications of uncertainty in very long-term dose projections on the issue of setting a peak dose limit (Docket Nos. EPA-HQ-OAR-2005-0083 0414 and EPA-HQ-OAR-2005-0083 0429). The actual performance of the disposal system at Yucca Mountain may be better or worse than that shown in our projections for a hypothetical system. One modeling exercise (Docket No. EPA-HQ-OAR-2005-0083-0386) was performed to provide some insight on the effects of uncertainties on a reference disposal system for the site that was at the "edge of compliance" at the 10,000 year time, i.e., a hypothetical disposal system was set-up as a reference starting point where the disposal system was delivering a mean dose of 15 mrem/yr at 10,000 years. The behavior of this reference case was then modeled under expected site conditions through the time of peak dose. The details of this modeling work and the results are contained in reports in the rulemaking docket (Docket No. EPA-HQ-OAR-2005-0083-0386), and briefly explained below along with their implications for the rulemaking.

The 15 mrem/yr mean dose limit was chosen as the reference case starting point for our uncertainty analyses because it is the dose limit established in 40 CFR part 191 and is also the 10,000-year dose limit in the proposed and final standards. Although the 15 mrem/yr limit is in the generic standards (40 CFR part 191) originally promulgated in 1985, it was intended to apply to any deep geologic repository site, and as such, it serves as a suitable starting point for examination of the Yucca Mountain site. However, this dose limit was specifically restricted to a performance period of 10,000 years in 40 CFR part 191 (as amended in 1993), based on the belief that increasing uncertainty after that time would reduce the credibility of such dose projections to such an extent that regulatory decision making would become overly burdened with speculative assessments of performance (58 FR 66401, December 20, 1993). However, the NAS recommendation to set a standard at the time of maximum risk within the period of geologic stability, and in response to the Court's findings, the Agency has had to re-examine the question of establishing a peak dose limit.

With the development of long-lived waste packages and highly corrosion resistant alloys, performance assessments of the Yucca Mountain disposal system (Docket No. EPA-HQ-OAR-2005-0083-0085) showed that the period of maximum risk would be well beyond the 40 CFR part 191 compliance period of 10,000 years, which was also the concern expressed by NAS. To examine both the subject of increasing uncertainty in performance projections and the implications for setting an appropriate and protective peak dose limit, the Agency has modeled a hypothetical Yucca Mountain disposal system that would be at the "edge of compliance" at 10,000 years, i.e., it would be delivering a mean dose of 15 mrem/yr to the RMEI. The analyses address the question – What would be the variations in dose projections for a hypothetical disposal system at Yucca Mountain that was performing at that level (mean dose of 15 mrem/yr at 10,000 years) when the time frame for the assessments increased to peak dose. This analysis examined the effects of uncertainty in natural barrier performance on dose projections, since the number of waste packages deliberately failed to generate the mean 15 mrem/yr reference case starting point was held constant for the rest of the time period to peak dose. The spread in dose estimates between the initial 10,000-year time period and the longer period time period at peak dose were compared to determine the effects of uncertainties on the projected doses over that time period. These assessments were possible because of the large database of site-specific information now available from characterization studies for the site, and the advances in performance assessment technology since 1985 (Docket No. EPA-HQ-OAR-2005-0083-0085).

The analyses showed that for a reference disposal system constructed to allow a mean dose rate of 15 mrem/yr at 10,000 years as a starting point, and allowed to continue to release radionuclides (from the fixed number of waste packages needed to result in the starting mean of 15 mrem/yr dose rate) under the ranges of site conditions over time, the uncertainties seen in the projections increased from 1.5 (at 10,000 years) to 3.5 orders of magnitude at peak dose, an increase of approximately two orders of magnitude. This level of uncertainty indicates that there is a considerable increase in the range of the dose projections. Peak doses for various modeling choices for this hypothetical system varied from approximately 160 to 400 mrem/yr. For a system where the early waste package failures result in a mean dose of 15 mrem/yr at 10,000 years and additional waste package failures continue to occur beyond that time, peak dose estimates would be considerably higher than those for our modeling exercise where the waste package failures were not permitted to increase after the 10,000 year time line. From this perspective, the 100 mrem/yr peak dose limit should not be regarded as a "loosening" of the 10,000 dose limit but is actually very strict in that it constrains the disposal system to keep waste package failure rates extremely low over long periods of time (tens to hundreds of thousands of years) in order to keep the peak dose below the 100 mrem/yr limit. Again, the actual performance of the disposal system at Yucca Mountain may be better or worse than that shown in our projections for a hypothetical system, which is based on a simplified site model that is not as complex as DOE's (Total System Performance Assessment) model.

The fundamental premise underlying these uncertainty assessments is that the 40 CFR part 191 dose limit was limited to 10,000 years, and was not intended to imply that a repository had to limit projected releases to that level indefinitely (see the preamble to the final amendments and Issue B of this section for more information). Results of our analyses address the two objectives mentioned above: (1) assessing the nature and extent of increasing uncertainties on dose projections over time and (2) providing some insight into the question of uncertainty in setting dose limits for the peak dose. The modeling results show that there is a meaningful quantitative increase in uncertainty in making dose projections.

We also examined the behavior of the Yucca Mountain disposal system with respect to "driver" processes that control the timing and magnitude of the peak dose and the general capability of the performance assessment tool to meaningfully distinguish between alternative conceptualizations of the disposal system (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083 0429). Results of these assessments illustrated that inherent uncertainties involved with probabilistic performance assessments and the uncertainties in data selection and scenario development for very long-term assessments limit the ability of the performance assessment tool to distinguish between some alternative conceptualizations of the disposal system.

Our results demonstrate that uncertainties in dose projections increase significantly over very long time frames. This observation supports the general assumption made about increasing uncertainties in the original 40 CFR part 191 standard. It also confirms the general thrust of international guidance on the subject of heavy reliance on numerical dose projections in the very long-term, referenced in the preamble to the proposed rule (70 FR 49036, August 22, 2005) and discussed in the preamble to the final rule and Section 4 of this document. With these uncertainties in mind, the degree of confidence possible in meaningfully distinguishing between alternative assumptions about the performance of the natural barrier, or alternative designs for engineered barrier components, decreases significantly over very long time frames. This increasing uncertainty makes regulatory compliance decision making more difficult and subject to speculation. Alternative assumptions about natural barrier performance reflected in alternative site conceptual models, or alternative designs of natural barrier components, may not be distinguishable if their effects on dose estimates are small compare with the wider variations that reflect the uncertainties in performance of the total disposal system over these very long time periods.

Comment 0167-1 makes the analogy between uncertainty increases and the real world options for setting design requirements for engineered materials and structures such as bridges. The analogy is not correct in that is confuses two very different situations. For engineered materials and structures such as bridges, in-service monitoring and maintenance are assumed to take place and remediate any detected failings. For deep geologic disposal in contrast, the disposal system is intended to operate passively during the compliance period, i.e., without the need for human intervention by monitoring or remediation.

Section 2 Dose Limits

Issue F: The 10,000-year standard

1. The near-term standard requiring DOE to demonstrate that a person living 11 miles away from the Yucca Mountain site would be exposed to no more than 15 millirem of radiation per year during the first 10,000 years of repository operations appears reasonable. This conclusion is based upon the fact that a routine chest x-ray emits 10 millirem, and a mammogram emits 30 millirem, medical procedures which Lincoln and White Pine County residents voluntarily undertake. (Comment 0211.1-3)

Response To Issue F:

This comment requires no response.

Section 2 Dose Limits

Issue G: EPA is backpedaling from its previous position on more than 15 mrem/yr

1. EPA has backpedaled from its previous stance that a 150 millirem is unacceptable. Four years later, the EPA has ignored its own stated position and instead proposed a standard for the Yucca Mountain project that's more than twice that. (Comments 0103-6, 0127-2, and 0145-6)

2. NAS noted that a "general consensus exists among national and international bodies on a framework for protecting public health," placing a limit of 100 millirems per year on continuous or frequent exposures from *all* anthropogenic non-medical radiation sources. *Id.* at 4. Following this apportionment principle, this consensus would assign to high-level waste disposal only 10 to 30 millirem per year. *Id.* at 4. (Comment 0226-2)

3. In its June 2001 Response to Comments document addressing its previous iteration of Part 197, EPA thoroughly rejected a suggestion that it should consider gradually relaxing its Yucca Mountain radiation standard over the progression of time. The commenter making this suggestion had proposed allowing the 15 millirem/year standard to increase to 150 millirem/year from 10,000 to 100,000 years, and to 1.5 rem/year from 100,000 to 1 million years. EPA rejected this proposal as "flawed," offering the observation that "[n]o 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." Responses to Comments at 3-8.

In its previous Yucca rulemaking, EPA vigorously defended 15 millirem/year as the appropriate public health and safety standard, rejecting additional suggestions that the standard could be relaxed to 70 millirem/year or even 25 millirem/year. EPA emphasized that "EnPA instructed us to write standards 'based upon and consistent with' the findings of NAS. The annual risk basis of the 15 mrem limit…is within the range of annual risk levels which NAS suggested." Responses to Comments at 4-5 (citing NAS Report at 5). A key part of EPA's rationale was therefore to conform its standards to risk levels suggested by NAS, corresponding to a range between 2 and 20 millirem/year. In its final rule, EPA observed that its adoption of the 15 millirem/year standard was based in part on the NAS Report, noting also that “[t]his level is 15% of the ICRP- recommended total dose limit. It falls within the range of standards used in other counties and the range recommended by NAS, and is also consistent with the individual-protection requirement in 40 CFR part 191.” 66 Fed. Reg. at 32088 (June 13, 2001).

In its defense of the 15 millirem/year standard, EPA disagreed "particularly strongly" with a commenter who recommended a 70 millirem/year standard as “adequately protective,” noting that the risk level associated with that standard “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.” Responses to Comment at 4-5, 6. EPA noted that a 70 millirem/year standard would result in “a risk level at Yucca Mountain that is significantly higher than any facility that falls under 40 CFR part 191, such as WIPP and future radioactive waste disposal facilities”; and would violate well-established norms of apportionment, because “70 mrem from one source is too high a proportion of the annual 100 millirem recommended by NCRP and ICRP (excluding background, occupational, accidental, and medical sources).” *Id*. at 4-5. On similar grounds, EPA even rejected several suggestions for a 25 millirem/year standard, concluding that even that level would be “higher than that recommended by the NAS.” *Id.*

The proposed rule fails entirely to support EPA's dramatic retreat from the consensus position of NAS and other regulatory and advisory bodies, including EPA's express rejection of a similar two-tier standard. EPA concedes that it earlier “rejected similar approaches” to that it now proposes, and expressly rejected a 150 millirem/year standard as one that “no regulatory body we are aware of” considered acceptable. 70 Fed. Reg. at 49031. Absent from EPA's new discussion is any reason to believe regulatory bodies would now consider that standard, much less one more than twice as lenient, acceptable for the general public. Instead, EPA's rationalizations seem to underscore the arbitrary and legally dubious nature of the new proposed rule. Most notably, EPA does not explain how its previous conclusion that such levels were inconsistent with the NAS's recommendations can now be dramatically reversed. (Comment 0226-4)

4. The unacceptable health risks posed by EPA's proposed 350 millirem/year (1000 millirem/year mean equivalent) standard should not be surprising, for a 350 millirem standard is higher than anything EPA, or any other regulatory body, ever has approved before. The NAS report recognized an existing international consensus supporting substantially more stringent protections. *See* NAS Report at 41. NAS recommended a starting point for EPA's rulemaking consistent with that international consensus. As EPA itself has acknowledged, that would produce a standard in the range of 2-20 millirem/year, far lower than the standard EPA now proposes.

In its prior rulemaking, EPA recognized that deviating from this international consensus and from this NAS recommendation would be inappropriate, and rejected as unsafe proposals to set standards well below the 350-millirem standard it now proposes.

Those past conclusions indicate that EPA has consistently viewed proposed standards much lower than the one it now proposes as unprotective of public health, internationally unprecedented, and beyond the limit of responsible regulation. This also applies to the EPA's proposal to adopt a two-tiered approach to the human intrusion performance assessment. (Comment 0226-6)

5. EPA's Colorado rationale is flatly inconsistent with EPA's past standards and conclusions, and with the NAS's recommendations. Although EPA has been regulating anthropogenic radiation exposures for decades, it has never used this type of standard or invoked this natural background rationale before. Instead, its consistent past practice has been to follow the international consensus and allow a maximum of 100 millirem/year of anthropogenic exposures *from all sources combined*, and to allow individual sources to contribute no more than 15 millirem/year of exposure, a level it noted was consistent with the NAS's recommendations (a range of 2 to 20), and that EPA continues to assert is appropriate for Yucca Mountain in the pre-10,000-year period. 66 FR 32088 (15 millirem/year is "within the NAS-recommended range"); *see* NAS Report at 41 (describing the international consensus supporting this level). EPA has viewed the 15 millirem/year level of protection as consistent with the specific recommendations of the NAS report.

In soundly rejecting suggested 25 millirem, 70 millirem, and 150 millirem standards, EPA never hinted that existing natural background levels in other places somehow would have made those higher levels appropriate. *See* EPA Response to 46 Comments at 4-5 to 4-6. Instead, EPA has taken the consistent position that 15 millirem is the reasonable limit on anthropogenic exposure from one source. Likewise, where the NAS spoke of natural background as a benchmark for acceptable exposures, it referred only to the "concept of negligible incremental dose (above background levels)," a concept that suggests that repositories should cause negligible incremental changes—not a doubling—of existing background levels. *See* NAS Report at 8-9 (parentheses in original). (Comment 0226-49)

6. EPA has for decades declared radiation doses above 15 to 25 millirems per person per year to be inadequate to protect public health. EPA has also gone on record that doses above 100 millirems per year produce unacceptable levels of risk. We urge EPA not to abandon this position that exposures from all nonmedical man-made sources be limited to 100 millirems per person per year. (Comments 0293-9 and 0302-2)

7. The proposed rule is EPA's attempt to comply – or get around – the court's order. EPA proposes a protective standard of 15 millirem/year for the first 10,000 years, and then a dose limit 23 times higher for the remainder of a million years. This 350 millirem/year proposal is a higher permissible dose than EPA has ever said is acceptable from radiation to the public from nuclear activities; higher than any international body indicates is acceptable for a public dose from planned exposures; and grossly outside EPA's historical risk range. (Comment 0296-1)

8. NAS made clear that the consensus among national and international bodies was there is a limit of 100 mrem/yr effective dose for continuous or frequent exposures from all man-made sources other than medical. To suggest that 350 mrem/yr is based upon or consistent with the NAS recommendations is absurd. (Comment 0311.1-6)

9. Over the last 30 years, EPA has repeatedly lowered the allowable radiation dose to the public. The administrative record is replete with EPA's own statements of what constitutes a protective standard, repeatedly rejecting 150 mrem/yr, and even 70 mrem/yr for the standard (EPA response to Comments, 40 CFR 197, at 3-8 (2001). (Comment 0311.1-7)

10. In describing the implications of its conclusions and the common elements with 40 CFR 191, NAS noted that "EPA has endorsed the dose limit and *dose-apportionment* recommendations of the ICRP. We endorse this approach." (Comment 0311.1-8)

11. In the past, the EPA has been extremely specific about what it believes to be the level of risk from exposure to anthropogenic radiation that is acceptable today. In an April 1997 statement on the Nuclear Regulatory Commission's standard governing licensing termination which set a 25 millirem per year dose limit with the potential for exposures to go up to 100 millirem per year under certain conditions, Ramona Trovato, the Director of the EPA's Office of Radiation and Indoor Air, concluded that "a cancer risk of 1 in 250" would be "simply unacceptably high." (Comment 0314.1-10)

12. An August 1997 memorandum from Stephen D. Luftig, the Director of EPA's Office of Emergency and Remedial Response, and Larry Weinstock, the Acting Director of the EPA's Office of Radiation and Indoor Air, reiterated these conclusions and included an analysis which stated that the 25 to 100 mrem per year dose limit proposed by the NRC was considered to "present risks that are higher than levels EPA has found to be protective for carcinogens in general and for radiation, in particular, in other others contexts." In setting previous regulatory standards, the EPA has repeatedly taken the position that a lifetime incremental risk greater than 1 in 10,000 would be unacceptable. This level of "acceptable" risk has been codified in the National Emission Standards for Hazardous Air Pollutants, the National Primary Drinking Water Standards, and the guidelines for cleanup of sites under the Comprehensive Environmental Response, Compensation, and Liability Act. In addition, the draft federal radiation protection guidance proposed by the EPA on December 24, 1994 also specified a goal of limiting the lifetime risk from exposure to cancer to less than 1 in 10,000. Finally, this level of "acceptable" risk is implicit in the use of the 15 millirem per year dose limit for Yucca Mountain during the first 10,000 years. (Comment 0314.1-11)

13. What is most disconcerting to the City is that EPA has previously rejected a radiation standard less than the level proposed for Yucca Mountain based on public health grounds. In its June 2001 Response to Comments document addressing its previous iteration of Part 197, EPA rejected gradually relaxing the Yucca Mountain standard over time. EPA stated

that "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." Additionally, in its previous Yucca rulemaking, EPA defended 15 millirem per year as the appropriate public health and safety standard, rejecting additional suggestions that the standard could be relaxed to 70 millirem per year or even 25 millirem per year. EPA's consistent past practice has been to follow international consensus and allow a maximum of 100 millirem per year of anthropogenic exposures from all sources combined, and to allow individual sources to contribute no more than 15 millirem per year. (Comment 0341-3)

14. These proposed standards clearly contradict the EPA's own assessment that radiation doses of 100 mrem/yr produce unacceptable levels of risk. (Comment 0349-4)

15. We do think that there would be under the proposed standards gross violations of scientific, ethical, and public health principles that consistently have characterized much of the conduct around proposals for Yucca Mountain. … We do believe that it doesn't meet minimal public health and safety requirements. Now proposing a 350 millirem per year exposure limit, …. is truly vastly outside what even your current rules say is acceptable. … a dose of 350 millirem per year does lead to a cancer risk of approximately one in 36, vastly outside the risk limits that we've been talking about together over the years of one in 10,000 to one in a million. (Comments 0368.2-1, 0368.9-4, and 0368.13-7)

16. EPA itself has for decades declared any radiation dose above 15 to 25 millirems per year to be inadequate to protect the public health. … gone on record that doses of 100 millirems per year produce unacceptable levels of risk. In its own final rule for the first Yucca Mountain radiation standard, EPA wrote in its response to a comment opposing 70 millirems per year standard, quote, "The risk level associated with 70 millirems 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. (Comment 0368.6-9)

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

A number of commenters questioned how we could propose to establish limits higher than those we had previously considered inappropriate or outside the Agency's risk range. Commenters 0226, 0311.1, 0341, and 0368.6 note that we rejected suggestions that we establish dose levels above 15 mrem/yr in our 2001 rulemaking. We did so in two instances. First, we rejected such suggestions regarding the 10,000-year standard, where we are retaining the 15 mrem/yr dose level. We believe this represents the appropriate level of protection for the initial 10,000-year period. In the second instance, we rejected suggestions that we should establish higher dose levels for the period beyond 10,000 years. We did so primarily because we believed it would be inappropriate to set a numeric compliance limit for times up to 1 million years, given the uncertainties involved at this extended time frame. We chose instead to require longer-term projections, but not to compare them to a specific compliance limit. NRC would then have flexibility to consider those projections in its licensing decision to the extent it deemed appropriate. In rejecting this suggestion, as the commenters note and we acknowledged in our proposal (70 FR 49031, Docket No. EPA-HQ-OAR-2005-0083-0001), we stated that "no regulatory body that we are aware of considers doses of 150 mrem to be acceptable." However, we also stated that "the uncertainties involved in very long-term assessments would make it more difficult to judge compliance with any numerical standard" (70 FR 49031-49032) and that "[s]etting a strict numerical standard at a level of risk acceptable today for the period of geologic stability would ignore this cumulative uncertainty and the extreme difficulty of using highly uncertain assessment results to determine compliance with that standard" (66 FR 32098, Docket No. EPA-HQ-OAR-2005-0083-0042). We did not attempt to project what that peak dose standard would have been, or the basis for its selection, had we chosen to establish one. In view of the language in the D.C. Circuit's decision and the weight accorded by the Court's decision to the committee's technical recommendations concerning the period of geologic stability, we are now in the position of establishing a peak dose limit applicable for the period of geologic stability. After considering factors related to the ability to project or control incremental doses at such long times and the role of our standards in the NRC licensing process, we proposed 3.5 mSv/yr (350 mrem/yr) as a level that would appropriately address those factors and "accommodate" our policy concerns. After considering substantive public comments opposing that proposed level, however, we are establishing an individual-protection standard of 1 mSv/yr (100 mrem/yr) to apply for the period beyond 10,000 years. This level is consistent with the overall public dose limit recommended and accepted by international organizations such as ICRP, IAEA, and NEA, as well as in the United States by NRC, DOE, and NCRP.[3] Adoption and acceptance by these organizations and entities of the 100 mrem/yr level as protective provides a clear basis for our determination that this standard will protect public health and safety in the far future.

Following the recommendation of the NAS, and extending the compliance period to 1 million years, a regulatory time frame unprecedented in this country, prompted us to

[3] Although it had used the concept of public dose limits previously, ICRP first described its recommendations for a comprehensive system of radiation protection in Publication 60 ("1990 Recommendations of the ICRP"). ICRP considered two referents in recommending a public dose limit: health detriment and "variation in the existing level of dose from natural sources." ICRP concluded that estimates of health detriment "suggest a value of the annual dose limit not much above 1 mSv." Similarly, "[e]xcluding the very variable exposures to radon, the annual effective dose from natural sources is about 1 mSv, with values at high altitudes above sea level and in some geological areas of at least twice this. On the basis of all these considerations, the Commission recommends an annual limit on effective dose of 1 mSv." (Docket No. EPA-HQ-OAR-2005-0083-0421, Paragraphs 190-191) ICRP re-affirmed this position in its most recent recommendations: "For public exposure in planned exposure situations, the Commission continues to recommend that the limit should be expressed as an effective dose of 1 mSv in a year." (Publication 103, Docket No. EPA-HQ-OAR-2005-0083-0423, Paragraph 245)
This recommendation was adopted in the 1996 International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, which was jointly sponsored by IAEA, NEA, the Food and Agriculture Organization of the United Nations, the International Labor Organization, the Pan American Health Organization, and the World Health Organization. (IAEA Safety Series 115, Schedule II, Docket No. EPA-HQ-OAR-2005-0083-0409)

contemplate the nature of public health protection over such times. As discussed in Issue B of this section and the preamble to the final rule, we do not believe it is appropriate to view a standard applicable for as long as 1 million years from within the Agency's traditional risk-management framework, and would not view a projected dose of 100 mrem/yr in the far future, with all the attendant uncertainties, as comparable to a 100 mrem/yr dose incurred today, or even projected to occur within 10,000 years. We conclude that it is appropriate to approach the post-10,000-year peak dose standard from a broader perspective of protectiveness. We proposed in the NPRM that the variation in background radiation across the U.S. could provide a basis for evaluating the significance of releases from the Yucca Mountain disposal system. We are not, however, using background radiation as the basis for our final long-term standard. We are instead adopting a level consistent with the widely-recommended overall public dose limit, which NRC applies to individual licensed operations today (10 CFR 20.1301).[4]

Commenters 0226, 0293, 0302, 0311.1, 0349, and 0368.6 raised the issue of apportionment, an approach in which individual sources or practices are regulated such that exposure to multiple sources or practices will not exceed an overall dose limit, which ICRP recommends be set at 100 mrem/yr. The commenters again questioned how we could propose a standard higher than 100 mrem/yr when we have in the past endorsed the apportionment approach. As with the range of risks suggested by NAS as a "starting point" for EPA's consideration, the standards we have established and successfully implemented for periods of 10,000 years are consistent with the apportionment approach. However, we do not believe it is either required or reasonable to apply the traditional approach to apportionment, which we have viewed as consistent with the risk-based standard we are applying for the initial 10,000-year period, over very long time frames, nor do we agree that NAS recommended an apportionment approach be applied in determining the peak dose standard (see also Section 24, Issue B of this document). NAS discussed the concept and concluded that it had been widely adopted (NAS Report pp. 40-41). However, NAS also noted that "guidance to date has been for expected exposures from routine practices. There is little guidance on potential exposures in the far distant future." (NAS Report p. 41) NAS made no specific recommendation that EPA apply the concept to Yucca Mountain, let alone how the concept should be applied.

We noted in our proposal that ICRP itself took a similar view in its Publication 81, "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste," stating that "as the time frame increases, some allowance should be made for assessed dose or risk exceeding the dose or risk constraint. This must not be misinterpreted as a reduction in the protection of future generations and, hence, a contradiction with the principle of equity of protection, but rather as an adequate

[4]Although this issue is no longer relevant, we do note, however, that the 100 mrem/yr level also reasonably comports with an analysis of background radiation as well; even when radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally, and is within the difference between average estimates for counties in the State of Nevada. (Docket No. EPA-HQ-OAR-2005-0083-0387) See Section 3 of this document for more discussion of background radiation.

consideration of the uncertainties associated with the calculated results" (Docket No. EPA-HQ-OAR-2005-0083-0087).[5] We view statements such as this as providing the additional guidance on interpreting long-term projected exposures that NAS found lacking. If we wish to acknowledge that "some allowance should be made" in this regard, "adequate consideration of the uncertainties associated with the calculated results" must be incorporated into the peak dose limit we select (see Section 6 of this document for discussion of uncertainty). Selecting 100 mrem/yr as the long-term dose standard strikes a middle ground between modifying the apportionment approach (e.g., with a somewhat higher dose constraint with the goal of maintaining total doses close to 100 mrem/yr) and rejecting it altogether. By doing so, we accept 100 mrem/yr as a standard that protects public health and safety and maintains a connection to ICRP's recommended system of radiological protection. Maintaining the 10,000-year standard at 15 mrem/yr is consistent with the long-held international view of 10,000 years generally as a demarcation point prior to which projections can be reasonably well-managed and apportionment applied, but beyond which projections become progressively more uncertain. Our final standards are protective of public health, meaningful, implementable, and provide for a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation.

Moreover, we note that under 10 CFR 20.1301, NRC requires that licensees conduct operations so that the total effective dose equivalent to individual members of the public from "the licensed operation" does not exceed 100 mrem/yr. Thus, this regulatory limit applies to individual licensees operating today, without reference to other potential sources of exposure to the public. Of course, some types of NRC licensees, such as fuel cycle facilities subject to our standards in 40 CFR part 190, must meet dose constraints lower than the 100 mrem/yr limit. Nonetheless, 100 mrem/yr is the public dose limit from licensed operations imposed in NRC regulations. Readers may object that all licensees are required to keep public doses As Low As Reasonably Achievable (ALARA), which provides another check on exposures. However, recognizing the uncertainties inherent in projecting disposal system performance over hundreds of thousands of years, and understanding the nature of the licensing process, it is reasonable to anticipate that DOE would make every effort to ensure its projected doses were as low as possible even without such a requirement. For this reason, NAS saw no reason to support an ALARA provision, equating it with "sound engineering practice." (NAS Report p. 125) Consistent with the NAS position, we have not included an ALARA requirement in our rule.

[5] Similarly, IAEA states, in discussing the application of an apportionment approach ("Safety Requirements for Geological Disposal of Radioactive Waste" (WS-R-4)): "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. *Care needs to be exercised in using the criteria beyond the time when the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making*." (Paragraph 2.12, emphasis added) Thus, IAEA recognizes in this consensus document the general agreement of the geologic disposal community that, while apportionment does apply to geologic disposal, it cannot be assumed to apply indefinitely. Moreover, IAEA reaches this conclusion on the basis of uncertainty in projecting exposure from a specific long-term source, without regard to the presumed knowledge, or lack thereof, of other potential sources of exposure.

Finally, as we discussed in our proposal, given our statutory responsibility to establish a site-specific standard, we believe that allocation of 100 mrem/yr to a single source at the time of peak dose in the far future is reasonable, as other contributors in the Yucca Mountain area are negligible by comparison (FEIS, DOE/EIS-0250, Section 8.3.2, Docket No. EPA-HQ-OAR-2005-0083-0086). By relying on current conditions, as recommended by NAS, rather than speculating on future sources of exposure to the local population, it is reasonable for EPA to allocate the entire 100 mrem/yr to the Yucca Mountain disposal system. By assuming that current conditions will apply in the future, we are applying an approach routinely applied internationally, as well as by EPA in its WIPP compliance criteria (the "future states" assumption at 40 CFR 194.25).[6]

As Commenter 0226 notes, we referred in our 2001 rulemaking to the NAS starting risk range as "recommendations." Because the "starting range" suggested by NAS was fully consistent with the dose limits and time frames in 40 CFR part 191, as well as with the time frames of the other regulatory precedents identified by NAS for EPA to consider, we saw no reason to view NAS as anything other than supportive of the 15 mrem/yr level for the initial period after disposal. (NAS Report p. 49) We therefore considered our previous decisions on this point as providing consistency with the NAS position for the time periods over which both could be said to apply, a fundamental legal requirement under the EnPA. From that perspective, our narrow view of the NAS suggested "starting range" did not acknowledge the broader discussion of the range of risks represented by the domestic and international regulations identified by NAS for EPA to consider, "all of which are consistent with recommendations from authoritative radiation protection bodies," and which included the ICRP-recommended public dose limit of 100 mrem/yr. (NAS Report p. 49 and Tables 2-3 and 2-4) However, NAS did not offer recommendations on the final peak dose limit, or suggest a range of risks that it believed to be scientifically justifiable for the final standard, leaving the final decision as a policy choice. Instead, NAS explicitly declined to recommend a level of protection, recognizing that this was a matter best left to EPA to establish through rulemaking: "We have not recommended what levels of risk are acceptable…The specific level of acceptable risk cannot be identified by scientific analysis, but must rather be the result of a societal decision-making process. Because we have no particular authority or expertise for judging the outcome of a properly constructed social decision-making process on acceptable risk, we have not attempted to make recommendations on this important question." (NAS Report p. 20) Indeed, NAS explicitly acknowledged "that determining what risk level is acceptable is not ultimately a question of science but of public policy." (NAS Report p. 5) Further, NAS noted that the final outcome of the rulemaking might diverge substantially from the starting point suggested by NAS: "Finally we have identified several instances where science cannot provide all of the guidance necessary to resolve an issue…In these cases, we have tried to suggest positions that could be used by the responsible agency in formulating a proposed rule. Other starting

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

positions are possible, and of course *the final rule could differ markedly from any of them*." (NAS Report p. 3, emphasis added) We believe NAS understood that dose projections would effectively become increasingly stylized as the time period covered by the assessments increased, and that a compliance standard applicable for times approaching 1 million years might be different in some important respects from their recommendations. For example, NAS acknowledged that "it is obviously impossible to predict in detail either the nature or the timing of future climate change" (NAS Report p. 77), and the committee's frequent references to "bounding" and other approaches reflect its concern that effectively addressing long-term uncertainties would be critical in implementing compliance assessments over periods of this length. (e.g., NAS Report pp. 9, 19-20, and 79) NAS's statement that "the final rule could differ markedly from" the "starting point" implicitly acknowledges that there might be valid reasons for departing from standards we (and others) had previously established for much shorter time frames. (NAS Report p. 49) Indeed, NAS noted a similar consideration in reaching its recommendation, stating that "selecting a time scale for analysis involves weighing how the scientific basis for analysis changes with time against the timing at which more numerous future health effects are likely to occur." (NAS Report pp. 30-31) We believe it is reasonable to consider not only how the scientific basis for the analysis changes, but also the demands of the regulatory process, in making the policy selection of a long-term peak dose standard applicable for times as long as 1 million years. Therefore, contrary to the view of Commenter 0311.1, we believe our consideration of the factors affecting the "feasibility" of compliance assessments at such times is consistent with the statements of the NAS committee. Commenter 0226 also suggests that the NAS committee's view of background radiation is reflected in its discussion of "the concept of negligible incremental dose (above background levels)." (NAS Report pp. 7-8) The commenter takes this to mean that the committee believed "that repositories should cause negligible incremental changes – not a doubling – of existing background levels." We disagree that the concept of "negligible incremental dose" is relevant to our establishment of an individual peak dose standard, for two reasons. First, NAS clearly intended this concept to address the potential that a much wider population outside the critical group (or RMEI) might receive very small doses, leading to statistically significant health impacts. NAS viewed this as a condition upon which the individual-protection standard would adequately protect the general public ("provided that policy makers and the public are prepared to accept that very low radiation doses pose a negligibly small risk." (NAS Report pp. 7-8). Second, the level of "negligible" dose (or risk) represented a level "that can, for radiation protection purposes, be dismissed from consideration." (NAS Report p. 59) Thus, far from an expression regarding the level of radiation exposures that should be regulated, or how that level should be derived, NAS was addressing levels that it recognized would be much lower, and suggesting they should not be regulated. We declined to adopt the NAS position, although for different reasons we agreed that the individual-protection standard would adequately protect the general public. See 66 FR 32094-32095.

Finally, Commenter 0314.1 refers to Agency statements and directives taking the position that doses of 25 mrem/yr are insufficiently protective. As the commenter notes, these statements and directives were issued in the context of site cleanups, license termination, and release of sites for unrestricted use. We do not agree that criteria applicable to remediation of existing contamination, even if very significant, are comparable to standards established to assess compliance of a geologic disposal system over hundreds of thousands of years. See Section 1, Issue C of this document for more discussion of this point. As noted above, our 10,000-year standards take an approach consistent with the statements and directives cited by the commenter.

Section 2 Dose Limits

Issue H: Impacts of radiation

1. EPA's proposal fails to consider the so-called "bystander effect," in which radiation produces changes in cells that were not directly hit by it but are in the vicin… (Comments 0103-7 and 0145-7)

2. In fact, Executive Order 13045 that requires federal agencies to specifically address the potential impact to children¹s health and safety was summarily ignored. The EPA believes there exists no disproportionate impact to children. Children are NOT negligible. (Comments 0130-7 and 0195-8)

3. Published data that clearly indicates that small amount of radiation can have a significant impact on the unborn and very young children. Dr. Abram Petkau, head of the Medical Biophysics Branch of the Canadian Atomic Energy research laboratory in Manitoba, announced over 30 years ago that chronic low-level nuclear radiation exposure produced far worse damage to living tissues than high-dose, short-term exposure. He named this the Petkau Effect. …

The Petkau Effect seems to cause damage to those cells, which are responsible for the body's resistance to disease. Swiss engineer and nuclear hazards expert Ralph Graeub explains in his expose of nuclear radiation hazards, the more drawn-out the radiation (the Petkau Effect), the lower the total dose required to break the membrane. Small doses of radiation can be more dangerous than large ones and low-level radiation magnifies all health risks. Small increases in the continuous radiation such that will be emitted by the stored high level nuclear waste will not be neutralized and thus cause significant impact to the very young and the very old, both who have a low immune system. (Comment 0131-2)

4. A group called The Radiation and Public Health Project (RPHP) (www.radiation.org) is a nonprofit educational and scientific organization, established by scientists and physicians dedicated to understanding the relationships between low-level, nuclear radiation and public health have been measuring the amount of SR-90 released and the impact on young children. They have collected and continue to collect baby teeth, and using the zip code have correlated the impact of very low level continuous radiation and the health of the children.

DOE with the approval of the EPA is attempting to do something that has never been done. Beat Mother Nature. EPA must show how the Executive Order 13045 will be met with the proposed radiation limit in light of the RPHP data. The proposed EPA must not be adopted until the conflicts are resolved. (Comment 0131-3)

5. 1) By what criteria and through what procedure(s) will the EPA positively determine that any given manifestation of disease is or is not radiation induced (once Yucca Mountain is in operation)?
2) What value constitutes the EPA proposed acceptable death rate per year resulting from EPA permissible level(s) of radiation emissions by the Yucca Mountain Repository? Is the much quoted value "one fatality per million per year" EPA generated?
3) What is the expected rate of onset of radiation-induced disease per year, from which will flow the EPA acceptable death rate per year?
4) By what methods does the EPA intend to measure and verify that the actual rate of disease onset and the actual death rate (resulting from EPA permissible radiation emission levels) are those that were predicted and deemed acceptable?
5) What are the anticipated forms of fatal radiation-induced disease in order of prevalence (by percentage) affecting the doomed individual(s)?
6) What is the expected average survival time and medical treatment cost of the doomed individual(s) between positive diagnosis of onset of radiation induced disease and death?
7) What are the anticipated forms of radiation-induced disease in order of prevalence (by percentage) among the population of non-fatal cases, within which the doomed individual(s) form a subset?
8) What is the expected average medical treatment time and medical treatment cost of those individuals rendered chronically (but not fatally) ill, as a result of radiation-induced disease? (Comment 0196-1)

6. Does E.P.A. know or presupposed if the dosages are "safe" or have the possibility of being the devastating cause of radiation disease deaths in Nye County? There have been no NCI reports for six years. (Comment 0198-3)

7. Is the figure "one person per million"(per year?) chosen to be allowed to die from radiation exposure correct? Is this the allowable death rate? (Comment 0198-4)

8. EPA ignore the bystander effect. And it's very clear in the recommendation, they [NAS] are making a reference to the 10 millirem by standard federal recommendation for research. (Comment 0209.1-2)

9. The proposed EPA standard, if ultimately adopted, would allow future residents of Nevada to suffer 100 times more radiation exposure from releases than levels the federal government currently permits to residents living near nuclear power plants. (Comment 0209.6-4)

10. You have willingly ignored the potential effect that this project could have on children, women, and the Native-American people we have in our state. We find this to be an unjust and irresponsible policy. (Comment 0209.13-3)

11. We blew up [a bomb] at Hiroshima, … there's a big city right there. … They're not dying, they're living, just where the atomic bomb was blowed up at. (Comment 0210.2-1)

12. Shroeder-Freschette said that 350 mrem/yr causes about three percent of all the fatal cancers in the U.S. If EPA permitted air polluters to follow such logic, they could save money and increase profits by claiming victims' health risks were acceptable merely because they were no worse than those caused by natural events. (Comment 0210.3-5)

13. I heard you say that the mountain could withstand earthquakes and everything else, but what if there's a freaky accident, and it happens within? How would we -- how would I tell that I've been exposed? I mean, what are the side effects if I'm exposed? (Comment 0211.2-1)

14. The EPA website states there is no safe level of exposure to radiation. Radioactive groundwater contamination from the Yucca Mountain repository is inevitable due to its siting in a geologically unstable area riddled with hundreds of known earthquake faults. After the lethal contamination reaches Lake Mead, less than 100 miles away, it eventually will be carried down the watershed into the Baja California where it will be dispersed into the Pacific Ocean. How much radioactivity will it take to kill the ocean? We don't know. How much radioactivity will it take to kill us? The ingestion of minute amounts will do the trick. (Comment 0211.3-1)

15. There are over 200 radioactive substances produced in nuclear reactors. Many of them have exceeding long half-lives. For example, Plutonium-239, one of the most poisonous substances known to man, has a half-life of 24,000-plus years. It causes genetic damage that is carried through subsequent generations without additional exposure. Genetic damage, in practical terms, means that your grandchildren won't look like you, and their grandchildren won't look human. If there are any. (Comment 0211.3-2)

16. It appears that the USEPA not fully incorporate findings and conclusions of the National Academy of Sciences' report on Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII report (13) into their proposed new EPA radiation standard for YMP. The … BEIR VII report identified some additional ways that radiation causes responses … in cells; processes which had not yet been recognized at the time of the last NAS report on this subject (BEIR V). Among these responses are: ... the "bystander effect", …and "Genomic instability" … While EPA used … the phrase "calculated dose and or radiation", it is our opinion that instead of using the above phrase there is a need for experimental data to verify assumption used both by DOE and EPA. (Comment 0214-2)

17. It is our opinion that the EPA should have taken a second look at epidemiology studies at Chernobyl accident and Three Mile Island concerning cancer risk before issuing their final radiation standard for YMP. .. epidemiological studies using the National Cancer Registry … in the Republic of Belarus … have shown a significant excess of incidence of cancers of the colon, urinary bladder, and thyroid gland, when compared with a corresponding adult population of the Vitebsk region. (Comment 0214-4)

18. However, the EPA should include some additional plain language explanations about possible radiation exposure and the health risks of the limits set in the proposed rule. This will help the public put in perspective inaccurate statements by repository opponents about the so-called “great danger” Yucca Mountain could pose to future generations. (Comment 0217-1b)

19. The final rule also needs to include perspective on the relative danger to the public posed 15 and 350 *mrem*/year levels. EPA should point out that repository worker dose limits during the preclosure period are set by the NRC at 5,000 *mrem*/year, per 10 CFR Part 63, which NRC believes adequately protects worker health. Even the 350 *mrem*/year dose limit is orders of magnitude less than what workers at the repository are allowed to be exposed to as well as others in the nuclear and medical field. (Comment 0217-7)

20. EPA's proposed rule is totally lacking any analysis of the health and safety implications of a 350-millirem (1000-millirem mean equivalent) standard. Such an oversight is not merely arbitrary and capricious; it represents irresponsible abdication of EPA's Congressionally defined regulatory role.

Had EPA performed any such analysis, the results would be obvious: the proposed standard creates a virtually limitless future of unreasonable risks. Nevada's health and safety consultant has completed the very analysis that EPA has declined to perform, and concludes (based on accepted correlations between radiation dose and adverse health effects) that exposure to a 350 millirem additional annual dose over a lifetime would create a 4.8 percent increase in adult risk of fatal cancer. Furthermore, the radiation dose that could be received in three to six years would be in the range over which a 40 percent increase in the cancer rate in children has been directly observed. [See Appendix A.] EPA offers no rationale explaining why such increases are acceptable. It should come as no surprise that the President of National Council on Radiation Protection (the premier expert U.S. body on radiation standards and science) strongly criticized the EPA proposal as inconsistent with long established national principles of radiation protection at a November 14, 2005 presentation to NRC’s ACNW. …

[Appendix A] provides a summary of the international literature and regulations concerning dose standards to further support the view that 350 millirem/year constitutes an unreasonable and dangerous incremental anthropogenic radiation source. [It] concludes among other things that EPA has selectively and misleadingly quoted from overseas and international sources in an effort to support its rule, and that the rule would allow an increase in cancer risk that no other regulatory body considers acceptable, even for geologic disposal. (Comment 0226-5)

21. EPA itself has acknowledged, as has the NAS, the general consensus views that natural background radiation levels are not "safe." The NAS noted that "[i]nternational scientific bodies currently accept what is called the linear, or no-threshold hypothesis for the dose-response relationship…. The no-threshold hypothesis holds that there is no dose, no matter how small, that does not have the potential for causing health effects." In its original 40 C.F.R. Part 197 rule, EPA, after discussing research on the health risks of radiation exposures, similarly noted that even natural background levels cause human harm. "We believe," EPA stated, "that the best approach is to assume that the risk of cancer increases linearly *starting at zero dose*. In other words, any increase in exposure to ionizing radiation results in a constant and proportionate risk in the potential for developing cancer." 66 FR 32080-81 (emphasis added). EPA specifically noted that the risk of anthropogenic radiation could not be considered in isolation, but instead must be considered in addition to the pre-existing risks created by background conditions. "The risk of interest," EPA stated, "is not at or near zero dose, but that due to small increments of dose above the pre-existing background level." *Id.* at 32080 n.6. It is for this reason that EPA in the past has always sought to keep anthropogenic exposures at levels well below background levels; it has respected the scientific consensus that even background levels kill. *See also* EPA, *A Citizen's guide to Radon*, OAR-2005-0083- 0058, at 2 (noting that background levels of radon kill an estimated 21,000 Americans every year, and that radon is a larger source of death than drunk driving). (Comment 0226-53)

22. Executive Order 13045 requires federal agencies to explicitly address the potential impact to children's health and safety. We see no evidence in this proposed rule that your agency has addressed this executive order. Does the EPA actually believe that there exists no disproportionate impact to children? (Comment 0268-4)

23. Human x-ray radiation accounts for about 79% of man made radiation exposure in the USA. High LET inhalation exposures due to radon are 52%; high LET for exposures ingestion is 5%, and cosmic radiation account for 4%. The natural background radioactivity in human tissue is in effect in equilibrium or steady state with the particular diet and water concentrations of the nuclide ingested. There is a slight deviation in body content which changes with age for a given exposure, and this has been recognized for ^{226}Ra and uranium isotopes. The low-LET directly ionizing photon component of cosmic radiation is 12%; low-LET radiation from earth exposure is 20%, and Low LET ingestion is 7% as cited in the BEIR VII report. It is unclear to us what type of radionuclide exposure are hypothesized in the EPA proposed new radiation standard what is the risk is relative mix of high or low LET exposures? (Comment 0270-6)

24. The important YMP health risk is posed by ingestion in contrast to background radiation where the principle concern is external radiation. Chronic exposure to internal radiation appears to be important according to Smith and Kemball in 1998. They concluded that chronic exposure to low activity sources may have the potential to become significant; this is of particular concern for internal doses of radiation...Finally, the EPA justifies the

new radiation exposure standards based on the radiation absorbed during routine x-rays. A typical dental x-ray, for example, results in 10 mRem of exposure and a mammogram produces 30 mRem. This analogy is misleading due to differences in the manner that one receives the radiation dose. Exposure to alpha radiation from plutonium in contaminated drinking water produces exposure to the entire body including bone marrow and other tissue that is sensitive to radiation damage. (Comment 0270-7)

25. Given that the reason EPA has to re-formulate this standard, a directive to comply with National Academy of Science guidance, I strongly recommend that the final standard take into consideration the BEIR VII observations that 70 year lifetime annual exposure to 350 millirem will lead to cancer in 1 in 40 men, 1 in 30 women, and even more in children. Of these incidents, half would be fatal. (Comment 0306-11)

26. Calculations of the 15 picocuries/liter limit for drinking water actually result in 713 millirem per year exposure, if 2 liters of drinking water at maximum "safe" levels are consumed per day. (Comment 0306-5)

27. Calculations for a 30 year exposure are very inappropriate. Local immigrant resident families are multi-generational, and Timbisha Tribal members are also likely to remain at their one homeland location in Death Valley. (Comment 0306-6)

28. 2 liters of water per day is absurd in this climate. Day-time temperatures can be over 125 degrees for a month or more. The most conservative estimates for daily water consumption are one gallon per person for an indoor sedentary lifestyle. A ranch worker in Death Valley drinking 12 liters a day for 70 years has an annual exposure of 4.278 rem at maximum permitted plutonium levels, and a lifetime exposure of about 300 rem. (Comment 0306-7)

29. EPA's and NRC's proposed allowance for 350 millirem per year radiation doses to people living downstream from the leaking dump - the, equivalent of about 58 full chest x-rays per year - will cause cancer, birth defects, and other maladies - as verified recently by the National Academies of Science Biological Effects of Ionizing Radiation (BETR VII) report -- at alarming rates and must be withdrawn. Current standards of 15 millirem per year from all pathways, and 4 millirem per year from drinking water, must be applied for the full million year regulatory period. (Comments 0310-2 and 0355-2)

30. The radiological impacts on children should be explicitly considered in the Department of Energy's performance assessments in order to ensure that they are not disproportionately affected by the repository. (Comment 0314.1-8)

31. International Commission on Radiological Protection leading to the development of age specific dose conversion factors for ingestion and inhalation. These dose models were published between 1989 and 1996 as a series of five ICRP reports that reveled that, for many radionuclides, children can receive higher doses than adults for the same level of ingestion or inhalation. These dose models have been adopted by the European Union's European Basic Safety Standards and the International Atomic Energy Agency's International Basic Safety Standards.

Following the publication of these ICRP reports, the EPA's 1999 Federal Guidance Report 13 included a discussion of the heightened cancer risk from radiation with decreasing age at exposure. The CD supplement to Federal Guidance Report 13 issued by the EPA in 2002 included an extensive database of both dose and risk coefficients for ingestion and inhalation showing a heightened risk to children from exposure to many radionuclides. Finally, the BEIR VII Committee has published the most up to date review of the available scientific information, and has made specific recommendations regarding age specific risk coefficients for exposure to low-level radiation. (Comment 0314.1-16)

32. Incredibly, EPA has claimed that "the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children." EPA, asks for evidence to the contrary. I would refer EPA to the work of Alice Stewart and George Kneale for starters (dating back to the 1950s, when Alice Stewart first proved that x-ray doses to the fetus in-utero causes cancer, leukemia, and other maladies) which shows clearly that children are disproportionately vulnerable to radiation's harmful impacts to health. Specifically, EPA should review the following peer-reviewed scientific studies. (Comment 0324-10)

33. Executive Order 13045 requires federal agencies to explicitly address the potential impact to children's health and safety. We see no evidence in this proposed rule that your agency has addressed this executive order. Does the EPA actually believe that there exists no disproportionate impact to children? (Comment 0328-3)

34. Without endorsing EPA's suggested repository annual dose limit of 350 mrem, it is noted that this limit is well below the dose at which physiological impacts to the human body from radiation can be discerned. Also, the proposed limit is below radiation exposure levels experienced by many people today, both occupationally and from natural background radiation. (Comments 0330-2 and 340-6)

35. The EPA should also review this ICRP Report and incorporate its findings on low dose impacts in further re-evaluation of exposures to future human populations. Merely offering token reductions in the permissible annual doses is insufficient. (Comment 0331-2)

36. For the 350 mrem/yr CEDE, it has been estimated that one in thirty-six persons so exposed will develop cancer. Such an exposure, we are told by the industry and its regulators, is now the "average exposure" experienced by members of the public from "background" radiation (including indoor radon). EPA must respond to the obvious question: what would be the total exposure from all radiation sources in the future for those who would also receive the maximum dose from the disposal facility plus "background" and doses from any of many other sources? What would be the biologic toll on recipients? (Comment 0331-5)

37. In the initial discussion of the "Reasonably Maximally Exposed Individual" (RMEI), EPA identifies this individual as an adult presumably male individual - the "Standard (or Reference) Man," who would be the equivalent of the nuclear industry worker of existing public dose standards. The persons for whom the exposure standard should be set are members of the public who are embryo, fetus, rapidly growing young child, pregnant woman and her ova, the elderly, and those with previously impaired health. All health and genetic impacts now associated with radiation exposures -- not only cancers and their risks -- must be included in the dose calculations. (Comment 0331-7)

38. In Section 197.2, Appendix A The values assigned for "radiation incident on the body or, for internal sources, emitted from the source" may have been generalized from available information, but they may not accurately represent the internal organ doses that are received by recipients other than the "reasonably maximally exposed individual" resident farmer (or other) -- who represents "standard man". The W R value for alpha particles remains at 20, despite research indicating that it is or may be substantially higher. A most conservative value would better provide a margin for error in our present beliefs of the hazard. The use of generalized weighting factors for organ doses fails to address the potential adverse impacts on actual dose recipients. (Comment 0331-9)

39. Not only would these horrifically lack standards cause cancer, but they would drastically increase birth defects, genetic damage, and other maladies. (Comment 0349-1)

40. The proposed level of protection at the time of peak dose is consistent with position statements of…[t]he Health Physics Society [which] has noted that there is substantial and convincing scientific evidence of health risks following high-dose exposures. However, the Society notes that below 5 to 10 rem (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are nonexistent. The Society…recommends against quantitative estimation of health risks below an individual dose of 5 rem/yr, or a lifetime dose of 10 rem (equivalent to an average annual dose of about 125 mrem) above that received from natural sources. The Society further notes that estimation of health risk associated with radiation doses that are of similar magnitude as those received from natural sources should be strictly qualitative and encompass a range of hypothetical health outcomes, including the possibility of no adverse health effects at such low levels. (Comment 0352-21)

41. It starts with the false idea that since too much radiation is harmful, some or any radiation is harmful. This is simply not how it works. There is evidence that areas with higher background radiation have better health, surprising as that seems. In any case, the amount of radiation exposure added by SNF shipments and storage is to small to make any difference, positive or negative. (Comment 0356.1-3)

42. If workers can face up to 500 millirems/year why is the public limit 350/year? (What is the threshold of negative health effects?) (Comment 0367.1-2)

43. Why aren't the recommendations of the Bier Report incorporated into the Standards? (Comment 0367.2-1)

44. Is EPA considering the effects of different types of radiation? (Comment 0367.2-3)

45. For the first 10,000 years, people exposed to … a lifetime cancer rate of one in 835 people. Then it dooms future generations to a new radiation standard of one in 36 cancer rate. …. This is a complete violation of EPA's responsibility to protect public health and the environment. A standard based on a one in 36 cancer rate is not a standard. It is a death sentence. This proposal to allow 350 millirem per year radiation doses to people living downstream … would cause cancers, birth defects, and genetic damage. (Comments 0368.1-3 and 0368.12-3)

46. I think there's been a consistent and deliberate attempt to downplay the effect of radiation on human health. (Comment 0368.15-1)

Response to Issue H:

Many of the commenters in this section have made reference to the risk estimates that EPA uses for assessing the impacts of radiation exposure. The comments were generally phrased in relation to the proposed peak dose standard of 3.5 mSv/yr (350 mrem/yr). We are not establishing the proposed 350 mrem/yr level as our final peak dose standard; instead, we are establishing 1 mSv/yr (100 mrem/yr) as the standard to apply for the period beyond 10,000 years and up to 1 million years. Because the comments addressed fundamental issues involved in estimating risks from radiation exposure, however, we are responding to the comments on this topic.

Using a conversion factor of 5.75×10^{-7} fatal cancers per mrem, our final peak dose standard of 1 mSv/yr (100 mrem/yr) represents a nominal annual risk of fatal cancer of 5.75×10^{-5}, or 5.75 in 100,000 (we note that NAS applied a smaller conversion factor of 5×10^{-7} fatal cancers per mrem). This is comparable to the range of risks represented by domestic and international regulations that NAS suggested EPA consider, and which NAS stated were "consistent with recommendations from authoritative radiation protection bodies" (Comments 0196-1 and 0198-4 appear to refer to the low end of the NAS starting range in their references to "one in a million per year"). (NAS Report p. 49 and Tables 2-3 and 2-4) EPA does not consider this level of risk to be excessive in the context of a standard applicable for the period from 10,000 years to 1 million years, given the increased uncertainty in dose projections and the questionable assumption that current risk estimates can be applied to the extreme far future. Risk correlations for any time frame (even the present) cannot be considered absolute and precise, particularly when applied in a prospective manner to the behavior of a disposal system that will operate passively for hundreds of thousands of years. When time frames on the order of 1 million years are considered, it is reasonable to view the nominal risk associated with the 100 mrem/yr peak dose standard as a reasonable level of risk. We are focusing discussion of the risk associated with the peak dose standard on annual risk, as this was the metric considered appropriate by the NAS committee, although it did not recommend a particular risk level. The Agency has determined that this standard will protect public health and safety.

Comments 0103-7, 0145-7, 0209.1-2, and 0214-2 (in part) refer to the bystander effect and ask why EPA did not consider it in setting the Yucca Mountain post-10,000 year standard. The bystander effect is one of the key areas of low dose effects research being funded by DOE and others around the world. ("Health Risks from Exposure to Low Levels of Ionizing Radiation" (BEIR VII), Docket No. EPA-HQ-OAR-2005-0083-0430, p. 314) It refers to experimental observations that cells in the vicinity of a cell hit by radiation show responses similar to the directly damaged cell. There are two reasons why we did not consider the bystander effect in this rulemaking. First, the experimental results are not always consistent and the biological mechanism behind the response is still being debated. Some experiments show a net beneficial impact and others an increased detriment. Also, most of the experiments are conducted in vitro and may not be reproducible in vivo. Therefore, we must conclude that the science is not mature enough to have an impact on our regulation. The second reason is that we rely on over 100 years of direct observations of the harmful effects of radiation on humans. Chief among the studies we rely on is the Life Span Study of the survivors of the atomic bombs in Hiroshima and Nagasaki, Japan. These epidemiological studies remain the best evidence we have for quantifying the apparently linear dose response of excess cancers resulting from radiation exposure. (BEIR VII, Docket No. EPA-HQ-OAR-2005-0083-0430, Chapter 6)

Comments 0130-7, 0131-2, 0131-3, 0195-8, 0209.13-3, 0268-4, 0306-11, 0314.1-8, 0314.1-16, 0324-2, 0324-10, 0328-3, and 0331-7 assert that EPA has not properly accounted for the disproportionate risk to children from exposure to ionizing radiation. Many of these comments claim that we have ignored Executive Order 13045, *Protection of Children From Environmental Health Risks and Safety Risks* (62 FR 19883-19888, April 23, 1997). In fact, the risk to children is explicitly accounted for in EPA's radionuclide cancer risk coefficients (Federal Guidance Report 13, EPA-HQ-OAR-2005-0083-0072). EPA's standards, whether risk-based or dose-based, are designed to be protective over a lifetime of exposure. Lifetime dose or risk is obtained by adding an individual's age-specific dose or risk for each year of exposure. Therefore, the somewhat higher risks per unit dose to infants and children are greatly offset by their receiving most of their total lifetime dose as adults.

Comment 0131-2 refers to the Petkau Effect in stating that chronic exposure at low levels of radiation can be more harmful than high doses, and that there is increased harm to fetuses, very young children, and the elderly from chronic exposure. Since the observations referred to as the Petkau Effect are from in vitro observations following a radiation dose of 700 millirads delivered over about 12 hours, they are not relevant at the level of the individual-protection standard (for low-Linear Energy Transfer (LET) radiation, the radiation weighting factor is 1, so 1 millirad is equivalent to 1 millirem – see the response to Comment 0331-9 below) Our standard would equate to a dose rate several thousand times smaller than that required for the alleged effect. (Docket No. EPA-HQ-OAR-2005-0083-0415) Nevertheless, EPA agrees that infants and children are at higher risk from radiation and that is why our standard is designed to be protective for all ages over a lifetime of exposure. Variations in risk at each age are accounted for in our risk model.

Comment 0131-3 refers to the studies of strontium-90 (Sr-90) in teeth conducted by the Radiation and Public Health Project (RPHP). The commenter suggests that the risks to children are higher than EPA's current estimates. EPA has examined the RPHP data and found serious flaws in the epidemiological methods used. For example, NRC reports on radionuclide releases from nuclear power plants consistently show that Sr-90 releases are far too low to account for the trend reported by RPHP (EPA-HQ-OAR-2005-0083-0381, EPA-HQ-OAR-2005-0083-0382). Further, RPHP has not identified the exposure pathway leading to the claimed increases. The most likely source of Sr-90 in deciduous teeth is milk. EPA's monitoring data show that Sr-90 levels in milk have been declining since the cessation of atmospheric nuclear weapons testing ("Historical Summary of Strontium-90 in Milk Surrounding the New Jersey/New York City Metropolitan Area," Docket No. EPA-HQ-OAR-2005-0083-0404). No environmental sampling was performed by RPHP to substantiate claims that Sr-90 concentrations in milk or any other media near nuclear power plants are different from concentrations in other parts of the country. For these reasons, we do not believe the studies referenced by the commenter are credible.

Comment 0196-1 asks a series of questions but makes no specific comment regarding the proposed amendments. The commenter is referred to EPA's cancer risk assessment methodology as described in Federal Guidance Report No. 13 [Cancer Risk Coefficients for Environmental Exposure to Radionuclides, EPA 402-R-99-001, Sept. 1999; (Docket No. EPA-HQ-OAR-2005-0083-0072)] and other relevant reports of the National Research Council of the National Academies of Science, such as the BEIR VII report, "Health Risks from Exposure to Low Levels of Ionizing Radiation," The National Academies Press, 2006 (EPA-HQ-OAR-2005-0083-0430), for answers to the risk-related questions asked in this comment. Questions about future health care delivery in the vicinity of Yucca Mountain are outside the scope of our standard-setting role.

Comments 0198-3, 0198-4, and 0209.13-3 refer to the harmful effects of radiation, question whether EPA has adequate knowledge to quantify these effects, and further question the acceptability of the risks that EPA has deemed acceptable for various exposure scenarios. Our estimates of cancer risk from radiation exposure are based on human data, primarily epidemiological studies of the Japanese atomic bomb survivors and, for radon risk, studies of underground uranium miners. (For discussion of Japanese survivor studies, see Chapter 6 of the BEIR VII report, Docket No. EPA-HQ-OAR-2005-0083-0430; for uranium miner studies, see the BEIR VI Report, "Health Effects of Exposure to Radon," Docket No. EPA-HQ-OAR-2005-0083-0426, particularly Appendices D and E) A small, but statistically significant, increase in excess cancers has been shown in these populations at cumulative exposures in the range of 5 to 10 rem above background. Estimates of excess cancer risk are assumed to vary linearly with dose below this observable range. Using this linear non-threshold (LNT) approach and detailed gender-, organ-, and age-specific data from these cohorts, we are able to estimate risks that are age and gender specific and integrate these risks to characterize the risk to an exposed population. Therefore, our risk estimates for a lifetime of exposure inherently account for variations in risk over a lifetime.

Comment 0209.6-4 states that our proposed peak dose standard of 350 mrem/yr is 100 times higher than the current NRC standard for residents living near nuclear power plants. This is incorrect -- the NRC facility limit is 1 mSv (100 mrem)/yr. For nuclear fuel cycle facilities, there are also other standards, such as EPA's regulations at 10 CFR part 190, that must be met. Nevertheless, since our standard beyond 10,000 years is now 1 mSv /yr, the NRC and EPA standards are comparable.

Comment 0210.2-1 implies that the current-day situation in Hiroshima, Japan, should mean that there is no risk from Yucca Mountain in the future. There is no similarity between the residual radioactivity on the ground in present-day Hiroshima and the future activity of the in situ wastes in Yucca Mountain. The initial activity in Hiroshima was from fission and activation products which have relatively short half-lives and are now mostly decayed away. The activity in Yucca Mountain at the time of peak dose will come from the much longer half-life radionuclides present in the waste.

Comment 0210.3-5 attempts to draw a correlation between our proposed use of variations in natural background as a metric for judging Yucca Mountain's performance in the extreme far future (as detailed in the 2005 proposal) and the approach used for setting air pollution standards today under the Clean Air Act. The comment is editorial, but we note that the statutory requirements for setting the peak dose standard at Yucca Mountain are in the Energy Policy Act of 1992 and are unrelated to the requirements of the Clean Air Act.

Comment 0211.2-1 refers to very low probability events at Yucca Mountain and raises the question of how the commenter would know he or she has been exposed. We have explained elsewhere in this document how these low probability events have been dealt with (see Section 16 of this document). However, in general, the performance standards for the disposal system during the time to peak dose are set at a level where the receptor is protected without requiring he or she have any knowledge of the release or take any subsequent corrective action.

Comment 0211.3-1 refers to lethal doses of radioactivity in ground water eventually reaching the ocean. The estimates of peak dose from plausible releases from Yucca Mountain do not support the scenario raised by this comment. The water that moves below Yucca Mountain moves south and southeast in a closed basin and therefore, there is no physical pathway for any contamination to reach Lake Mead or the Pacific Ocean in the ground water. (See the 2001 BID, Docket No. EPA-HQ-OAR-2005-0083-0050)

Comment 0211.3-2 is a rhetorical statement about genetic risks from radiation exposure. Based on human epidemiology ["Health Risks from Exposure to Low Levels of Ionizing Radiation" (BEIR VII), The National Academies Press, 2006 (EPA-HQ-OAR-2005-0083-0430)], no observable genetic effects would be expected as a result of releases from Yucca Mountain at the level of our peak dose standard.

Comments 0214-2, 0310-2 and 0367.2-1 state that we did not fully incorporate the findings and conclusions from the NAS BEIR VII report. In fact, it will take us the next few years to incorporate the BEIR VII recommendations and make necessary updates to its risk assessment methodology. However, the overall risk estimates of the BEIR VII Committee are compatible with EPA's current risk estimates found in Federal Guidance Report No. 13 (FGR 13). [BEIR VII, p. 15 (EPA-HQ-OAR-2005-0083-0430); FGR 13, p. 182 (EPA-HQ-OAR-2005-0083-0072)] Any changes that result from our incorporation of BEIR VII would not likely have any impact on the individual protection standard.
Comment 0214-4 encourages us to take into account the results from epidemiological studies of populations exposed from the Chernobyl accident, particularly Belarus, and from the accident at Three Mile Island. We do not believe that there is any evidence of increased cancer incidence from the Three Mile Island accident, from which there were very low off-site doses. The commenter makes note of increased colon, urinary tract and thyroid cancers among exposed individuals. Current epidemiology shows a significant and increasing risk of thyroid cancer among those exposed as children from the Chernobyl accident. There are anecdotal reports of increases in other cancers among first responders and other highly exposed cohorts. This data is not yet statistically significant, but we continue to follow these studies. At present, the Chernobyl data does not indicate a need for us to make changes to ours risk estimates. See the 2003-2005 report of the Chernobyl Forum, Docket No. EPA-HQ-OAR-2005-0083-0419.

Comment 217-1b states that we should include some additional plain language explanations about possible radiation exposure and the health risks of the limits set in the proposed rule. We believe that the preamble of the final rule adequately presents understandable information about radiation exposure and risk associated with the standard. In the preamble, we state that the nominal annual risk of the 100 mrem/yr long-term peak dose standard is 5.75×10^{-5}, which the Agency has determined will protect public health and safety.

Comments 0217-7 and 0367.1-2 compare our proposed standards for exposures after 10,000 years with NRC's current standard of 5 rem per year for radiation workers (although Commenter 0367.1-2 incorrectly states that this limit is 500 mrem/yr) and suggest that this perspective should be highlighted in the rule. Exposure limits for workers are always higher than for the public for many reasons, e.g., voluntary vs. involuntary exposures. Therefore, we believe that this information is not germane to our Yucca Mountain standards, which apply to the health and safety of the general public, not workers.

Comment 0226-5 notes that we did not perform a health analysis for the post-10,000 year proposal. At extreme far future times, such an analysis becomes so uncertain as to be meaningless. As we discuss in the preamble to the final amendments, the approach that we have taken relies instead on setting a standard that requires a reasonable expectation that the period of peak dose in the next 1 million years will not cause the reasonably maximally exposed individual (RMEI) to receive more than 1 mSv/yr (100 mrem/yr). As discussed in the preamble, the 100 mrem/yr level is protective of public health and safety and constitutes a robust standard for public health protection in the far future. (70 FR 49040) International organizations such as ICRP, IAEA, and NEA recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Domestically, both NRC and DOE adopt the 100 mrem/yr level in their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, Docket No. EPA-HQ-OAR-2005-0083-0407). EPA therefore acknowledges and concurs in the broad consensus in the protectiveness of the 100 mrem/yr level that makes it especially suitable for application to the extreme far future, when planning for and projecting public exposures is much less certain.

This commenter also estimates that the excess lifetime fatal cancer risk from receiving 3.5 mSv per year (the 2005 proposed standard) for life is 4.8%, whereas EPA calculates a risk that would be close to 1.5 % for this extreme case. The commenter's assertion is also addressed in Section 5 of this document.

The same commenter (0226-5) quotes from the BEIR VII study a statement that "…studies of cancer in children following exposure *in utero* or in early life indicate that radiation-induced cancers can occur at low doses. For example, the Oxford Survey of Childhood Cancer found a '40 percent increase in cancer rate among children up to [age] 15.' This increase was detected at radiation doses in the range 10 to 20 mSv." The commenter then suggests that the proposed Yucca Mountain standard of 3.5 mSv per year received each year for 3 to 6 years could achieve doses in this range and result in exposed children having an excess cancer rate that is 40 percent higher than the baseline risk. The commenter has misinterpreted the BEIR VII report. The Oxford Survey of Childhood Cancer found the 40 % increase in the cancer rate among individuals who were exposed *in utero* to doses of 10 to 20 mSv. In other words, excess cancers were observed up to age 15 that could be attributed to the *in utero* dose, not to doses received over a period of years after birth. The maximum allowed dose that an embryo/fetus could receive under the final Yucca Mountain standard would occur over a 9-month period and likely be below 1 mSv and thus far below 10 mSv. EPA's current risk estimates take into account age-dependent differences in sensitivity to radiation. Comment 0270-9 in Section 5 of this document refers to the same study.

Comment 0226-53 refers to EPA's current position that background levels of exposure carry some risk of cancer under the Linear No Threshold model of carcinogenesis, an assertion that EPA supports.

Comments 0270-6, 0270-7, and 0367.2-3 refer to differences in low- and high-Linear Energy Transfer (LET) radiation and internal and external exposures as a function of the radionuclides contributing to the projected doses from Yucca Mountain. The commenters are referred to DOE for projections of which radionuclides are expected to be dominant contributors to projected doses across time. (DOE Final EIS, Chapter 5, Docket No. EPA-HQ-OAR-2005-0083-0086). EPA's standards are expressed as committed effective dose equivalents that explicitly account for differences in low- and high-LET radiation and internal and external exposure to different organs. Overall correlations between dose and risk are commonly used in establishing standards for long-term disposal.

Comments 0306-5, 0306-6, and 0306-7 refer to the doses from ground-water ingestion at the time of peak dose and take issue with EPA's ground-water ingestion pathway default exposure parameters (i.e., consumption of 2 liters per day). We believe that these comments are out of the scope of our present rulemaking since they pertain to the details of the ground-water standards compliance assessment which was not affected by the D.C. Circuit decision on the challenges to the 2001 standards.

Comments 0306-11 and 0324-2 refer to the risk estimates in the NAS BEIR VII report. The commenters calculate that the excess cancer incidence risk for 70 years exposure at 3.5 mSv/yr (the 2005 proposed individual protection standard) is 1 in 40 for men and 1 in 30 for women (2.5% and 3% excess risk, respectively). These calculations are slightly higher than the BEIR VII Committee's estimates of fatal cancer risk using their preferred risk estimates for low-LET radiation exposure (BEIR VII, Table ES-1, p. 15, EPA-HQ-OAR-2005-0083-0430). This comment also incorrectly interprets EPA's responsibility as being to "comply with National Academy of Science guidance." Apparently the commenter is referring to the ruling of the U.S. Court of Appeals for the District of Columbia Circuit that on July 9, 2004, remanded the portions of the standard that addressed the compliance period (Nuclear Energy Institute v. Environmental Protection Agency, 373 F.3d 1 (D.C. Cir. 2004). The BEIR "guidance" referred to by the commenter is unrelated to the court ruling regarding the Yucca Mountain report issued by the National Academy of Sciences in 1995 (Docket No. EPA-HQ-OAR-2005-0083-0076).

Comments 0330-2 and 340-6 are identical and are supportive of EPA's proposed standard, stating that the proposed standard reflected levels experienced by many people today from background radiation.

Comment 0331-2 urges EPA to incorporate ICRP's findings on low dose impacts. EPA does review and, where appropriate, incorporate the scientific data published by ICRP. Examples of how ICRP reports are used by EPA can be found in the response to Comment 0331-7 below.

Comment 0331-5 states that EPA should consider the total toll on the future RMEI from background radiation, releases from Yucca Mountain, and other sources. Any estimation of other sources of exposure are beyond the scope of EPA's statutory authority and this rulemaking. EPA's dose standard refers to the dose arising from radionuclides released from the waste emplaced in Yucca Mountain, and does not include the dose from natural background radiation.

Comment 0331-7 wrongly assumes that the RMEI is based on an adult male. In proposed Appendix A to 40 CFR Part 197 (70 FR 49064, Docket No. EPA-HQ-OAR-2005-0083-0001), EPA specifies that effective dose equivalent must be calculated using the tissue weighting factors from ICRP Publication 60 (ICRP 60) and the methodology for dose conversion found in ICRP Publication 72 (ICRP 72) (Docket Nos. EPA-HQ-OAR-2005-0083-0421 and 0427, respectively). The dose conversion factors (DCFs) in ICRP 72 are age-averaged values that account for age- and gender-specific differences in organ dose distribution and detriment.

Comment 0331-9 asserts that the radiation and tissue weighting factors used by EPA to calculate effective dose equivalent may underestimate the true dose, particularly regarding the W_R for alpha radiation. EPA's use of a W_R for alpha radiation of 20 is consistent with the recommendations of the ICRP (ICRP 60, p.6) (Docket No. EPA-HQ-OAR-2005-0083-0421) and the NCRP (NCRP Report 116, p. 20). (Docket No. EPA-HQ-OAR-2005-0083-0407) EPA believes that the value of 20 currently applied to alpha particles is reasonable. EPA also uses the tissue-weighting factors recommended by ICRP and NCRP to determine effective dose equivalent. In contrast to the commenter's assertion, these tissue-weighting factors may overestimate certain doses. The projected doses from the presumed dominant radionuclides at the time of peak dose, neptunium-237 (Np-237) and plutonium-242 (Pu-242) (DOE Final EIS p. 5-29) will lead to an overestimation of the bone surface dose that is the largest portion of the dose. The reason is that both the ICRP-26 and ICRP-60 tissue-weighting factors for bone surface are in reality the tissue-weighting factors for uniform deposition of a radionuclide in bone. The ICRP acknowledged that the current methodology overstates the risk to the bone from certain transuranic bone-surface-seeking radionuclides by a factor of about 5 (Puskin and Nelson, Health Physics, Vol. 63, No. 5, pp. 579-580; with response from ICRP on p. 590; Docket No. EPA-HQ-OAR-2005-0083-0394). Since dose is a surrogate for risk, it follows that the bone dose portion of the weighted effective dose equivalent will lead to an overestimation of the effective dose equivalent for these radionuclides.

Comment 0349-1 refers to the genetic effects and birth defects that would result from the proposed standard in addition to the excess cancers. These additional endpoints are accounted for in the tissue weighting factors used to calculate effective dose equivalent.

Comment 0352-21 states the position of the Health Physics Society that risk should not be quantified below individual doses of 5 rem per year or lifetime doses greater than 10 rem. The commenter further notes that there is a possibility that there are no adverse health effects at exposures of 3.5 mSv/yr (350 mrem/yr). While EPA uses the LNT model for calculating cancer risk at low doses, we also acknowledge that there is a possibility of no adverse effects. There is, however, insufficient evidence to fully define the dose response curve at very low doses, so EPA follows the recommendations of the ICRP, NCRP, NAS and others in assuming that the dose response is linear for all doses above zero.

Comment 0356.1-3 states that the doses from SNF shipments and storage will be too small to affect the Yucca Mountain dose compliance assessment. Since neither transport nor storage will be relevant dose pathways at the time of peak dose, this comment is outside the scope of the rule. The commenter also raises, as an aside, the possibility of a beneficial (hormetic) effect from the radiation. This possibility is not considered for the same reasons addressed in the response to Comment 0352-21.

Comments 0368.1-3 and 0368.12-3 refer to the possible health effects from the proposed 3.5 mSv (350 millirems)/yr standard as unacceptable, including cancers, birth defects, and genetic damage. The nominal annual excess cancer risk of the 100 mrem/yr peak dose standard is 5.75×10^{-5}, which the Agency has determined will protect public health and safety. The risk of birth defects and genetic damage from exposures at 100 mrem/yr is much smaller than the risk of cancer.
Comment 0368.15-1 indicates that EPA has attempted to downplay the effect of radiation on human health. This is incorrect. In setting a dose rate limit for up to 1 million years, a task unprecedented in U.S. regulatory history, EPA considered international guidance and regulations. The great majority of those guidance and regulatory approaches urged caution when establishing compliance standards over very long times because the uncertainty in projecting doses is so great that quantitative limits of the type applied for shorter times are not as reliable.

Section 2 Dose Limits

Issue I: Use qualitative standards

1. EPA should consider justifying qualitative performance standards based upon actual measurements to be taken at prescribed future intervals. The future capacity of any agency to regulate and enforce protection standards promulgated at this time is in all likelyhood even more uncertain than the projections of exposure rates at those future times. The emphasis should be on the safest disposal system we can engineer at this time, with provisions for monitoring and improvement when (and if) such future capacity exists. (Comment 0277-2)

2. Furthermore, the EPA acknowledges that it considered setting a long-term standard of 100 millirem or 200 millirem. Yet, in justifying their decisions to choose the weakest standard, the EPA essentially argued that given the time frame, there was essentially no difference between 100, 200, and 300 millirem of exposure. .... That is, when taking increasing uncertainties into account in the very long term, the effects of factors that would distinguish projections of 100, 200, or 350 millirem per year within a 10,000 year time frame are more difficult to identify clearly at very long times so that such projections may be qualitatively identical to each other. Yet, this begs the question, if the EPA maintains that these standards are essentially indistinguishable, why choose a number? (Comment 0368.10-6)

Response to Issue I:

The Energy Policy Act of 1992 requires EPA to "prescribe the maximum annual effective dose equivalent to individual members of the public." Furthermore, the NAS recommended that EPA establish "a standard that sets a limit on the risk to individuals." (NAS Report p. 2). Therefore, the Agency does not have the discretion not to establish a public health and safety standard in the form of a dose limit that prescribes the maximum annual effective dose equivalent to individual members of the public

With respect to requiring qualitative performance standards based upon actual measurements to be taken at prescribed future intervals (Comment 0277-2), we believe that it is unreasonable to assume that there will be monitoring programs for Yucca Mountain in place over the next 1 million years.

Section 2 Dose Limits

Issue J: Increase the proposed dose limit

1. I believe the proposed standard is excessively conservative, goes well beyond what is legally required, and is potentially environmentally counter productive because it may unnecessarily reject the Yucca Mountain repository site thus forcing society to unknown and potentially greater environmental risk waste management scenarios for spent nuclear fuel and high level radioactive waste. There is no risk free method for managing

radioactive waste. Unnecessary conservatism can result in de facto rejection of any geologic repository site resulting in significant negative safety, security, public health, environmental and economic impacts. Such unnecessary rejection, due to unrealistically conservative standards, leaves no known methodology for ultimate disposition of radioactive materials. Nuclear wastes exist, are currently being produced to support important societal needs, and will likely increase in the future because of climate, clean air and economic necessities. This current generation has an intergenerational responsibility to future generations for a solution to the waste material being made today. Unnecessarily stringent environmental standards for such unprecedented time periods can result in needless refutation of an acceptable solution and force society into a no solution alternative. Although strict very long term standards, as proposed, may sound environmentally protective, they may actually be counterproductive to the environment because they may force society into less environmentally benign nuclear waste management approaches. Unnecessary rejection of the Yucca Mountain site with its relatively low environmental impact for unknown approaches that our grandchildren will have to develop is just irresponsible societal environmental action by this generation. (Comment 0264-1)

2. …if EPA chooses to require a dose standard for the period of peak dose, the proposed 350mrem/yr standard should be increased to approximately the 1,000mrem/yr level to be consistent with radiation level risks that are commonly encountered in natural environments, e.g. thorium sands and radon deposits, or occupational environments, e.g. commercial airline workers. There is no need to require such a restrictive 350mrem/yr standard when there are no discernable impacts at higher levels. Overly restrictive criteria, like 350mrem/yr, increase the risk of rejection of a geologic repository and force society to look for unknown solutions. (Comment 0264-3)

3. The proposed radiation protection standards are far more restrictive than necessary. There is no realistic way that the material to be stored there can pose a public health hazard to people or the environment, even under extreme casualty conditions. (Comment 0269-1)

4. I believe the proposed standard is excessively conservative, goes well beyond what is legally required, and is potentially environmentally counter productive because it may unnecessarily reject the Yucca Mountain repository site thus forcing society to unknown and potentially greater environmental risk management scenarios for spent nuclear fuel and high level radioactive waste.

If EPA chooses to require a dose standard for the period of peak dose, the proposed 350 mrem/yr standard should be increased to approximately 1,000 mrem/yr level to be consistent with radiation level risks that are commonly encountered in natural environments, i.e. thorium sands and radon deposits, or occupational environments, e.g., commercial airline workers. (Comment 0351-1)

Response to Issue J:

We agree that our standards should provide a reasonable test of the overall safety of the Yucca Mountain disposal system. However, our standards similarly do not have the purpose of advancing geologic disposal as a concept. Our authority extends only to setting public health and safety standards for the Yucca Mountain disposal system; they are not based upon considerations of their impact upon other portions of the nuclear fuel cycle. We believe we have balanced the factors important to regulatory decision-making over very long times, the relative confidence that can be placed in projections over different time frames, and the nature of the current generation's commitment to future generations, as well as how that commitment can be demonstrated. Further, as discussed in more detail in the preamble to the final standards and in other sections of this document, we believe that the standards promulgated today will protect the health and safety of future generations while recognizing the uncertainties involved in projecting doses for up to 1 million years.

Section 2 Dose Limits

Issue K: Use a graduated standard

1. I do believe, however, that the proposed increase in the dose criterion at 10,000 years is too large to be reasonable over the entire time out to one million years. Rather, I would argue in favor of a more gradual increase to acknowledge that difficulties in projecting performance (i. e., increases in uncertainties) should not be as great within a few tens of thousands of years as they are beyond a few hundred thousand years.

Specifically, given the existing annual dose criterion of 0.15 mSv that applies for the first 10,000 years, I support using an annual dose criterion of 1 mSv from 10,000 to 100,000 years and, with one caveat described in the following paragraph [see Issue M, Comment 1], an annual dose criterion of about 3.5 mSv from 100,000 to 1,000,000 years. (Comment 0186-7)

Response to Issue K:

We agree with the commenter that the uncertainties involved during the unprecedented compliance period over which performance must be projected make an approach similar to the suggestion appropriate.

The Court remanded the standards based upon its judgment that we had not been consistent with the NAS recommendation of setting a standard for the time of peak dose within the period of geologic stability (which the NAS said would be on the order of 1 million years). Based upon preliminary information from NAS (NAS Report p. 6) and DOE, e.g., in the supplemental EIS, the peak dose will likely occur after several hundred thousand to 1 million years. In light of public comments, we have modified our approach and adopted a 1 mSv (100 mrem)/yr standard for the period between 10,000 and 1 million years. We believe this standard is protective of public health and adequately addresses our concerns regarding the increased uncertainty in long-term performance projections. Therefore, EPA has decided to maintain the transition at 10,000 years for the reasons articulated in the preamble for the final amendments and Section 4 of this document.

Section 2 Dose Limits

Issue L: Use a dose target

1. Given the uncertainties in projecting performance of the Yucca Mountain facility over very long times, I also think it would be better to round 3.5 mSv to one significant figure (either 3 or 4 mSv), even if EPA does not specify a gradual increase in the dose criterion. The difficulty I have with using 3.5 mSv is that a projected dose of 3.6 mSv would indicate noncompliance but a projected dose of 3.4 mSv would indicate compliance when the truth of the matter is that there is no significant difference whatsoever between those two doses. Thus, regardless of the dose criteria that EPA chooses to apply beyond 10,000 years, they should be presented in the regulations in such a way that it is clear that only one figure (digit) is significant. For example, if 1 mSv were chosen, the regulations should specify 1 mSv (0.1 rem), rather than 1.0 mSv (100 mrem). (Comment 0186-8)

2. …the Supplementary Information briefly considers an option of using a standard expressed as a dose target, rather than a limit. In my opinion, EPA has not given this option the consideration it deserves. Indeed, this may be an attractive option compared with using dose criteria expressed as limits that must be met (with "reasonable expectation"). The attractiveness of using a dose target, rather than a dose limit, is laid out in the report from the UK Environment Agencies (Docket No. OAR-2005-0083-0063) discussed in the Supplementary Information. To be sure, the approach used in the UK presents its own challenges, some of which are noted in the Supplementary Information. What I believe EPA needs to appreciate about use of a dose target, without specifying a dose limit in regulations, is this: The approach laid out by the UK Environment Agencies is largely the same as the approach to regulatory decision making in cleanup of contaminated sites under CERCLA (Superfund). Then, cleanup levels at each site are selected by a process of negotiation among all stakeholders. Thus, regulatory decision making in the absence of specified limits is something we have been through hundreds of times by now and is quite familiar. It is not something new and untried. There is another parallel between cleanups under CERCLA and disposal of waste at Yucca Mountain that is worth noting. Both are concerned with pre-existing situations that must be dealt with one way or another. Even if EPA does not wish to consider this option, I believe that EPA needs to be more thoughtful in dismissing it. It has advantages, and it is an option that most stakeholders would be familiar with, owing to striking parallels with the CERCLA decision process. (Comment 0186-20)

Response to Issue L:

As set forth in Section 2, Issue I, EPA must establish a specific peak dose limit; it does not have the discretion to adopt an amorphous standard. Further, not only does it fail to meet the basic mandate of the Energy Policy Act of 1992, an amorphous standard also fails to give NRC or DOE clear guidelines as to the necessary performance requirements for licensing. Comment 0186-8 suggests that the dose standard be expressed in one significant digit, presumably so the mean of the distribution of projected peak doses can be rounded to show compliance with the standard. However we believe the "reasonable expectation" principle employed in 40 CFR part 197 already gives NRC the flexibility and authority to consider the entire record before it and consider all aspects of the performance projections in finding a reasonable expectation of meeting the standard either has or has not been provided. We believe the Commission will use this flexibility with full integrity and cautiously. We do not believe that the Commission would issue a license unless it is fully convinced that there is "reasonable expectation" that the disposal system will perform acceptably.

Comment 0186-20 stresses the similarities between CERCLA sites and Yucca Mountain and the practice of negotiating clean-up goals. As we stated on page 49038 of the preamble to the proposed amendments: "We believe the circumstances involved in today's proposal are significantly different from the situations addressed under Superfund or any other existing U.S. regulatory program, and that it should be clear that comparisons between the two are inappropriate." That, together with the legal requirements in the Energy Policy Act of 1992, is why, despite the uncertainties involved, we need to establish a numerical limit.

Section 2 Dose Limits

Issue M: Peak dose calculation

1. Additionally, the supposed "peak" doses are not peak at all. They are merely averages of hundreds of computer runs with different input assumptions and tweaking of scenarios. Indeed, they are averages of different computer runs for the same point in time, rather than averages of the peak dose from each scenario. Peak dose – highest calculated dose to the public – which is what should be regulated by such a rule, is not at all. (Comment 0296-4)

Response to Issue M:

The commenter is referring to two calculational methods known as "peak of the mean" and "mean of the peaks." As noted by the commenter, "peak of the mean" is a calculation in which the mean of the results of "all computer runs" (or realizations) is calculated for increments in time. This results in a curve that represents the mean (average) value throughout the compliance period; where that curve peaks is the value used to compare to the dose rate limit. The "mean of the peaks" refers to finding the maximum dose of each realization, no matter when it occurs, and calculating the mean (average) of those values for comparison to the dose rate limit. The Agency has specified that the peak of the mean approach, termed the "peak mean dose" in 40 CFR 197.13, be used for the compliance determination, meaning that the peak of the curve that represents the arithmetic mean of the distribution of all the projections will be used. We believe NAS intended the peak of the mean be used, as indicated by its recommendation to assess compliance with the standard "at the time of peak risk." (NAS Report p. 2) There is no "time of peak risk" if the mean of the peaks is the measure of compliance.

The peak of the mean approach has the advantage of being a more realistic description of the range of potential receptor dose rates at all points during the compliance period, whereas the mean of the peaks approach cannot be considered to reflect the dose potential for the RMEI at any particular time since it averages peak dose rates that are separated in time. From a regulatory perspective, because it represents the evolution of the entirety of the disposal system over time, the peak of the mean may provide a more meaningful basis for decision-making. At each point in time, the progression of the individual realizations and the mean dose curve can be more easily viewed in relation to one another as indicative of "expected performance." The mean of the peaks, on the other hand, relies on the combination of specific points of distinct realizations that may make it more difficult to relate to the overall safety of the system, and the remainder of each realization is of no consequence in the evaluation of that system. Except perhaps in the extreme situation where all (or substantially all) of the realizations exceed the regulatory standard, it is not clear exactly what information the mean of the peaks conveys about the disposal system as a whole. There is further discussion of this issue in Section 7 of this document.

The Agency disagrees with the commenter's final sentence that indicates that the highest calculated dose to the public should be used for compliance. The Agency's reasonable expectation approach calls for extreme assumptions and results to be considered but not overriding. Nor should a focus on "expected performance" be interpreted as meaning that no person at any time will be exposed to doses above the standard. Therefore, a reasonable approach is to use the results that indicate where the preponderance of the performance is projected to be, i.e., neither the most pessimistic nor the most optimistic results. In addition, the commenter's approach would not be in concert with the NAS Report in which the NAS recommended using the mean of the calculations, not the theoretically highest possible outcome. (NAS Report p. 123)

Section 2 Dose Limits

Issue N: EPA must explain how other contributions are considered

1. I also want you to pay some attention to cumulative doses. With the nuclear industry and the nuclear cycle having to do with nuclear power, the limit is 100 millirem from all -- all sources. And when you come in with the 350, which is very, very, high, I'm not sure that's supposed to be added to background, which would now, I guess, include whatever is emitting from the low-level dose site that's nearby from the Nevada Test Site, from other nuclear activities out there. (Comment 0211.11-3)

2. The 10,000 years standard for a repository at Yucca Mountain was, I believe, arrived at, in part, by considering potential exposure to the residents of Amargosa Valley from radiation releases from other sources, with each source being allocated a maximum annual dose of 15 millirem. For the affected residents, these other source which would have the effect of increasing exposure over and above natural levels. The other potential sources of man-made exposure are the low-level radiological dump south of Beatty, the groundwater contamination from the nuclear weapon testing activities at the NTS, and releases from the wastes deposited in the bore-holes at the NTS. Radionuclide releases and migration from the latter two sources are currently under active study by the DOE. If it had been the intent of the EPA to have the post 10,000 year exposure limit (proposed to be 350 millirem for the Yucca Mountain disposal facility) to include all sources of man-made radiation (i.e., the Beatty dump, the NTS testing contamination and the NTS waste wells), this would have been explicitly stated in the proposed regulation. In the absence of such a statement then the EPA must consider that a radiological protection level of 350 millirem from each of these radionuclide waste locations to be protective to the Amargosa Valley population after 10,000 years (i.e., a potential annual dose of 1.4 rem). EPA should identify in their proposed regulation how these releases from multiple sources (which will occur in the million year time frame) are to be considered such that the local residents are protected. (Comment 0263-15)

3. Neither portion of the "double-standard" addresses the multiple-pathway cumulative exposure problem at the Yucca Mt. site, which is bracketed by the Beatty toxic waste dump, already in possession of a plutonium plume, and the Nevada Nuclear Test Site, home of over 1,000 nuclear bomb detonations. (Comment 0306-10)

4. EPA is using today's background radiation to set a standard well into the future. Since we know less about the future than the present, EPA should be assuming greater background radiation levels than exist today. In the past 60 years, radiation levels have been altered because of the actions of man and of government, such as the fallout and effects from nuclear weapons testing and nuclear materials both in the United States and other locations. The EPA rule assumes that background radiation levels will not change over the period from 10,000 years up to one million years. There are many speculative parts about making a rule to apply far into the future. One thing that should be clear to the EPA is that today's conditions cannot be assumed to be the same in 300,000 years or a million years. EPA should assume greater background radiation levels in the future than today, and the proposed standard should reflect these conservative assumptions. (Comments 0353-5 and 0361-5)

Response to Issue N:

Pursuant to Section 801 of the Energy Policy Act of 1992, EPA's mandate is to set standards that apply to radiation released from the potential Yucca Mountain disposal system, not to quantify or require projection of potential exposures from other possible sources.[7] In addition, after considering the comments on the use of background radiation to establish a quantitative dose standard and other technical factors, the Agency has decided not to use background radiation as the basis for the 10,000- to 1-million-year standard. Instead, the Agency has decided to establish a peak dose standard consistent with the internationally recognized limit of 1 mSv (100 mrem)/yr. (Please see the preamble to the final amended standards for further discussion of the new compliance period and dose-rate limit.)

Section 2 Dose Limits

Issue O: Other dose limit comments

1. EPA specifically chose not to set a dose standard beyond 10,000 years because no "proof" was possible. When the court demanded that EPA set a standard beyond 10,000 years, because NAS requires it, EPA consistently passes the decision on to NRC (as if EPA really doesn't want to be responsible for any decision beyond 10,000 years). (Comment 0113-1)

2. What factors determine the radiation and what is the level? What assurance can the DOE and EPA give the public that the 15-millirem level can be maintained for 10,000 years? (Comment 0209.3-3)

3. When we had our meetings with you, it's very difficult to know what we should have talked about. We never in the world realized that you'd go to 350 millirem. The suggestion was made that somebody had said perhaps 100 was a good idea. And we all said no. But you couldn't possibly have thought that we meant that that was too low. So I don't know where in the world that came from. (Comment 0209.14-4)

4. We recommend that the proposed regulatory standards for the period of time beyond 10,000 years be adopted for the Yucca Mountain repository. However, for the implementation of the standard, NRC should develop a probabilistic safety goal comparable to those in use for the risk-informed regulation of nuclear power plants. However, when issues are raised in the future that relate to the integrity of the repository (such as possible evidence for historic water intrusion, earthquakes, or volcanic activity),

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[7] We note, however, that even if the Agency did have authority to address radiation released from other sources in these standards and releases from the other sources actually reached the RMEI, the releases at issue would not likely add contemporaneously to any impact on the RMEI. That is, the peak doses from the sources cited by the commenters likely would not 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 most likely to occur at least hundreds of thousands of years later.

they should be addressed probabilistically against compliance with the probabilistic safety goal. (Comment 0215-7)

5. What limit did the NAS recommend? (Comment 0367.1-3)

6. 15 millirem additional to what? (Comment 0367.1-4)

7. Why 350? (Comment 0367.2-5)

8. I believe you should go [setting the dose limit] according to cancer incidence risks and protect to standards like one in 10,000 for cancer incidence, not cancer fatalities because fatality rates are changing all the time, fortunately coming down due to improved medicine. (Comment 0368.3-9)

9. You must consider the pregnant women, the fetus, the – those who have suffered from other illness, from age, in setting a radiation protection standard that will truly protect and to be honest, to take a very strong position concerning the desirability of generating far more radioactive wastes. (Comment 0368.4-4)

Response to Issue O:

We received a number of other comments or questions related in some way to the dose level. Commenter 0113 suggests that we have not "set a standard beyond 10,000 years." We have set such a standard at a level of 1 mSv/yr (100 mrem/yr), which is protective of public health and appropriately addresses our concerns regarding the uncertainties associated with assessing compliance for periods approaching 1 million years (see Section 6 of this document). The determination of compliance with that standard is NRC's responsibility, as it has always been under the Nuclear Waste Policy Act of 1982 and the EnPA of 1992. We have defined how the assessments are to be performed in certain respects, such as the definition of the reasonably maximally exposed individual (RMEI) and the treatment of features, events, and processes (FEPs) beyond 10,000 years (see Sections 8 and 16 of this document). However, we have left the details of implementation to NRC as the licensing authority.

Commenter 0209.3 asks basic questions regarding the calculation of dose and the level of assurance that can be provided that our standards will be met. The primary factors affecting radiation dose, in addition to the amount of the radionuclide present, are the type of radiation emitted and the exposure pathway. Gamma radiation is the primary concern for external exposures. Alpha and beta radiation are of limited concern externally, but are the primary contributors to internal exposures if inhaled or ingested. The energy associated with the radiation and which organs are preferentially exposed are also significant factors. For example, some radionuclides when ingested will migrate to bone (e.g., strontium or radium, which are chemically similar to calcium), the thyroid (i.e., iodine, which is important for healthy thyroid function), or other specific organs. See Issue H of this section, as well as Sections 5 and 11 of this document, for more discussion of this issue. More information may also be found at http://www.epa.gov/radiation.

The determination of compliance with our standards will be based on DOE's performance assessments. NRC will determine whether there is a "reasonable expectation" that the standards will be met before it may issue a license. In addition to quantitative dose projections, NRC will also consider the other factors that are important to the overall judgment of safety and how they are reflected in the performance assessment. For the initial 10,000-year period, the ability of the engineered barriers (e.g., waste packages and drip shields) to contain the waste and prevent releases will be of most importance, so assumptions regarding those components of the repository will be most critical for that period, when the thermal stresses are most significant. Examples of factors NRC will consider in reaching its determination of "reasonable expectation" may be found in Docket No. EPA-HQ-OAR-2005-0083-0376, p. 45.

Commenter 0209.14 expresses concern that we gave no indication in pre-proposal stakeholder meetings of considering levels as high as 350 mrem/yr for the period beyond 10,000 years. The primary purpose of those meetings was to provide basic information on the status of our rulemaking and to listen to the concerns and advice of stakeholders that could influence our decisions, not to foreshadow regulatory decisions before the Agency's internal review processes had been conducted. The level of 100 mrem/yr mentioned by the commenter had been suggested in a report by the Electric Power Research Institute (EPRI) (Docket No. EPA-HQ-OAR-2005-0083-0087). That level is consistent with the overall public dose limit for practices involving radioactive material that is recommended and accepted by international organizations such as ICRP, IAEA, and NEA, as well as by NRC, DOE, and NCRP. We have established that level as our final individual-protection standard for the post-10,000-year period. See Section 14 of this document for more discussion of public outreach.

Commenter 0215 suggests that "NRC develop a probabilistic safety goal comparable for those in use for the risk-informed regulation of nuclear power plants." The commenter's suggested approach appears to be as a supplement to the individual-protection standard to be assessed using the RMEI (the commenter also supports the probabilistic approach recommended by NAS). In this approach, the health detriment to the wider population from releases from the Yucca Mountain disposal system at the level of the standard would be compared to the "natural incidence of death." Below a specified fraction of that rate, the probabilistic safety goal would be met. We have established a standard to limit doses to individuals, as directed by the EnPA. Further, EnPA Section 801(a) specifies that the public health and safety standards we establish "shall be the only such standards applicable to the Yucca Mountain site." We note, however, that NAS concluded that an individual-risk (or dose) standard would be sufficient to protect the wider population. (NAS Report p. 65)

In response to Commenter 0367.1, NAS identified "the spectrum of regulations already promulgated that imply a level of risk, all of which are consistent with recommendations from authoritative radiation protection bodies" for EPA's consideration, among which were the 100 mrem/yr public dose limit recommended by ICRP. (NAS Report p. 49 and Tables 2-3 and 2-4) Consistent with this discussion, NAS suggested as "a starting point for EPA's rulemaking" an annual risk range of 1 in 100,000 to 1 in 1,000,000. (NAS Report pp. 5, 49) NAS's starting risk range is consistent with the 15 mrem/yr level we had established in 40 CFR part 191 and used in other applications, so we viewed the NAS "recommendation" as supporting that level at Yucca Mountain for the initial 10,000-year period. NAS explicitly declined to recommend a final risk level for the time of peak risk, viewing that as a policy decision best left to the standard-setting authority (EPA): "determining what risk level is acceptable is not ultimately a question of science but of public policy." (NAS Report p. 5) Both the 15 mrem/yr standard for the first 10,000 years and the 100 mrem/yr standard beyond that time refer only to releases of radionuclides from the Yucca Mountain disposal system. Natural background sources and other exposures caused by human activities are not included in those dose levels.

In response to Commenter 0367.2, we note that the comment is now moot. We are establishing 100 mrem/yr as the final dose standard to apply for the post-10,000-year period. This level is consistent with the overall public dose limit recommended and adopted both internationally and domestically today, and as such provides a clear basis for determining that our standard will protect public health and safety in the far future. Most residents of Amargosa Valley would be expected to receive much lower exposures than the RMEI, if any, from Yucca Mountain.

Commenter 0368.3 recommends using cancer incidence as a benchmark for regulation, rather than fatality, because fatality depends on factors such as the availability of effective medical treatment. We discussed this question in our 2001 rulemaking, and noted that "NAS concluded that nonfatal cancers are more common than fatal cancers. Despite this conclusion, NAS cited an ICRP study that judged that non-fatal cancers contribute less to overall health impact than fatal cancers 'because of their lesser severity to affected individuals.' (NAS Report pp. 37-39)". (66 FR 32081, June 13, 2001) Based on the factors we use, both the incidence and fatality rates associated with 15 mrem CEDE/yr are approximately 3×10^{-4}, accounting for rounding differences, which is consistent with the Agency risk range. The overall factors we employ were reaffirmed by the recent BEIR VII report (Docket No. EPA-HQ-OAR-2005-0083-0087).

As discussed in the preamble to the final rule and Issue B of this section, however, we do not believe it is reasonable to view the post-10,000-year peak dose standard of 100 mrem/yr from the perspective of the Agency's traditional risk-management framework (typically applied to situations where results can be confirmed, modeling is utilized on a more limited scale, or institutional controls are more applicable). We would not view a projected dose of 100 mrem/yr in the far future, with all the attendant uncertainties, as comparable to a 100 mrem/yr dose incurred today, or even projected to occur within 10,000 years. Although NAS explicitly referred to risk as "the expected value of a probabilistic distribution of health effects" (NAS Report p. 4), the use of long-term projections of risk as a measure of future health detriment is discouraged by ICRP (in part because of reasons cited by the commenter, such as advances in medical treatment). ICRP recognizes, however, that relation of projected risk to future health detriment is common practice and somewhat more defensible for periods up to about 10,000 years. (ICRP Publication 81, Docket No. EPA-HQ-OAR-2005-0083-0417, Paragraphs 41 and 71) Therefore, while we believe it is reasonable to discuss the 15 mrem/yr 10,000-year standard in terms of risk and relate it to overall Agency policy, we are more cautious in applying current risk estimates to the 100 mrem/yr standard applicable for the period beyond 10,000 years. We estimate the nominal annual risk associated with 100 mrem/yr, based on current risk conversions, is 5.75×10^{-5}, which we find to be comparable to the range of risks represented by the domestic and international regulations that NAS suggested EPA consider. (NAS Report p. 49 and Tables 2-3 and 2-4) As noted above, as a matter of Agency policy, the estimated lifetime risk associated with 15 mrem/yr is considered consistent with the risk range even though it is slightly higher than 10^{-4}. When time frames on the order of 1 million years are considered, the level of risk represented by the 100 mrem/yr peak dose standard is reasonable, and we conclude that our final peak dose standard will protect public health and safety. See the preamble to the final rule, as well as Issue H of this section and Section 5 of this document for more discussion of risk.

Commenter 0368.4 urges us to use more vulnerable populations in setting standards. In relating dose and risk to health effects, we use factors that incorporate considerations of age (including fetal development), gender, and other factors. As we stated in our 2001 rulemaking, although exposures *in utero* appear to have greater impact, the relative length of the period of exposure compared to the lifetime tends to reduce their significance, particularly at low dose rates (such as background radiation). See also Issue H in this section for discussion of radiation risks and their effects on children's health.

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Section 3 Background Radiation

Issue A: Oppose use of natural background radiation to establish the dose limit

1. The new standard is based on EPA's unstudied view that it is appropriate to expose unconsenting local populations to high levels of radiation so long as they do not exceed the highest levels of natural background radiation tolerated in the most radiation-prone states. (Comment 0103-1)

2. Why should EPA allow people in the Yucca Mt. vicinity be exposed to 350 mrem/yr in the future if they have no choice in the matter? Just because Colorado is nearby and has 700 mrem/yr in some areas is no reason….I see no ethical or logical reason to allow man to expose other men to any additional radiation at all much less 350 mrem/yr which a lot of people are not exposed to "naturally"….To me, your reasoning is like saying (hypothetically) "Rockfalls kill 270 of the people hit by them every year, so it is ok for man to stone 270 of the people to death every year". Does that make any sense at all? I hope not. Just because Mother Nature does harm doesn't give man the right to do it too, does it? (Comment 0113-4)

3. EPA's proposed 350 millirem dose limit would be in addition to natural background radiation exposure levels (which according to EPA's definition, includes indoor radon, an artifact of construction). In other words, the EPA wants to allow future generations to be exposed to the equivalent of twice the level of background radiation. (Comments 0130-2; 0195-2)

4. EPA tries to convince the public that radiation exposures, no matter how high, can justify additional exposure of Nevadans if it can be shown that somewhere those levels exist naturally, but this is not how EPA should or has written regulations. There is no doubt that EPA's traditional thinking went out the window regarding Yucca Mountain. (Comment 0145-1; 0257-4)

5. EPA's proposed rule offers a convoluted and arbitrary rationale for what its second-tier standard should be. EPA suggests that "given the large uncertainties surrounding the outcomes at these unprecedented time frames," it is reasonable to set a standard based on natural background radiation levels in one of the nation's more radioactive states: not Nevada, where Yucca Mountain actually is, but Colorado. On this rationale, EPA concludes that allowing 350 millirem/year of anthropogenic exposures to Nevada's citizens is appropriate. EPA's background rationale is flawed. (Comment 0226-48)

6. There is good reason for EPA's (and other standard setting agencies') past reluctance to use natural background or variations in natural background as a basis to establishing acceptable levels of risk. A risk is not acceptable just because it is "natural." Societies undertake extraordinary measures to eliminate or mitigate such natural hazards as hurricanes, tornados, and toxic substances found in nature like botulism. The concept that variations in natural background pose acceptable risks is based on the highly doubtful

premise that people are knowledgeable about these radiation levels, and the associated health effects of radiation, when they choose where to live or work. Finally, even if these comparisons were relevant, EPA cannot explain how they are uniquely relevant to the period after 10,000 years. (Comment 0226-51)

7. Similarly, EPA's implication that it can safely create Colorado-like levels of exposure in Nevada because people live in Colorado is untenable. Simply because a risk exists naturally in one location does not mean that it is acceptable or "safe" for humans to create it somewhere else. We would never accept as "safe" a human project that creates San-Francisco-like levels of earthquake risk in Chicago, or that subjects Washington D.C. to the risks of hurricane damage that Miami naturally faces, even though millions of people live in the at-risk areas. Similarly, EPA has no basis in implying that because people live in Colorado now, the radiation levels they may face may acceptably be created elsewhere. (Comment 0226-54)

8. In setting other health and safety standards, EPA has frequently rejected comparisons with natural background. Earlier this year, EPA rejected the concept that emissions of hazardous materials should not be regulated if the resulting levels in the environment are within the bands of variation in ambient background levels. 70 FR 19992, April 15, 2005 (rule limiting emissions from coke oven batteries), citing with approval 54 FR 38044, September 14, 1989 (rule limiting emissions of benzene and other hazardous materials). EPA also rejected a natural background radiation rationale when it set health-based emission standards for radioactive materials under a statutory regime (the Clean Air Act) identical to the Atomic Energy Act, 54 FR 51654, December 15, 1989, and when it set standards limiting radioactive emissions from uranium mills, 51 FR 42573, November 2, 1986. EPA rejected comparisons with natural background when it proposed changes in guidance to all federal agencies on the formulation of radiation protection standards. 66 FR 66414, December 23, 1994 ("although the average level of exposure to natural background provides perspective, it does not, however, provide justification for the RPG [Radiation Protection Guidance], since it represents an uncontrollable source of risk, and the RPG applies to controllable sources"). (Comment 0226-55)

9. Additionally, EPA's rationale misunderstands the role of radon in creating natural exposures in Colorado and elsewhere. As EPA acknowledges, most natural exposures, in Colorado and elsewhere, result from radon. In Colorado radon accounts for approximately 87% of total radiation exposure. S. Cohen and Associates, *Assessment of Variations of Radiation Exposure in the United States* (2005), OAR-2005-0083-0077, at 4. But radon exposures are locally variable, site-specific, and amenable to mitigation; a person lives with radon risk because either they are ignorant of that risk or they have made a conscious choice not to deal with it. (Comment 0226-56)

10. It was interesting to follow EPA's development of the dose requirement after 10,000 year. Given that the EPA Web site has a whole section devoted to radon exposure, radon health hazards, and potential mitigating measures for indoor radon. (The posting of the announcement of National Radon Action Month, 2005 was enlightening as the text starts out by reminding our Nation of the serious danger that radon gas poses in our home. It

continues by stating that it encourages all Americans to join in this crucial effort and learn more about the health risk posed by radon, test for it, and where warranted take steps to reduce expose to it). Other pages of the EPA web site tells us how we can mitigate the effects of radon exposure by relatively simple and inexpensive measures to reduce indoor radon concentrations to the much lower outdoor concentration levels (around 0.4 pCi/L). In fact the document cited by EPA in the draft regulation (Assessment of Variations in Radiation Exposure in the United States, page 12) tells about the large mitigation effort that has taken place during the last 10-15 year in regions where indoor radon levels are 4 pCi/L or greater, which include Colorado, were not considered in the data presented and subsequently used by EPA in the proposed regulation. This statement regarding data applicability indicates that the proposed EPA regulation is based on old and not currently valid data. This is not a sound legal or scientific basis for a regulation governing the public health and wellbeing. Given the high current rate of applying radon mitigation, it is likely that mitigation will be universal used in dwellings before the proposed repository is closed. Therefore, on one hand EPA is really concerned about the health risk associated with the present day level of exposure from indoor radon in States such as Colorado where the expected indoor radon concentration is abnormally high (>4 pCi/L). While on the other hand EPA is setting a regulatory standard for Amargosa Valley residents for more than 990,000 years based on this acknowledged unnecessarily excessive present day exposure to radon for Colorado residents (i.e., in the highest 10 % of the nation). These positions seem to be contradictory in terms of protecting the wellbeing of all present and future citizens of our nation. The Amargosa Valley resident is proposed to be given the radiological protection that is based on the annual natural background dose of 700 millirem received by an average resident of Colorado (47.5 millirem/yr cosmic, 42.6 millirem/yr terrestrial, and 610 millirem/yr radon) over and above the estimated level of 350 millirem for Amargosa Valley residents (100 millirem/yr from terrestrial and cosmic sources plus 250 millirem/yr from radon). However, according to the EPA, the informed resident of Colorado will know about the radon hazard and will have taken steps to mitigate its effect to a degree (EPA acknowledges that there are a large number of household mitigations being undertaken every year). The radon contribution to dose for Colorado residents can be reduced by a about an order of magnitude to about 61 millirem per year based on EPA figures of typical outdoor radon concentrations of 0.4 pCi/L and unmitigated indoor concentrations in Colorado of over 4 pCi/L. The Colorado resident who has followed, because of health and safety reasons, the EPA safety guidelines for radon will receive an annual dose of 151.1 millirem (47.5 millirem/yr cosmic, 42.6 millirem/yr terrestrial, and 61. millirem/yr radon). Thus, to give the Amargosa resident the natural radiological protection that an aware and radon mitigated Colorado resident has today (using EPA recommended radon alleviation measures) means that the total annual dose could be increased to 151.1 millirem per year from a present day Amargosa Valley natural background plus mitigated radon dose of 125 millirem per year. Thus the allowable additional radiation dose (i.e., Colorado annual dose minus the Amargosa Valley annual dose) from releases from the proposed repository would be 26 millirem per year rather than the non-radon mitigated increase proposed of 350 millirem per year. Thus if EPA applies a consistent exposure logic the future additional dose from a repository then this argument would appear to support not quite doubling the present 10,000 years annual dose standard of 15 millirem. (Comment 0263-18)

11. It is ethically unacceptable to set public health and safety standards based on levels of background radiation in the particular vicinity. All US citizens deserve the same level of protection regardless of where they live. Levels of other toxicants vary across the US, e.g., high levels of mercury or arsenic in drinking water. Are we going to allow higher levels of these in some areas than in others? (Comment 0293-12)

12. The proposed rule makes entirely inappropriate reference to doses from natural background radiation, estimated by EPA in the proposed rule as 350 millirem per year (when radon gas exposures are included). Yes, we live in a sea of radiation from which we cannot escape. That doesn't mean it is safe. The National Academy of Sciences, as discussed above, estimates that 350 millirem/year of background radiation produces a cancer in roughly 3% of us. In other words, 9 million Americans (out of a current population of ~300 million) will get a cancer from their exposure to background radiation. Since ~40% of us will get cancer, that means that about 7% of U.S. cancers are attributable to background radiation. Adding to that another 350 millirem per year, on top of the already lethal background dose we can't escape, just as a political favor to a powerful industry, is unacceptable. (Comment 0296-6)

13. The proposed rule implies that the proposed Yucca dose would be less than or equal to background radiation. No. It would be on top of background, roughly doubling the dose those members of the public get, and significantly increasing the numbers of cancers in the exposed population. If we determined what is acceptable pollution or deaths based on what cancers are produced from background radiation, all modern environmental standards would go out the window. If this rule is approved, every polluter – every pesticide manufacturer, every smelter, every chemical factory – will come in and demand that they be permitted to release orders of magnitude higher levels of carcinogens. If it is OK to let the nuclear industry give doses with a risk of 1 in 36 rather than 1 in 10,000 to 1 in a million, then every other polluter will demand the "right" to produce cancers in the innocent public at those astronomical levels. (Comment 0296-7)

14. EPA claims that the 350 millirem/year exposure limit is an acceptable level of risk since it is only slightly higher than that already received from natural-background radiation. What the EPA rule does not take into account is that individuals exposed to radiation from Yucca will receive these doses in addition to, not in place of, background radiation…Reports from the United Nations Scientific Committee on the Effects of Atomic Radiation, the International Atomic Energy Agency and other scientific groups have already established that natural-background radiation causes about 3 percent of fatal cancers – roughly 18,000 U.S. deaths annually. (Comment 0301-6)

15. No U.S. or international regulations use background radiation to set public health standards for radiation exposure. (Comment 0302-3)

16. About 3 percent of American public will get a cancer from background radiation, which is equivalent to almost 9 million people of the current U.S. population. Of the fatal cancers in the U.S., approximately 7% are attributable to exposure to background radiation. (Comment 0302-4)

17. EPA incorrectly argues that a radiation standard of 350 millirems per year, in addition to the presumed background radiation level in Amargosa Valley (350 millirems per year), is protective of the public, because the total (700 millirems per year) is equal to an inflated estimate of the current average background radiation in Denver, Colorado. This is not a sound basis for EPA's standard, because not only is background radiation not a safe level of exposure, but background levels of radiation across the U.S. are highly variable, with Colorado being significantly above the average. (Comment 0302-5)

18. While the concept of matching "background" radiation seems benign, it should be noted that the 350 millirem limit is for a maximum exposure nationwide. Even at Yucca Mt., next to the Nuclear Weapons Test Site, annual background exposure is about 110. Furthermore, background radiation causes serious cancers each year, skin cancers, melanomas and more, especially in this sunny desert region. (Comment 0306-9)

19. In addition, the City does not believe it is appropriate to develop radiation standard; based on the highest levels of natural background radiation tolerated in the most radiation-prone states. Developing a radiation health protection standard in this way is not condoned by any other standard-setting body in the world, including the National Academy of Sciences. (Comment 0341-8)

20. Groundwater is the most important receptor, not background levels of radiation, as a benchmark. (Comment 0367.2-29)

21. The EPA has said that this is the same as background radiation. From our perspective, clearly it is on top of background radiation. (Comment 0368.2-7)

22. First, it is completely false to claim that the level of radiation is safe as long as it does not exceed the highest levels of background radiation in the highest radiation prone states such as Colorado. Background levels of radiation across the U.S. are highly variable with Colorado being significantly above the average. No U.S. or international regulations use background radiation to set public health standards for radiation exposure. (Comment 0368.6-3)

Response to Issue A:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule. We received a significant number of comments taking issue with the concept of using background radiation as an indicator of "safe" levels of exposure from an engineered facility. We also received additional information that provided insights into our consideration of background radiation. For example, monitoring stations operated by the Desert Research Institute provided monitoring data indicating that the unshielded (outdoor) background radiation from cosmic and terrestrial sources in Amargosa Valley is roughly 110 mrem/yr. Commenters 0357 and 0359 also informed us that roughly 90% of the population in Amargosa Valley lives in mobile homes, which has implications for indoor radon exposures. Other commenters supported the use of a different factor for converting radon concentrations into dose.

In considering these comments, as well as those taking issue with the overall premise described in the proposal, we found the relatively simple approach used in the proposal evolving into a more complex undertaking requiring numerous decisions where science did not provide a clear answer. Indoor radon estimates presented the greatest challenge, and also represented the highest proportion of overall background radiation. Complicating factors included multiple ways of calculating radon dose, the prevalence of mobile homes in Amargosa Valley, limited data sets primarily from the early 1990s, and data for individual counties in a different format than State-wide data. We concluded that there was no generally agreed-upon approach in the context of Amargosa Valley for incorporating indoor radon exposures into an analysis of background radiation that would lead to a regulatory standard.

We continue to believe that references to natural sources of radiation can provide useful insights into the "significance of" projected doses (in IAEA's words) over hundreds of thousands of years. For example, as noted above, 100 mrem/yr is roughly the value reported by the Desert Research Institute for cosmic and terrestrial radiation at Amargosa Valley (unshielded). When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally. Within the State of Nevada, the difference in average estimates of background radiation for counties is greater than 100 mrem/yr. (Docket No. EPA-HQ-OAR-2005-0083-0387) This suggests that 100 mrem/yr can be considered to be a level such that the total potential doses incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain will remain below doses incurred by residents of other parts of the country from natural sources alone. It may also be noted that the 1 mSv/yr (100 mrem/yr) public dose limit recommended by ICRP is itself related to background radiation. (ICRP Publication 60, Docket No. EPA-HQ-OAR-2005-0083-0421, paragraphs 190, 191) However, in the absence of compelling reasons for selecting specific background radiation estimates and points of comparison, we conclude that comparing background radiation estimates from specific locations does not provide a clear or sufficient basis for a regulatory compliance standard applicable to the Yucca Mountain disposal system.

Section 3 Background Radiation

Issue B: Support the use of natural background radiation to establish the dose limit

1. These levels have not been found to cause harm to human health. If you question this information, then it behooves you to develop the data to support the alternative view, and you owe such to the American people. If you accept natural world levels, then you have no basis for setting any limits that are less than these ranges allowing for a reasonable safety margin and certainly no basis for alarming the American people Above natural radiation, we are already subjecting ourselves to some 60+ mrems with no apparent health danger, and will increase this. (Comment 0100-1)

2. The reason the mean is larger than the median is due to the fact that the distribution of performance assessment dose results is not symmetric about the most probable value but rather is skewed to high values. The infrequent larger values can more strongly influence the mean than the median. The same skewness feature exhibited by performance assessment doses characterizes the distribution of doses from indoor radon. To be consistent the EPA should have used median values rather than mean values for indoor radon contributions to the background dose in deducing the excess background Colorado residents receive as compared to Amargosa Valley residents. The result of such a calculation gives approximately 200 mrem/yr rather than 350 mrem/yr. (Comment 0183-1)

3. The new proposed limit for the period 10,000 to 1,000,000 years after closure of Yucca is a good start! However, with all the conservative assumptions that will be made in modeling the radiological releases from Yucca over that period, the actual exposures will be much lower than the modeled exposures, so limiting the MODELED exposures to the national average is needlessly restrictive. Perhaps a more appropriate limit would be the 95th or 99th percentile of the natural background exposures that U.S. Citizens accept as part of everyday life. (Comment 0187-1)

4. Radiation is a naturally occurring substance which every person on Earth is exposed to every day at some level - from X-rays in hospitals to granite rocks in some tunnels to airplane flights high above the atmosphere's protection. Setting a lower radiation level would not significantly change the additional health risk to people near the storage facility. (Comment 0193-2)

5. People in the U.S. and elsewhere have lived in higher-than-average radiation environments, such as Colorado with 700 millirem per year average, as well as individuals who have been overexposed to low-level radiation, such as more than 35,000 nuclear shipyard workers, have been shown to have lower cancer rates and increased longevity. In other words, many studies have indicated that radiation at these levels is good for people, not the converse. So it's been from tens to hundreds of billions to ensure a near-zero exposure is a waste of the public's money. This isn't the government's money we're discussing here; it's mine, it's ours, and it's yours. (Comment 0209.9-2)

6 Because the revised proposal for a dose limit of 350 *mrem* per year for the period past 10,000 years is comparable to levels already experienced in other parts of the country, it makes good sense. (Comment 0217-5)

7. Lincoln County is also concerned that EPA has chosen to utilize the levels of natural background radiation in Colorado (averaging 700 mrem) in concluding that the addition of 350 mrem of exposure resulting from Yucca Mountain to natural background radiation in the vicinity of Yucca Mountain is acceptable … Use of Colorado levels of natural background levels of radiation might be appropriate if the Yucca Mountain project were being proposed in Colorado …EPA should consider the Yucca Mountain repository as being allowed to only contribute an incremental increase in exposure risk which is consistent with the variation in natural background radiation in the vicinity of Yucca Mountain. (Comment 0219-3)

8. In fact, 350 mrem per year is within the range of variations in natural background that exist within the State of Nevada which range from a low of 200 mrem per year in Clark County to 680 mrem per year in Pershing County. Moving from low to high natural background areas in Nevada and across the United States is not generally perceived to represent a radiological health risk. Radiation levels in this range are generally believed to be well below the point at which public health and safety would be compromised. Furthermore, the 350 mrem per year standard is not at odds with the 1995 NAS Report or the court mandate in the *NEI* decision. (Comment 0298-14)

9. The proposed rule prescribes a dose limit to be used beyond 10,000 years that is based on current average annual background radiation levels in Amargosa Valley, Nevada, and in Colorado. If those background values are higher now, or in 2000, say, than they were in 1900, because of Hiroshima, Nagasaki, atmospheric nuclear weapons testing, Chernobyl, ongoing reactor plant operation, etc., then would it not be appropriate to extrapolate those increases; i.e., to accumulate the century-on-century increases in average annual background radiation in Amargosa Valley and Colorado out to 10,000 years and beyond? Would using those larger extrapolated values not be more consistent with the “comparison with background radiation levels” rationale that undergirds the new 350 mrem/year limit? Indeed, the extrapolation should perhaps not be a linear one, given (based only on my cursory survey of the past 10,000 years) (Comment 0307-1)

10. The Department agrees with EPA that it is appropriate to consider potential exposures from natural sources of radiation in establishing the acceptability of a peak dose standard for Yucca Mountain…Relating the level to the variations in background radiation, rather than the average, gives a clearer sense that these levels are routinely accepted by society and do not influence an individual's decision to live in one part of the country to another. (Comment 0352-19)

Response to Issue B:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule.

We disagree with the suggestion in Comment 0209.9-2 that there is no utility in regulating low-dose radiation. We realize that the question of health effects resulting from low-dose radiation remains unresolved, although much work is being done in this area. To say this question is unresolved, however, is not to say that that radiation health effects are only hypothetical. The NAS in its BEIR VII report concluded that there is insufficient evidence at this time to abandon the linear no-threshold approach (i.e., that any incremental radiation exposure carries a proportionate increase in risk). (Docket No. EPA-HQ-OAR-2005-0083-0430) From a regulatory perspective, the linear no-threshold approach provides a prudent framework or developing cautious, but reasonable, radiation protection requirements.

Section 3 Background Radiation

Issue C: Indoor radon is not natural background radiation

1. Includes home radon exposure in calculations of natural background levels used to set thresholds, a practice never done in such calculations because home radon exposure is routinely mitigated. (Comment 0103-3)

2. EPA misleads the public by implying that the level is set at truly “natural” background levels. EPA’s own documents show that EPA has included man-made sources of radiation, such as indoor radon exposure, in its estimates. To call this “natural” is simply misleading. (Comment 0293-11)

3. EPA also improperly includes indoor radon exposure as part of its estimates of natural background radiation. Radon is normally never included as part of background dose, because indoor radon exposure is a man-made public health risk. (Comments 0145-3 and 0302-6)

4. Indoor radon is a technological artifact and not part of natural background. Excluding the indoor radon component, but retaining all other aspects of the EPA proposed rule, would lower the limit from 350 mrem to approximately 100 mrem per year. (Comment 0314.1-2)

5. The Toxic Substances Control Act recognizes that indoor radon is an artifact of building construction and sets a long-term goal of reducing radon levels indoors to those experienced outdoors. Hence, including the present level of indoor radon in natural background is contrary to the intent of this law.
Specifically, the Toxic Substances Control Act states that

> "the national long-term goal of the United States with respect to radon levels in buildings is that the air within buildings in the United States should be as free of radon as the ambient air outside of buildings."

It is reasonable to assume that this goal could be met within the next few hundred years as the building stock in turned over and that, therefore, long before 10,000 years, the average population exposure to the US population will have been reduced to something closer to 100 millirem per year from its current value of 300 millirem per year. Thus the inclusion of radon doses in the proposed rule appear to be inconsistent with both the spirit and the letter of this section of the law.

Following the passage of the section of the Toxic Substances Control Act in which the "national long-term goal" was set forth, the NCRP issued a report on radon control technologies in which they concluded that the information presented in this report shows that there is a variety of methods available for the control of radon inside houses. All systems can be effective when properly installed, but the best performance is achieved by active soil ventilation techniques. For new houses being planned or under construction, the installation of barriers between the soil and the house can be very effective. Properly done, this approach will solve the problem for the duration of the use of the house. (Comment 0314.1-3)

6. The inclusion of indoor radon levels as part of "natural background radiation" is not scientifically correct and fails to take into account both the letter and the spirit of current U.S. law (see below). This inappropriate inclusion of radon has led the EPA to draw erroneous conclusions regarding the regional variation in background exposures as part of the proposed rule.

The "average annual effective dose equivalent to individuals in the U.S. population" as estimated by the National Council on Radiation Protection and Measurements includes 200 millirem from radon and its decay products and 100 millirem from other sources such as cosmic rays and the ingestion of primordial radionuclides. The DOE has estimated that the exposure of people in the Amargosa Valley is equal to the average exposure reported by the NCRP, while the EPA has estimated a higher radon dose of 250 millirem per year.

The exposure to indoor radon, which accounts for two-thirds of the average population exposure in the United States, is, however, a result of human activities and not a result of natural processes alone. As noted by the National Research Council in 1999

> "Many human activities – such as mining and milling of ores, extraction of petroleum products, use of groundwater for domestic purposes, and **living in houses** – alter the natural background of radiation either by moving naturally occurring radionuclides from inaccessible locations to locations where humans are present or by concentrating the radionuclides in the exposure environment."

The National Research Council considered indoor radon to be a "technologically enhanced naturally occurring radionuclide [TENORM]." The treatment of other TENORM from a radiation protection standpoint is thus illustrative in the present context. For example, playground equipment and fences contaminated with TENORM waste from the oil industry containing radium has been found at a number of locations in Mississippi and Louisiana. Earlier, a Federal Court held Chevron Oil liable for damages to workers at a salvage company for Chevron's failure to conduct adequate inspections of the equipment and to warn the workers about the possible risks. Exposure to these TENORM materials was not considered to be natural background exposure despite the fact that the radionuclides involved were all naturally occurring. The EPA has itself referred to indoor radon as a technologically enhanced naturally occurring radionuclide and has highlighted the mechanisms by which the construction of homes and other buildings cause radon to build up to higher levels than would be experienced outside. Because this exposure to indoor radon is a result of human activity, it is scientifically incorrect to combine it with the exposure to unavoidable background sources such as cosmic rays. Comparing indoor radon to background radiation is like comparing taking a shower to getting wet from rain. The EPA is aware of this legally mandated goal, and, since 1994, has published technical advice for how to limit radon levels in new and existing homes as well as in new schools and other large buildings. In fact, the EPA's 2005 *Citizen's Guide to Radon: the Guide to Protecting Yourself and Your Family from Radon* notes that

> "Radon reduction systems work and they are not too costly. Some radon reduction systems can reduce radon levels in your home by up to 99%. Even very high levels can be reduced to acceptable levels."

Already, people living in well-constructed buildings on upper floors are exposed to indoor radon at a level that is not significantly different from outdoor levels.

Significantly, the exclusion of indoor radon from the assumed background radiation level is consistent with the recommendations of the International Commission on Radiological Protection. In its 1990 recommendations, the ICRP excluded the contribution from indoor radon in its choice to use 100 millirem per year as the typical average "annual effective dose from natural sources." The ICRP was even more explicit in its view on this matter in its draft 2005 recommendations. In this report the ICRP stated that

> "The Commission considers that the annual effective dose from natural radiation sources, and its variation from place to place, is of relevance in deciding the levels of maximum constraints that it now recommends. The existence of the natural background of radiation does not provide any justification for additional exposures, but it can be a benchmark for judgment about their relative importance and the need for action. **The Commission uses the background dose without the radon contribution because that component is significantly enhanced by human activities and is thus subject to recommendations from the Commission for its control at home and at work."**

The Commission went on to caution that "[e]xposures that are within the natural background range are legitimate matters for concern, sometimes calling for significant action."

There is no scientific or legal basis for the EPA to consider exposures to indoor radon as part of natural background radiation. The proposed rule has not cited any and has not addressed legal and scientific view to the contrary. The final rule should exclude the contribution of indoor radon from its discussion and use a reasonable value for natural background radiation of about 100 millirem per year as estimated by the National Council on Radiological Protection for the U.S. population and in line with the recommendations of the International Council on Radiological Protection for a global average. The use of 100 millirem would also be consistent with the estimated exposure from non-radon sources for people living in the Amargosa Valley reported by the DOE. The existence of this background radiation does not provide a justification for any increase in the allowable level of exposure for this or future generations. (Comment 0314.1-13)

7. White Pine County is also concerned that EPA has chosen to utilize the levels of natural background radiation in Colorado (averaging 700 mrem) in concluding that the addition of 350 mrem of exposure resulting from Yucca Mountain to natural background radiation in the vicinity of Yucca Mountain is acceptable because the total exposure is similar to natural background radiation in other areas of the United States (i .e. Colorado). Use of Colorado levels of natural background levels of radiation might be appropriate if the Yucca Mountain project were being proposed in Colorado. In reality, persons living in the vicinity of Yucca Mountain might be exposed to twice the level of natural background radiation. EPA suggests that this level of exposure (700 mrem) is an acceptable risk because natural background radiation in Colorado is 700 mrem. If this argument is valid, then could one conclude that if the repository were located in Colorado, the EPA standard could be set at 700 mrem and the acceptable level of exposure risk would be 1,400 mrem? In lieu of the 350 mrem standard between years 10,001 and 1,000,000, EPA should consider the Yucca Mountain repository as being allowed to only contribute an incremental increase in exposure risk which is consistent with the variation in natural background radiation in the vicinity of Yucca Mountain. Pages 100 and 101 of EPA's proposed rule place said variation at 70 to 100 mrem. A standard allowing Yucca Mountain to contribute not more than 70 to 100 mrem would result in Yucca Mountain related exposure levels not exceeding the variation in natural background radiation in the vicinity of the project. (Comment 0315-3)

8. EPA's use of Colorado's higher level of "background radiation" in an attempt to justify allowing added doses of 350 mrem/yr to persons living downstream from Yucca's, leaking radioactive wastes is twisted and unacceptable. EPA cites the national average for background radiation as 350 mrem/yr. But even this is wrong and misleading. About two thirds of that figure is due to radon exposures within houses and buildings. Only natural radiation, such as from cosmic rays and other natural sources that people are exposed to outdoors, which is difficult to avoid or control, should be considered "natural background." EPA's proposed. 350 mrem/yr dose from Yucca's leaking radioactive wastes would be *in addition t*o the background radiation (including indoor radon) that people would already be exposed to. It should be noted that residents near Yucca are also exposed to additional radioactive contamination from the nearby Nevada Test Site's nuclear weapons explosions

and "low" level radioactive waste shipments and dumping, nuclear rocket and other radioactive experiments at the Nevada Test Site, as well as additional "low" level radioactive waste dumping at a commercial facility in Beatty,
Nevada. In NAS's recent BEIR VII study, it reported that about 1 in 100 Americans will contract cancer just from the non-radon component of background radiation. A full three percent of the American public can already be expected to contract cancer from their exposure to outdoor natural radiation plus indoor radon, so that a “background radiation” dose of 350 mrem/yr is far from safe. (Comment 0324-8)

9. Amargosa Valley residents now mostly live in mobile homes. As a consequence they have low indoor radon doses. Colorado residents have better insulated houses and so have higher indoor radon doses. This makes for a higher Amargosa Valley-Colorado difference, and therefore under EPA's theory a higher Yucca mountain dose standard than might otherwise be the case. Are future Amargosa Valley residents to be punished simply because current residents cannot afford well -insulated houses? Should we assume the status of Amargosa Valley residents will improve in the near future and their indoor radon doses will increase? Similarly, EPA is encouraging indoor radon abatement in Colorado. Congress has set a national goal to reduce indoor radon levels to those outdoors. Should we assume some of this will have been successful? Both assumptions together could reduce the Amargosa Valley-Colorado difference to a small number, even to zero. In pursuing the Amargosa Valley-Colorado radiation dose comparison, EPA is not basing its health standard on sound science but on quicksand. (Comments 0357-2 and 359-2)

10. But 350 millirem as a background reference is wrong. It includes indoor radon, … it is wrong to include indoor radon as background because indoor radon is an artifact of construction. It's like taking a natural sample of lake water, boiling it, and then saying that the resultant salt concentrations are natural concentrations. This is conceptually a very wrong way of characterizing background. Natural background is about 100 millirem with some variations in altitude due to cosmic rays and sun variations …. But the proper way to characterize radon in natural background is outdoor radon, not indoor radon. I have given you a very specific analogy and I expect that in the comments that EPA will respond to this analogy. I do think that the proper reference point is not even the 100 millirem natural background, but the small variations in cosmic rays or internal radiation that we might get when we move from one place to another. That's a good reference. Twenty-five millirem comes from approximately there. It's a good way to proceed if there is a drinking water sublimit. (Comments 0368.3-3, 0368.3-4, and 0368.4-1)

11. Second, by including radon exposure as part of the natural background radiation, EPA is dishonestly inflating background levels. Radon is normally never included as part of background dose because indoor radon exposure is a man-made public health risk. EPA itself has classified radon as a known human carcinogen. (Comment 0368.6-10)

12. … in establishing the standard for natural background radiation levels, the EPA blatantly includes exposure to indoor radon which is a man-made product and not a part of natural background. (Comment 0368.10-4)

Response to Issue C:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule. Notwithstanding, we should note that we disagree with the basic conclusions of the commenters. The terminology "natural radiation" routinely includes consideration of radiation doses from indoor radon exposures. As we stated in the preamble to the proposal (70 FR 49037), background radiation is the radiation that humans receive from the natural sources of radiation in the environment. The emphasis we wish to highlight here is *natural* sources. This dose consists of external exposures from cosmic and terrestrial sources, and internal exposures from naturally occurring radon. These sources consist principally of cosmic rays entering the earth's atmosphere; gamma rays largely from uranium and thorium, including their decay products, found in various concentrations throughout the Earth's crust; potassium-40, a radioisotope which is mixed in small concentrations in nature with stable potassium; and radon decay products. Through natural background radiation, people are exposed to external radiation and internal radiation by inhalation and ingestion of radioactive substances in the natural environment (NEA Issue Brief, http://www.nea.fr/html/brief/brief-10.html).

Radon is a naturally occurring gaseous element that is commonly included in definitions of natural background ((NCRP Report 94, Exposure of the Population of the United States and Canada From Natural Background Radiation, http://www.ncrponline.org/Publications/94press.html, IAEA Fact Sheet, http://www.iaea.org/Publications/Factsheets/English/radlife.html; UNSCEAR, Sources and Effects of Ionizing Radiation, 2000, Annex B, p. 89; (http://www.unscear.org/unscear/en/publications/2000_1.html); Background as a Residual Radioactivity Criterion for Decommissioning, US Nuclear Regulatory Commission, NUREG-1501, 1994 (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1501/)). In fact, the widely cited figure of 300 mrem/yr as the average natural dose rate in the United States includes radon (NCRP 94). Nor do we agree with the commenter 0314.1-13 that ICRP excluded radon from its public dose limit because it did not view radon as a component of natural background radiation. There can be tremendous fluctuation in the overall dose people receive based on several determinants, namely altitude and geology, but by far the largest portion of the dose received is from radon and as such, we believe (along with most national and international radiation experts, see above) that radon should be included in any assessment of natural background radiation. In homes and buildings, there are radioactive elements in the air. These radioactive elements include radon, and by-products formed by the decay of radium (radium-226) and thorium present in many sorts of rocks, building materials, and in the soil.

There is a distinction between sources of radon to which people are exposed, and this may possibly lead to the confusion over whether radon is a "construction artifact." The two main sources of radon are from technologically enhanced naturally occurring radioactive material, or TENORM, that is in radium-bearing construction or fill materials from which radon and its progeny escape into a closed space, and undisturbed radium-bearing rock or soil. An example of exposure from TENORM is from radon or its progeny inhaled by people exposed to certain types of wallboard or fertilizers produced with phosphogypsum that contains radium. These types of exposures were not included in our definition of background radiation because they are artifacts of the construction of the wallboard, or exposure to a technologically enhanced product such as fertilizer, and it is difficult, if not impossible, to determine average rates of exposure from TENORM. We do include, however, radon exposure resulting from undisturbed radium-bearing rock or soil beneath or near buildings ("Assessment of Variations in Radiation Exposure in the United States," Docket No. EPA-HQ-OAR-2005-0083-0077, updated for the final rule at Docket No. EPA-HQ-OAR-2005-0083-0387, p. 2). This is a naturally occurring exposure that is a major contributor to the annual dose we all receive. Commenters who refer to this exposure as "man-made" (e.g., Comments 0293-11, 0368.6-10, and 0368.10-4) are incorrect. However, we recognize that indoor radon concentrations, and resulting exposures, are influenced by the type of dwelling (as noted in Issues D and G of this section, the use of mobile homes by residents of Amargosa Valley may significantly affect their radon exposures).

As described earlier, radon exposures can vary widely even in localized areas for a number of reasons. While average doses from radon are widely cited to be roughly 200 mrem/yr, based on the correlation with a concentration of 1 pCi/L (see NCRP 94), measurements indicate that some exposures could be more than ten times that level in unique situations. The concentration at which EPA recommends action be taken to mitigate exposures is 4 picocuries per liter (pCi/L). The Agency further recommends that homeowners consider taking action only if the measured concentration is above 2 pCi/L ("A Citizen's Guide to Radon: The Guide to Protecting Yourself and Your Family from Radon," EPA 402–K–02–006, May 2004, Docket No. OAR–2005– 0083–0058). (As an aside, the Citizen's Guide was written in response to the direction EPA received in the Toxic Substances Control Act (TSCA), 15 USC 53, 2663. Comment 0314.1-3 mentioned that TSCA recognizes that indoor radon is an artifact of building construction. That is not entirely correct. The Act mentions construction types and materials, geology, weather and other variables that may affect radon levels in new buildings.) It should be understood that EPA's recommendation of an action level is not based solely on risk, but considers factors such as the voluntary nature of the exposure, the application to private property, and the capabilities of mitigation technology. As a result, we also disagree with commenter 0341.1-3 that universal mitigation should be assumed. EPA's radon abatement program is voluntary rather than a regulatory requirement. The action level represents a decision point related to technological achievability rather than health risk. Because of the voluntary nature of the program, EPA cannot make assumptions regarding how much remediation may or may not occur in the future.

Section 3 Background Radiation

Issue D: The background radiation dose rate in Amargosa Valley

1. We here at Amargosa have been measured at 110 mR in our state, and 15 mR compared to 110 mR is insignificant compared to the other risks we accept or take. We've worked a number of years to establish the background in this area, and when people worry (unintelligible) parked in all these (unintelligible) stations, (unintelligible) our station is measured at 110 and it's consistent. But I don't mean any point other than this: we should use, measure and establish background characterization in this community at 110 per year and that added to 15 mR. A good background (unintelligible) site characterization…. (Comment 0364.2-1)

2. Why wasn't local data on radon levels used? (Comment 0367.1-8)

3. Record of 110 millirems/year in Amargosa (plus radon 200 millirems). (Comment 0367.1-14)

4. We are far below the national average. (Comment 0367.1-15)

5. Need to get a real number for background in Amargosa. (Comment 0357.1-19)

Response to Issue D:

We accept the commenters' data stating that 110 mrem/yr is a reasonable value to use for the unshielded, cosmic and terrestrial background radiation dose rate in Amargosa Valley since it is based upon monitoring data rather than assumptions regarding generalized regional rates. In light of public comments, we have modified our approach and adopted a 1 mSv (100 mrem)/yr standard for the period between 10,000 and 1 million years. We believe this standard is protective of public health and adequately addresses our concerns regarding the increased uncertainty in long-term performance projections.

Section 3 Background Radiation

Issue E: Other background radiation-related comments

1. Many articles I've seen on this subject are deliberately misleading the public by stating that the limit for releases from Yucca is stepping up from 15 mr/yr to 350 mr/yr at the 10,000-year point, conveniently ignoring the fact that the 350 mr/yr limit includes existing background sources. Perhaps EPA should clarify this point in press releases so the public can have the truth, or at least the media's deception will be outed. (Comment 0187-2)

2. Vague references have been made regarding radiation levels in other states. Only Colorado has been named. (Comment 0209.3-2)

3. EPA's new methodology really shows that you spend a lot of time with the Department of Energy. I have a handout that I recently picked up when I was over at the DOE's office, and it's their fact sheet on the American's average exposure. And it almost is word for word for what we keep hearing from Betsy at these roundtables. They're talking about the radiation exposure coming out of the repository and then adding to background.

And to put this dose in perspective, 660 millirem, which is what they come up with when they add the releases from Yucca Mountain to the background, is somewhat higher than the 360 and the national average on a yearly basis. But it's well below levels received by people living in other parts of the United States. And you're just constantly saying that.

So it appears that you're seeing off the same sheet that the Department of Energy did, or you certainly had some help with this thing. (Comment 0209.14-2)

4. Is it possible that we have a higher background here in Nevada because of the Test Site? (Comment 0210.6-1)

5. We do not understand what scientific rational that EPA is using in comparing natural background radiation to potential radiation exposures from YMP in setting the YMP radiation standard. There are scientifically significant differences between potential YMP radiation exposure and natural background exposure including the drinking exposure mode; the composition of radionuclides and energy levels; tissue deposition of radionuclides, and cancer risk. The important YMP health risk is posed by ingestion in contrast to background radiation where the principle concern is external radiation. Finally, the EPA justifies the new radiation exposure standards based on the radiation absorbed during routine x-rays. This analogy is misleading due to differences in the manner that one receives the radiation dose. (Comment 0214-3)

6. While the concept of matching “background” radiation seems benign, it should be noted that the 350 millirem limit is for a maximum exposure nationwide. Even at Yucca Mt., next to the Nuclear Weapons Test Site, annual background exposure is about 110. Furthermore, background radiation causes serious cancers each year, skin cancers, melanomas and more, especially in this sunny desert region. (Comment 0306-9)

7. The proposed rule prescribes a dose limit to be used beyond 10,000 years that is based on current average annual background radiation levels in Amargosa Valley, Nevada, and in Colorado. If those background values are higher now, or in 2000, say, than they were in 1900, because of Hiroshima, Nagasaki, atmospheric nuclear weapons testing, Chernobyl, ongoing reactor plant operation, etc., then would it not be appropriate to extrapolate those increases; i.e., to accumulate the century-on-century increases in average annual background radiation in Amargosa Valley and Colorado out to 10,000 years and beyond? Would using those larger extrapolated values not be more consistent with the “comparison with background radiation levels” rationale that undergirds the new 350 mrem/year limit? Indeed, the extrapolation should perhaps not be a linear one, given (based only on my cursory survey of the past 10,000 years) (Comment 0307-1)

8. We believe that it is misleading to make a comparison between natural background radiation and that which comes from nuclear waste. (Comment 0341-7)

9. What effect does the old NRDS project have on levels today? (Comment 0367.1-10)

10. NRDS has been included in background. (Comment 0367.1-23)

11. How can EPA know what background radiation levels will be like in 10,000 years? (Comment 0367.2-24)

Response to Issue E:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule.

Comment 0187 suggested that we clarify the dose standards that DOE will be required to meet from the time of repository closure out to 10,000 years, and from 10,001 years to 1 million years. These standards, respectively, are 15 mrem/yr, and 100 mrem/yr *in addition* to background radiation. Our rationale behind the setting of these limits can be found in the Dose Limits section of this document (Section 2).

Commenter 0306-9 stated that background radiation causes serious cancers each year, skin cancers, melanomas and more, especially in a sunny desert region like Yucca Mountain. As we discussed in our proposal, background radiation can be highly variable. We would point out that the commenter refers specifically to skin cancers, for which sun exposure is the leading cause. Sun damage is caused primarily by radiation in the ultraviolet portion of the spectrum, and while the higher-energy portion of the ultraviolet range can be ionizing (sufficient energy to break chemical bonds and remove electrons), it is significantly lower in energy than the gamma radiation typically included in "background radiation." See http://www.epa.gov/sunwise/.

Comment 0214 stated that we justified our radiation standard based on the radiation absorbed by routine x-rays. That is incorrect. We justified the 15 mrem/yr standard within 10,000 years as consistent with EPA's risk management policies, representing a lifetime risk of roughly 3×10^{-4} (given a 30-year exposure period). As the commenter points out, the factor used to convert dose to risk is based on external radiation (but not x-rays). Risks from internal exposures could be slightly higher or lower, depending on the radionuclide. However, we find that this conversion provides a reasonable estimate of overall risk when multiple radionuclides and exposure pathways are involved in projecting doses over long time periods.

Commenters 0210.6-1 and 0367.1 questioned whether there could be higher background radiation levels because of either the Nevada Test Site or the Nuclear Rocket Development Station (NRDS). We are not aware that radiation levels in the Yucca Mountain or Amargosa Valley areas are significantly higher because of the Test Site and NRDS activities.

Section 3 Background Radiation

Issue F: Comparison with radiotoxicity of ore

1. Other questions would include, how can one defend any conclusion that Yucca would be "unacceptable" hundreds of thousands of years from now when the radioactivity (and radiotoxicity) level of the waste is already more than an order of magnitude less than the uranium ore that was originally dug up to make it? After the waste has become less radioactive than the original ore, all obligations should end. At that point, the only difference between the waste and the ore is that it is less radioactive, and that it is far more isolated from humanity than the ore would have been (as the ore has no man-made confinement, and is randomly distributed all over the place, in contact with ground water, etc…). (Comment 0201-8)

2. In fact, only one thing about the next million years is known for certain – that during this time, the hazard of used nuclear fuel will become less than that of the natural uranium from which it was produced. This does not mean to imply that we would support a standard setting a compliance period extending to the time at which the radiotoxicity of used fuel becomes less than that of uranium ore. As EPA has correctly pointed out in its proposal, there is a general lack of agreement in the scientific community on the practicality and appropriateness of this measure. Calculations differ, based on assumptions, as to the point at which the radiotoxicity of the fuel equals that of the uranium ore from which it was produced. However, this point is generally believed to fall somewhere between 10,000 and 300,000 years. This measure, while not useful in establishing a regulatory compliance period, does provide a figure of merit for comparing the relative significance of the hypothetical hazard from which EPA is proposing to protect the next 25,000 generations – demonstrating that, for most if not all of the period beyond 10,000 years, the hazard is comparable to naturally occurring hazards and is continually becoming even less significant over time. (Comment 0298-4)

3. EPA's proposed 350 mrem/yr dose would not just occur for a brief time and then decrease to far lower levels. Under EPA's proposal, these large doses would be permitted to occur year after year, generation after generation, forevermore into the future (well, out to a million years, after which time regulations would end, although certain radionuclides would remain hazardous and deadly even much further into the future than that). Under EPA's proposal -- given the lack of a cap on maximum doses and the hundreds of thousands of years these leaking wastes would remain harmful – significant numbers of the

people most exposed to radiation doses could suffer a statistical 100% risk of contracting cancer. The State of Nevada has noted that EPA, on page 108 of the proposed rule, holds that exposures of the magnitude associated with un-mined uranium ore bodies meet the standard of "minimal justice." EPA further states that estimates of the risks from un-mined ore bodies range upward to 100,000 excess cancer deaths over 10,000 years, So it follows that EPA believes ten excess deaths per year are acceptable For a 1,000,000 year assessment period called for by the proposed Yucca rule, this means that ten million excess deaths would be acceptable to EPA. Ten million excess cancer deaths, however, is again nightmarishly unacceptable. (Comment 0324-5)

4. A level of protection at 350 mrem/yr also is supported by a comparison of that level of protection with the effects of existing uranium ore bodies. In setting the release standard in Part 191, EPA evaluated the health risks to future populations from the ore needed to produce 100,000 metric tons of reactor fuel, if the ore had not been mined to begin with, and concluded that the population risks ranged between 10 and 100,000 premature cancer deaths over 10,000 years. The acceptability of the release standard was supported by the observation that "...leaving the ore unmined appears to present a risk to future generations comparable to the risks from disposal of wastes covered by these standards." (Comment 0352-26)

5. Additional emphasis on ore body comparison as a fundamental rationale for the acceptability of the proposed dose limit, however, would strengthen the rationale for selection of the proposed level of protection, both through consistency with the philosophy of protection in Part 191, and as an additional independent rationale for the proposed limit. Background radiation gives a perspective on the significance of the risk in terms of other omnipresent radiation risks that are routinely accepted. The ore body comparison provides an ethical argument as well; this generation should not be expected to improve upon the situation that would have resulted if the ore had not been mined in the first place, as would be the case in the very long run after the engineered features have done their job and the repository looks much like an ore body. (Comment 0352-27)

6. The idea of using the original unmined ore body as a basis for comparison in regulating high-level radioactive waste disposal in the United States was suggested in the early days of development of EPA regulations by the Natural Resources Defense Council, in a paper on radioactive waste management prepared for the Department of Energy. That paper recommended a principle of strict neutrality with respect to imposition of risks on the future, i.e., there should be no net increase in risks imposed on future generations by the use of nuclear power, independent of any consideration of the benefits this generation might achieve from such use. The report concluded that this policy toward the future would be the most fair way to proceed and stated that "This policy's practical embodiment is a disposal system producing no more risks to the future than would have been produced by original uranium ore bodies utilized in nuclear power, assuming they had remained unmined." One can disagree with the ethical argument that a policy of strict neutrality toward the future-considering only risks, ignoring benefits-is obligatory. However, even holding to this strict principle leads to a comparison with the original ore body, not to an abstract standard of safety. (Comment 0352-28)

7. Another report prepared for the Department in 1980 looked at comparisons of releases from a potential repository to the unmined uranium ore deposits from which the fuel was originally taken and presents calculations for individual doses for actual ore bodies, using various water consumption scenarios, including a well within one mile of the ore body. The report presents a comparison of reasonable ranges of performance for reference repositories to doses associated with numerous ore bodies. The report calculates annual doses significantly above 100 rem for several ore bodies. Furthermore, the 350 mrem/yr level proposed by EPA is just under half the median and geometric mean of the annual doses estimated from actual measurements of radium-226 in water at 14 locations associated with ore bodies analyzed in that report. In comparison, EPA noted that the predicted effects of the release standard in Part 191 (1,000 statistical deaths in 10,000 years) were at the midpoint of the range of ore bodies analyzed. Since that range was 1,000 deaths to 100,000 deaths, EPA was clearly using a midpoint in the sense of median or geometric mean, rather than the arithmetic mean. (Comment 0352-29)

8. In summary, comparison of the repository to existing ore bodies is relevant to establishing a peak dose standard from two perspectives. First, from the technical perspective, it has not been shown that a geologic repository can reasonably be expected to perform much better than a uranium ore body at a time in the distant future when the engineered barriers have deteriorated and the repository looks very much like an ore body. Second, from an ethical perspective, it has not been shown why a repository should be expected to do so. (Comment 0352-30)

9. The release limit in Part 191 was not mathematically derived from the analyses of ore bodies or of conceptual repositories. Rather, it was determined to be a level that was achievable and that was clearly acceptable in view of those analyses. Using the same approach for the peak dose standard, EPA should emphasize that the comparisons with ore bodies and background radiation levels are just that, comparisons, rather than the basis for a rigorous mathematical derivation of the 350 mrem/yr limit. The Department believes this interpretation is consistent both with the logic used in establishing Part 191 and with EPA's acknowledgement that the proposed level of 350 mrem/yr "…will limit total radiation exposures of the RMEI to levels *comparable to* those incurred today from natural sources by residents of a nearby western State (emphasis added)." The phrase *comparable to* implies a looser relationship than strict equality. Translation of this objective into a quantitative rule should be informed, but not dictated, by use of a specific example or examples, such as the comparison between Amargosa Valley and Colorado. In other words, EPA should make it clear that the basis of the 350 mrem/yr standard follows from comparisons with both unmined ore bodies and incremental doses that would be incurred by moving from Amargosa Valley to another area with a higher level of background radiation, in the sense that it is in the range of estimates of such doses and for that reason is judged to be acceptable. This logic would be fully compatible with the reasoning supporting the performance standards that apply to other geologic repositories. (Comment 0352-31)

Response to Issue F:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule.

Although the comparison of the repository to a natural ore body is no longer relevant, we briefly address the comments on this topic.

We agree with comments that, over periods up to 1 million years, the hazard of used nuclear fuel becomes less than that of the natural uranium from which it was produced. In fact, we discussed the concept at length in the preamble to our proposal (70 FR 49039). We also agree with Commenter 0352-31 who states that the release limits for 40 CFR part 191 were not derived from the analyses of ore bodies, and that comparisons with ore bodies and background radiation levels were not the basis for a rigorous mathematical derivation of the originally proposed 350 mrem/yr limit.

Comment 0324-5 is correct that a peak dose rate may continue for more than one year. However, the commenter infers that the peak dose would last forever, and states that there would be a "lack of cap on the maximum dose," inferring that the peak dose would increase as time went by, and that is incorrect. The maximum allowable dose for the purposes of compliance, represented by the mean of the distribution of the projected doses, is 1 mSv/yr (100 mrem/yr). We have not, however, required that compliance be assessed against the "worst case" projected dose, if that is what the commenter means.

As Comment 0352-29 noted, the release limits in 40 CFR part 191 were scaled to a level estimated to result in 1,000 fatal cancers over 10,000 years from disposal of 100,000 metric tons of heavy metal (the midpoint of a range estimated between 10 and 100,000 excess fatalities). Thus, Commenter 0298 is incorrect in implying that the high end of the estimated range of risks from uranium ore represents the level upon which the 350 mrem/yr individual peak dose standard is based.

Section 3 Background Radiation

Issue G: Dade Moeller report

1. A recent calculation by an internationally renowned health physicist, using information on estimating effective dose rates from radon that is more recent than that used by EPA and data specific to Amargosa Valley, Nevada…was able to gather the necessary site-specific data and compare background levels in Amargosa Valley to a specific location in Colorado (Leadville). Using *location-specific data* for Amargosa Valley and Leadville, the calculations…indicate a difference in background radiation of 410 mrem/yr with the new equivalency factors. This information provides additional support for the conclusion that EPA's proposed level for individual protection at time of peak dose of 350 mrem/yr is reasonable. (Comment 0352-20)

2. The initial purpose of this [Dade Moeller] review was to compare the estimated total effective dose rate to residents of the Amargosa Valley, NV, due to exposures to naturally occurring radiation sources, to that of a comparable group that was known to have a relatively high dose rate from these same sources… Such an approach would be in accord with a long-standing recommendation of the International Commission on Radiological Protection, namely, that differences in natural background dose rates can serve as a useful basis for the establishment of dose rates that would be acceptable for members of the public on a long-term basis. (Comment 0352-42)

3. In its Proposed Rule, the USEPA stated that, in making such assessments, it was their intention to limit the sources to "external exposures from cosmic and terrestrial sources, and internal exposures to naturally-occurring radon." This, however, left open the question of whether only indoor exposures, outdoor exposures, or a combination of the two, would be considered. The contractor hired by the USEPA prepared a report in which they addressed indoor exposures only. In addition, rather than comparing the dose rates in two communities, they compared average dose rate estimates for the States of Nevada and Colorado. (Comment 0352-43)

4. [S]urveys show that about 91 percent of the Amargosa Valley residents live in mobile homes. According to staff members in the Florida and North Carolina State Radiation Control Programs, and the USEPA, the average *indoor* radon concentration, for this population group, will be essentially the same as that outdoors. The reason is that mobile homes are typically placed on supports such that the floor is a foot or more above the ground. For this reason, there is a relatively small [if any] pressure gradient to "force" the radon, released from the ground, to move into the home. In addition, the supporting structures for such homes include several layers of plywood, that are covered by floors that, not only have no open cracks or joints but also are, in turn, supported by a steel box frame enclosed within an impervious outer steel sheet metal container. (Comment 0352-44)

5. EPA chose a key conversion rate from radon concentration (actually, the concentration of radon daughter products) to lung irradiation that is substantially different from the one chosen by an NCRP expert committee. Dr. Moeller is a recognized authority on the subject and he reported that the NCRP committee dealing with these standards had changed that key factor by a factor of two, and that EPA had relied on the older figure. Using the correct conversion factor generally reduces radon dose estimates by a factor of two. Moreover, Dr. Moeller points out that it had been widely known for some time that the previous number was not used by the standard international reference; EPA gave no recognition of this in its *key* background report and in using that report to concoct its dose standard for Amargosa Valley. That EPA made such a skewed choice for the key conversion factor when it knew or should have known better undermines the credibility of its technical backup generally. (Comments 0357-1 and 0359-1)

Response to Issue G:

The comments refer to an article in the October 2006 edition of *Health Physics* by Dr. Dade Moeller ("Comparison of Natural Background Dose Rates for Residents of the Amargosa Valley, NV, to Those in Leadville, CO, and the States of Colorado and Nevada," co-authored by Lin-Shen Sun). Dr. Moeller is a well-known health physicist and past chair of the Health Physics Society. Dr. Moeller also presented his results at a public meeting of the NRC's Advisory Committee on Nuclear Waste (ACNW) in November 2005 (Docket No. EPA-HQ-OAR-2005-0083-0376), and a preliminary version of his paper was submitted with public comments by the Department of Energy (Docket No. EPA-HQ-OAR-2005-0083-0352).

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule. In addition to the comments we received that supported the use of natural background in setting a dose standard, we also received a significant number of comments taking issue with the concept of using background radiation as an indicator of "safe" levels of exposure from an engineered facility. We also received additional information that provided insights into our consideration of background radiation. For example, monitoring stations operated by the Desert Research Institute provided monitoring data indicating that the unshielded (outdoor) background radiation from cosmic and terrestrial sources in Amargosa Valley is roughly 110 mrem/yr. Commenters 0357 and 0359 also informed us that roughly 90% of the population in Amargosa Valley lives in mobile homes, which has implications for indoor radon exposures. Other commenters supported the use of a different factor for converting radon concentrations into dose.

In considering these comments, as well as those taking issue with the overall premise described in the proposal, we found the relatively simple approach used in the proposal evolving into a more complex undertaking requiring numerous decisions where science did not provide a clear answer. Indoor radon estimates presented the greatest challenge, and also represented the highest proportion of overall background radiation. Complicating factors included multiple ways of calculating radon dose, the prevalence of mobile homes in Amargosa Valley, limited data sets primarily from the early 1990s, and data for individual counties in a different format than state-wide data. We concluded that there was no generally agreed-upon approach in the context of Amargosa Valley for incorporating indoor radon exposures into an analysis of background radiation. As a result, we determined that we could not satisfactorily derive a standard from such an analysis, particularly given the fact that many commenters viewed the entire concept as arbitrary.

We continue to believe that references to natural sources of radiation can provide useful insights into the "significance of" projected doses (in IAEA's words) over hundreds of thousands of years. For example, as noted above, 100 mrem/yr is roughly the value reported by the Desert Research Institute for cosmic and terrestrial radiation at Amargosa Valley (unshielded). When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally. Within the State of Nevada, the difference in average estimates of background radiation for counties is greater than 100 mrem/yr. (Docket No. EPA-HQ-OAR-2005-0083-0387) This suggests that 100 mrem/yr can be considered to be a level such that the total potential doses incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain will remain below doses incurred by residents of other parts of the country from natural sources alone. It may also be noted that the 1 mSv/yr (100 mrem/yr) public dose limit recommended by ICRP is itself related to background radiation. (ICRP Publication 60, Docket No. EPA-HQ-OAR-2005-0083-0421, paragraphs 190 and 191) However, in the absence of compelling reasons for selecting specific background radiation estimates and points of comparison, we conclude that comparing background radiation estimates from specific locations does not provide a clear or sufficient basis for a regulatory compliance standard applicable to the Yucca Mountain disposal system.

Dr. Moeller also employed a radon dose conversion factor lower than ours, which he cites as consistent with UNSCEAR and forthcoming NCRP recommendations. The factor we employed for our proposal is that published by NCRP in its initial studies of background radiation in Publications 93 and 94. Much work has been done in this area, but there is no consensus that the earlier factors are outdated. Nevertheless, we have revised the background radiation elements in our supporting technical document using the conversion factor suggested by Dr. Moeller. Readers can judge for themselves the significance of this factor in deriving such estimates.

Section 3 Background Radiation

Issue H: Why Colorado?

1. Discerning how the Colorado rationale is actually supposed to justify EPA's proposed standard is not easy, for EPA's explanation of the rationale is far from clear. EPA never performs any kind of risk assessment that concludes that a 700 millirem total exposure is safe. Nor does it ever suggest that the fact that people's choices to live in Colorado reflect a societal judgment that such exposure levels are safe; EPA specifically states that "[i]t should be clear that we are not arguing that most people take into account levels of background radiation when deciding where to live or work, or that it in any way plays a major role in their decision-making." 70 FR 49038. Instead, EPA reasons that since levels of exposure near 700 millirem/year occur naturally in a few isolated places, and people live in those areas without obviously dying in droves, a standard that allows 350 millirem/year anthropogenic exposures on top of the already occurring 350 millirem/year of natural exposures in the Amargosa Valley must suffice. As EPA puts it, risk levels apparently are fine so long as "in EPA's view" those levels "do not 'pose a realistic threat of irreversible harm or catastrophic consequences.'" *Id.* EPA does not explain why it holds this view. But the rationale is in any event arbitrary. EPA's role is to establish a standard protective of public health and safety and never in the past has it considered that role to be fulfilled merely through avoidance of "a realistic threat of irreversible harm or catastrophic consequences." Instead, it has set standards, both to protect people from radiation and in other regulatory contexts, designed to allow only the most minimal of increases in the levels of cancer and other illnesses already induced by background levels of radiation. (Comment 0226-52)

2. Independently of these errors, EPA's method of choosing its natural background benchmark is irrational. If EPA were to utilize a natural background standard, the most logical benchmark for that standard would be natural levels in the Yucca Mountain area or, perhaps, in the nation as a whole, which has average radiation levels significantly lower than those that already exist in the Amargosa Valley. But EPA has deliberately rejected both possibilities, and has chosen Colorado for two simple reasons: first, because Colorado has substantially higher natural background radiation than the Amargosa Valley or the country as a whole; and second, because Colorado also is in the western United States. (Comment 0226-57)

3. EPA's reliance on the former reason is completely circular. In effect, EPA has determined that increased radiation is appropriate by comparing conditions in the Amargosa Valley to a subset of other states, all of which it selected specifically because they have higher exposure levels, and within that subset has chosen Colorado over Idaho apparently just because Colorado is more radioactive. EPA thus based its conclusion that higher exposure levels are allowable on the premise that its analysis must produce a conclusion that higher exposure levels are allowable. Put differently, EPA has proposed that Nevada can have substantially higher exposure levels because Colorado does, and has said that Colorado is an appropriate comparison because it has substantially higher exposure levels. This reasoning lacks any logic. Comparing Nevada to Colorado because

both are in the West, and therefore determining that Colorado's natural background levels are appropriate for Nevada, is as reasonable as suggesting that humans could appropriately recreate New Orleans' flood risk in Atlanta because both are in the South. EPA has provided no other reason for its selection of Colorado. That selection therefore appears to represent an obvious effort by EPA to rig its analysis, and to justify its predetermined conclusion that an unprecedented high standard should be employed. As the report by Dr. Fleming in Appendix D establishes, EPA cannot assume that natural background or variations in natural background are acceptable risks. Yet this appears to the basis for EPA's proposal. (Comment 0226-58)

4. The adoption of the so-called "Colorado standard" demonstrates the depths of rationalization and self justification that's been employed to weasel out from the intent of the NAS and Circuit Court of Appeals decisions. (Comment 0309-4)

5. The rule's explanation does not adequately explain why Colorado was chosen. The figures for background radiation for Amargosa Valley are not clearly documented. EPA is being arbitrary in choosing the background radiation for Colorado. It is our understanding that radon is a major contributing factor to that background radiation and thus is not similar to the Amargosa environment. In addition, just because a risk exists naturally in one location does not mean that it is acceptable or "safe" for humans to create it somewhere else. Why choose the background radiation level for the area that will not be directly affected? Wouldn't it be more appropriate to use background radiation level for Nevada or for the nation as a whole? It appears to us that when it is to the advantage of the government to use site-specific standards, they are promulgated. But when site specific numbers are problematic for the repository to meet standards, then the government opts for generic standards. (Comments 0353-4 and 0361-4)

6. Why does EPA use Colorado as a comparison? (Comment 0367.2-6)

Response to Issue H:

After considering all of the comments that we received on the use of background radiation to establish the long-term dose limit, we have decided not to adopt the proposed 3.5 mSv/yr (350 mrem/yr) level as the compliance standard for the period beyond 10,000 years, nor have we adopted the reasoning used to support the proposed standard (i.e., considerations of background radiation) in the selection of the 1 mSv/yr (100 mrem/yr) level established in our final rule. Given the adoption of a standard that is protective of public health and safety, and the existence of a rational basis therefor, it is not necessary to respond to comments on the earlier justification for the 350 mrem/yr level, and, in particular, whether a location in the State of Colorado was an appropriate reference point.

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Section 4 Two-Tiered Standard

Issue A: Oppose use of a two-tiered standard

1. EPA is proposing the least protective radiation standard in the world. No other US or international radiation protection standard permits a dose of 350 millirems per year to members of the public. Most other countries proposing a geologic repository have proposed or established a radiation standard of 10 millirems per year. Swiss regulations explicitly set no "expiration date" on protecting future generations. Calculations done for Nevada's Agency for Nuclear Projects demonstrate this standard is "ten times greater than what EPA, NRC, and other regulatory bodies have previously allowed for all non-medical sources combined." (Comments 0126-4, 0127-4, 0133-6, 0135-6, 0137-6, 0144-5, 0146-6, 0147-6, 0148-6, 0150-3, 0159-6, 0163-6, 0164-5, 0182-4, 0189-4, 0190-5, 0195-1, 0293-8, and 0302-1)

2. I think it is absurd to apply a new definition to maximum safe levels of radiation exposure in order to justify the dumping of nuclear waste on Nevada. (Comment 0142-1)

3. I strongly object to the two-tiered standard that jeopardizes the health and safety of the future residents of Nevada. The EPA proposal would set a horrible precedent and is in contravention of internationally accepted radiation protection standards, not to mention basic ethical standards. There is a Native American proverb which the current leadership of the EPA would do well to contemplate: We do not inherit the earth from our ancestors, we borrow it from our children. (Comment 0128-1)

4. Please re-evaluate the radiation double standard and stop committing these terrible injustices against the people of Nevada, both citizens and the Native Americans. (Comment 0140-2)

5. EPA's proposed double standard must be withdrawn. The proposal would protect people for the first 10,000 years to currently applied standards of protection, but would then doom future generations after that to a 1 in 36 cancer rate (or even worse, up to 100% cancer rate, due to EPA mathematical manipulation), and a 1 in 72 fatal cancer rate (or even worse). Such proposed cancer rates and fatal cancer rates are horrifying… (Comments 0175-1 and 0177-1)

6. Instead of 10,000 years, a more appropriate conversion point would be when the engineered barriers are expected to fail completely and when protection will be afforded on by the natural barriers. (Comments 0180-1 and 0181-1)

7. We strongly oppose the new radiation standards that have been proposed for Yucca Mountain, which call for differing levels of protection—one level for the first l0,000 years, and then catastrophically reduced standards for all following generations of humans. It is absolutely essential that you retain the current standards for all future generations. (Comment 0200-1)

8. At the roundtable presentation, vague references have been made to radiation standards in other countries. Which countries and what levels of radiation? (Comment 0209.3-1)

9. And I would refer you to 10 CFR, Part 50, Appendix 1, Section 2A: By accepting a false premise that no man may package relief within the first 10,000 years – and I would submit that's a complete – that's totally preposterous.

EPA has created a bifurcated standard, which fails to protect the public in the first 10,000 years of the repository's operation. And, unquestionably, in the period beyond the first 10,000 years, fails at nearly astronomical rates. (Comment 0209.6-5)

10. EPA's unprecedented proposal – proposed maximum dose for an individual after the first 10,000 years is 14 times higher than the dose allowed for low-level waste disposal in the United States currently. It's also ten times higher than the level of protection recommended by the National Academy, as you've heard earlier, 35 to 100 times more -- less protective than those living near nuclear power plants. (Comment 0209.7-6)

11. If the Bush Administration is successful, these nuke standards will be the least protective radiation standards of the world. (Comment 0209.12-8)

12. Your attempt to bifurcate this radiation standard throws out all attempts at generational equity and puts future generations at tremendous risk, the very risk that mandated not happen -- Congress mandated not happen. (Comment 0209.13-2)

13. Use of a two-tiered standard is unstable, and we don't know if it's protective to humans one million years in the future. (Comment 0210.1-3)

14. With regard to EPA's proposed multiple-dose standards, Lincoln and White Pine County believe said standard adequately considers protection of public health. (Comment 0211.1-2)

15. Concerning the longer-term radiation standard, Lincoln and White Pine Counties are concerned that the proposed requirement that DOE demonstrate that a person living 11 miles away from the Yucca Mountain site would be exposed to no more than 350 millirem after 10,000 years of repository operations represents a theoretically arbitrary and seemingly unjustifiable increase between years 10,000 and 10,001 of repository operations. (Comments 0211.1-4 and 0315-2)

16. It is not clear how DOE will be able to demonstrate through performance assessment that, in the year 10,000, radiation exposure is limited to no more than 15 millirem and then demonstrate that, in the year 10,001 of operations, the allowable exposure is increased to 350 millirem. EPA is encouraged to give further consideration to the justification for and public health implications of such a significant one-year increase in allowable exposure. (Comments 0211.1-5 and 0315-2)

17. As it stands, Lincoln and White Pine County residents are left wondering if EPA believes the 15-millirem standard is required to protect public health and the environment during the first 10,000 years of repository operation, why would the Agency ever consider increasing the allowable exposure limit by a factor of 23? (Comment 0211.1-6)

18. Conversely, if an exposure limit of 350 millirem provides for protection of public health and the environment in the year 10,001, why would it require a more stringent standard in prior years? (Comment 0211.1-7)

19. According to the group Public Citizen, you are proposing the most harmful radiation standards that this world has ever seen. As far as the EPA radiation standards goes, this is a bad thing in general. If we allow standards like this to be approved in our society, we will eventually perish. It is illogical, immoral, and irresponsible to set standards with such apathy for these American taxpayers. (Comment 0211.4-2)

20. I would hope that you guys wouldn't lower the standard. It's dangerous as it is. I did work at the Test Site 18 years, and you read in the newspaper every day about people that have been at the Test Site working that's dying. (Comment 0211.6-1)

21. With regard to EPA's proposed multiple dose standards, Lincoln County believes said standard adequately considers protection of public health. The near term standard requiring DOE to demonstrate that a person living 11 miles away from the Yucca Mountain site would be exposed to no more than 15 millirem of radiation per year during the first 10,000 years of repository operations appears reasonable . Concerning the longer-term radiation standard, Lincoln County is concerned that the proposed requirement that DOE to demonstrate that a person living 11 miles away from the Yucca Mountain site would be exposed to no more than 350 millirem after 10,000 years of repository operations represents, a theoretically arbitrary and seemingly unjustifiable increase between years 10,000 and 10,001 of repository operations. (Comment 0219-1)

22. EPA is encouraged to give further consideration to the justification for, and public health implications of, such a significant one-year increase in allowable exposure. As it stands, Lincoln County residents are left wondering if EPA believes a 15 millirem standard is required to protect public health and the environment during the first 10,000 years of repository operation. Why would the agency ever consider increasing the allowable exposure limit by a factor of 23. Conversely, if an exposure limit of 350 millirem provides for protection of public health and the environment in year 10,001, why would it require a more stringent standard in prior years? The public needs surety that EPA fully understands the health and environmental consequences of exposure to various levels of radiation. (Comment 0219-2)

23. Standards should not be "degraded" simply because a certain amount of time has elapsed. If a standard is set for a legitimate reason, it should remain intact until an equally legitimate reason is found to make an adjustment. The adjustment should be performance based and not simply because a time limit has passed. A similar concept is the recent revision of NRC provisions for decay-in-storage for radioactive waste containing byproduct material. This is a performance based provision rather than simply holding the materials for a set length of time. EPA should take the same regulatory path and set a viable, legitimate standard for future generations which can always be reviewed over time. (Comment 0223-1)

24. Like its predecessor, EPA's proposed rule would after 10,000 years terminate its only radiation standard that protects public health. The only innovation in EPA's new approach is to propose a nominal second-tier standard, 70 times weaker in mean-equivalent terms, for the longer-term period in which all of DOE's modeling runs show leakage from the repository. That approach again abrogates the central point of the NAS and the Court: that the repository should safeguard citizens *at the time of the peak dose* that will occur from repository leakage, whenever that occurs. See *NEI*, 373 F.3d at 1273 ("NAS recommended that *the compliance period extend to the time of peak risk.*") (Emphasis added). Most importantly, EPA does not and cannot show that its standard will result in a safe geologic repository at Yucca Mountain… Rather than suggesting any relaxation of the standard after 10,000 years, NAS only qualified the statement by noting that the occurrence needed to be [w]ithin the limits imposed by the long-term geologic environment, which is on the order of one million years." NAS Report at 2… In short, a rule that terminates the health-protective standard at 10,000 years despite the absence of any scientific basis, and thereafter applies a standard dramatically exceeding all established norms for radiation exposure, using a compliance method that ignores many exposures that are even greater, cannot possibly qualify as "based upon and consistent with" NAS's peak dose recommendation. (Comment 0226-1)

25. EPA's proposed rule never comes to terms with this sharp divergence from its past practice. EPA insinuates that international bodies support its notion that anthropogenic sources should be able to double existing natural background levels. But in fact they do not. EPA's citations are misleading and out of context. See Appendix A. As EPA itself noted, "[n]o regulatory body that we are aware of considers doses of 150 mrem to be acceptable," and those international bodies have never suggested that natural background levels should create an exception to the more stringent limits they have created. EPA, Response to Comments at 3-8. (Comment 0226-50)

26. EPA suggests its rule is "unprecedented" because it was commanded by NAS and the Court to address time periods after 10,000 years. But that is no rationale. EPA never explains how a standard that is obviously inadequate can suddenly become adequately protective at 10,001 years. Nor can it, for EPA has no basis for assuming that human

susceptibility to radiation will change. Additionally, EPA's suggestion that it need not be consistent with international precedents, because those precedents do not address long time frames, is demonstrably false. Many international and national bodies do recommend or impose regulation over long time frames, and none permits the type of two-orders-of-magnitude increase in risk that DOE's non-protective second-tier standard would allow. *See* Appendix A. (Comment 0226-122)

27. There is no justification for a two-tiered standard or allowing more risk to future generations than today's. (Comment 0257-9)

28. However, in proposing this rule change the EPA has constructed an illogical house of cards around failed policy based on wishful thinking. The EPA rests its case for a dual radiation dose standard for near-future and far-future generations on the vast uncertainties surrounding enterprises projected 10,000 to a million years in the future. (Comment 0267-1)

29. The EPA's policy must address the certainties that, given the present design and location, the containment will fail and harm will occur. The EPA has chosen to address these certainties not by seeking to avert such disaster—i.e. by forcing the whole enterprise back to the drawing board—but by pulling a set of numbers out of the (uncertain, incalculable) future that would justify the currently planned design. These numbers are not based on science; they are based on hope—hope that the containment will not fail for hundreds of thousands of years rather than mere thousands or tens of thousands (when we're using materials that have existed less than a century); hope that humans will not molest the buried treasure (and assuming their drilling tools are no more penetrating than our own and they will stop when they hit the treasure chests); hope that the worst geologic and climatic disasters will not occur (and that pervasive changes will have no effects); hope that the inevitable exposures are not too harmful; and, above all, hope that the future over which we have no control will present no surprises we haven't already imagined and taken into account. (Comment 0267-3)

30. The assigning of a dual standard thus does not meet the Court directive to comply with NAS analysis and recommendations. The NAS recommended basing the regulatory standard on peak exposure. Implicit in that recommendation was the expectation that one size *does* fit all when it comes to human beings and radiation exposure. No one should be exposed to more risk than any of us is willing to bear. And we must count our descendents as equal members with ourselves of the human race. To do otherwise is to guarantee our place in future histories as barbarians. (Comment 0267-5)

31. Environmental Protection Agency is supposed to be an agency to protect the environment, not protect a polluting industry like the nuke industry. If Yucca can be shown to be safe; it should be approved. If it can't meet acceptable safety standards, it should be rejected. But relaxing the standards by orders of magnitude in order to help get an unsafe project OKd because it can't meet protective standards is immoral. (Comment 0296-8)

32. Since…the existing 10,000 year standard is sufficiently protective (meeting all four of NAPA's principles for balancing risks, costs, and benefits fairly across future generations) and can be developed to address the deficiencies specified by the court in *NEI* – it should remain unchanged by this proposal. Any effort to address regulatory compliance beyond 10,000 years must, therefore, be considered as separate and distinct from the existing standard. It is the nuclear energy industry's belief, supported by international scientific and regulatory precedent, that the nature of repository safety analysis fundamentally changes beyond 10,000 years, and that any extension of the regulatory compliance period beyond this time must recognize this difference. International regulatory bodies have explicitly recognized the appropriateness of addressing longer time-frames differently, with several such organizations also recommending a dual track approach similar to that which EPA has proposed. Most do this by recommending some sort of stylized or generalized and less detailed approach for longer time periods, such as defining assumptions by regulation instead of trying to speculatively predict them. (Comment 0298-12)

33. It is important to note that just because the approach to regulation must, of necessity, change at 10,000 years, it does not follow that the level of protection is being reduced at this point. (Comment 0298-13)

34. Rather than setting a stringent health-based standard that the Yucca Mountain site should meet to be licensed, the EPA appears to be creating a "two-tiered standard," which is intended to help get the repository approved and open for business. DOE has publicly estimated radiation doses of 250 millirem/year at 200,000 to 300,000 years in the future, so EPA now proposes a standard above that level. Such blatant disregard for scientific objectivity and public health is very disturbing. (Comment 0301-4)

35. Furthermore, if accepted, EPA's proposed standards would be, by far, the worst standards among those of developed nations. For example, the French high-level nuclear waste repository program recommends limiting maximum doses, estimated to occur hundreds of thousands of years into the future, to 25 millirem/year. The proposed EPA limit beyond 10,000 years (350 millirem/year) would allow more than ten times higher radiation doses than the limit recommended under the French repository program. The Canadian repository program limits doses to about 10 millirem/year for 10,000 years but does not allow a sudden increase after that period. The EPA proposal would allow a sudden jump from 15 millirem/year to 350 millirem/year after 10,000 years, a 23-fold increase. (Comment 0301-11)

36. the agency has leapt from that well-defended position to a proposed standard of 350 millirem per year in year 10,001 was something EPA staff could not explain at all when asked at the Amargosa Valley, NV, Hearing on October 3rd. (Comment 0306-1)

37. Year 10,001 to 1,000,000: While EPA claims that "Phase II" of their standard, 350 millirem per year from years 10,001 to 1,000,000, is consistent with other nations, I do not find compatible evidence. This limit is more than 10 times higher than France's goal for long-term high-level waste, and 35 times higher than Canada's, next door. (Comment 0306-8)

38. I fail to understand why you have proposed a two part standard for the dumpsite when the Court rejected the standard you had previously. It is my understanding that the Court threw out the 10,000 year standard because it was in conflict with the recommendations that you were supposed to follow - and here you go putting the same rejected standard back again. The only standard should be the peak dose one. (Comment 0261-1)

39. EPA's proposed a two-tiered system that would permit a 15 millirem per year dose limit from Yucca Mountain for the first 10,000 years, but which would suddenly rise to an unacceptable 350 millirem per year, after the first 10,000 years has elapsed. Such an increase flagrantly ignores the law and the findings of the NAS, by establishing a two-tiered system which allows a far greater level of exposure to radiation after an arbitrary coverage period of 10,000 years. I have serious concerns about a two-tiered system that allows higher radiation exposure levels at Yucca Mountain in the future, given that the longer that the waste is buried there, the more deadly it will become over time. The National Academy of Sciences spoke clearly when it said this standard should cover the peak levels of danger created by waste slated to go to Yucca Mountain. It must be noted that the NAS found in June of this year that radiation exposure at any level increases cancer risks, and that there is no safe threshold. (Comment 0271-2)

40. EPA's and NRC's proposed double standard be withdrawn that protects people for the first 10,000 years to currently applied standards of protection, but dooms future generations after that time to a 1 ~~1~~ in 36 cancer rate (or even worse), and. a 1 ~~1~~ in 72 fatal cancer rate (or even worse). Such proposed cancer rates and fatal cancer rates are horrifying, and both agencies must withdraw such an unacceptable proposal. This is a complete violation of principles of intergenerational equity, justice and morality. (Comment 0310-1)

41. EPA's two-tiered approach is not based upon and consistent with the recommendations of the NAS. It fails to comply with EPA's fundamental charter as specified in the NWPA and 1992 EnPA – to protect public health and the environment. (Comment 0311.1-3)

42. EPA's two-tiered approach is the same as the initial approach that was vacated. DOE assumes that the engineered barriers will not corrode or leak for the first 10,000 years. Also, DOE's models suggest that once the barriers fail and waste begins to migrate, a median peak of 300 mrem/yr will result and will continue for thousands of years. NAS recommended that "it is not reasonable to assume that a system for post-closure oversight of the repository can `be developed based on active institutional controls, that will prevent an unreasonable risk of breaching the repository engineered barriers or increasing the exposure of individual members of the public to radiation beyond allowable limits. Additionally, there is no technical basis for making forecasts about the long-term reliability of passive institutional controls such as markers, monuments, and records." EPA responded with a standard that DOE can meet. (Comments 0311.1-5 and 0311.1-10)

43. No country has proposed a standard as lax as that proposed by the EPA. No other standard that has been proposed for times beyond 10,000 years would allow such lax long term rules. (Comment 0314.1-4)

44. The second tier standard of 3 .5mSv for the period from 10,000 years post -closure up to one million years is inadequate to protect future generations of Clark County residents. The long-term standard is roughly twenty times higher than the short-term standard and it is unclear what the rationale is for such a large discrepancy. (Comment 0327-1)

45. for an allowable post-closure dose of 350 millirem CEDE per year proposed by EPA for years 10,000 to 1,000,000 in the distant future, unquestionably 350 mrem/yr is entirely unacceptable. (Comment 0331-3)

46. The new radiation standard for Yucca Mountain is contrary to internationally accepted radiation standards. (Comment 0342-1)

47. The proposed standards represent a large –scale weakening of environmental and public health protection standards and are the worst such standards, by far, in the Western world, in violation of international norms. (Comment 0349-3)

48. We do not accept EPA's reasoning that a two tiered standard is necessary. The rule does not adequately explain why the 15 millirem per year standard for less than 10,000 years should not apply beyond 10,000 years. The rule also does not adequately address the fundamental challenge: to have a standard that is protective of public health and safety at the time of maximum releases into the environment. The rule should be written to protect public health and safety rather than to accommodate the many flaws in the site, and the site's inability to contain the radiation. (Comments 0353-3 and 0361-3)

49. 1. How did EPA go from 15 to 350, and aren't we talking about these numbers in addition to natural background levels? (Comment 0367.1-5)

50. Why isn't it safe to be exposed to 350 millirems today if it is safe in 10,000 years? (Comment 0367.1-11)

51. Unfortunately the rules that we are looking at, and as we've examined them, are weaker than the original standards. They do propose and argue a dramatic reversal of international and public health standards. And we do believe that there is a two-tiered system, a double standard. (Comment 0368.2-2)

52. I'd like to point you to the French standard, … the French regulation says that for the short term, you make accurate … calculations and you meet your 25 millirem limit with reasonable best estimate parameter characterization. And for the long term, you actually have conservative or upper bound parameter characterizations because you cannot do characterization, but you still have to meet the same dose limit. … let me recommend a specific alternative to you for a standard which would be somewhere between 10 and 25 millirem for the effective dose equivalent per year from all pathways with a sublimit for four millirem per year from drinking water. (Comment 0368.3-7)

53. We find the two-tiered dose limits for before and after 10,000 years to be an appropriate recognition of the greater degree of uncertainty for the longer period. (Comment 0368.5-1)

54. Extending the concept of individual dose standard to one million years is meaningless when the standard after 10,000 years is 14 times greater than what EPA itself has stated is protective of public health and more than 23 times higher than the first 10,000 years. In fact, EPA's proposed rule is the least protective radiation standard in the world. No other U.S. or international protection standard emits a dose of 350 millirems per year to individuals. (Comments 0368.6-2 and 0368.13-4)

55. We believe the EPA's recently revised standard , … fails to comply with the court ruling and the intent of the National Academy of Sciences' recommendations. Instead of extending the 15 millirem per year limit through the time of peak risk, EPA has proposed the two-part standard 15 millirem per year for 10,000 years and then the 350 millirem per year standard thereafter which would be at two million years. Such a standard is not scientifically justified and would perhaps be the least protective radiation standard in the world. No other U.S. or international radiation protection standard permits a dose of 350 millirems per year to individuals. And, in fact, EPA's proposed standard is not even consistent with the agency's own previous recommendations. (Comment 0368.7-1)

56. I'm here to express our shared concern and opposition to the dangerous double standards recently set for radiation regulations at Yucca Mountain. (Comment 0368.12-1)

57. Nevada has heard some Yucca Mountain proponents recently draw favorable comparisons between EPA's proposed rule for Yucca and the Finnish standard, promulgated by its Radiation and Nuclear Safety Authority ("STUK"). In fact, as explained below, the Finnish standard…is far more protective and responsible than what EPA has proposed for Yucca. Indeed, the two standards are night and day.

First, the STUK standard requires that the *maximum* radiation dose over long time scales be comparable to that from naturally occurring radioactive substances. Communications between the State and STUK have confirmed that this refers to doses from radionuclides of terrestrial origin, to the exclusion of doses from atmospheric fallout, cosmic radiation, natural radionuclides in houses such as radon, and other human-enhanced impacts. This means that the STUK standard is on the order of 50 mrem per year for the *maximum*, in contrast to EPA's proposed post-10,000-year standard of 350 mrem per year for he *median* dose, or about 1000 mrem per year for the mean dose, to EPA's Reasonably Maximally Exposed Individual (RMEI).

Surely it cannot be EPA's position that the citizens of Nevada deserve less protection than the Finns. (Comments 0399-1 and 0401-1)

Response to Issue A:

Many of the comments arguing against having different dose limits over different time periods offered similar reasoning to the comments addressed in Section 2, Issue C ("extend the use of 15 mrem CEDE/yr to the time of peak dose"). These points include the justification for a different, higher dose limit beyond 10,000 years, the legality of the proposal or its consistency with the NAS recommendation, the risks presented by the proposed post-10,000-year dose limit, intergenerational equity, and comparability with international standards. See the earlier section for additional discussion.

The comments were generally phrased in relation to the proposed peak dose standard of 3.5 mSv/yr (350 mrem/yr). In our final amendments, however, we are not establishing the proposed 350 mrem/yr level as our final peak dose standard; instead, we are establishing 1 mSv/yr (100 mrem/yr) as the public health and safety standard to apply for the period beyond 10,000 years and up to 1 million years. As discussed in the preamble to the final amendments, a dose level of 100 mrem/yr level is well-established as protective of public health and as such represents a standard that is protective of public health and safety in the extreme far future. (70 FR 49040) International organizations such as ICRP, IAEA, and NEA recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Domestically, both NRC and DOE incorporate the 100 mrem/yr level into their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," Docket No. EPA-HQ-OAR-2005-0083-0407). Because we are adopting the same approach described in our proposal, however, we are responding to the comments on this topic.

Commenters 0353 and 0361 charged that we have established a standard to ensure the site can be licensed. Commenter 0311.1 claims that the proposed approach is "the same as the initial approach that was vacated." The commenter then cites a finding of the NAS committee that institutional controls cannot be relied upon to prevent human intrusion or degradation of the repository. The commenter's point is not clear to us. This statement in the NAS Report was made in response to a specific Congressional question using the same language. There is no indication that DOE intends to rely on institutional control to maintain the repository indefinitely, or that it will attempt to take credit for such controls in its license application. Further, it is EPA's goal that a geologic disposal facility be able to provide adequate containment and protection in the absence of maintenance or even if knowledge of the facility is lost.

On the larger question of consistency with the NAS recommendation and Court ruling, Commenter 0261 also believes we are "putting the same rejected standard back again." Commenter 0368.7 agrees that our proposal "fails to comply with the court ruling and the intent of the National Academy of Sciences' recommendations". Other commenters stated that "Rather than suggesting any relaxation of the standard after 10,000 years," NAS only qualified its recommendation by reference to geologic stability (Commenter 0226), and "[i]mplicit in [the NAS] recommendation was the expectation that one size *does* fit all when it comes to human beings and radiation exposure" (Commenter 0267, emphasis in original). As discussed in more detail in Section 2 Issue C of this document, we disagree with this interpretation of the NAS recommendation and Court ruling. NAS was silent regarding the level of the peak compliance standard, and explicitly declined to recommend a level for that standard. Rather, NAS expressed its intent to leave that decision to EPA as "not ultimately a question of science but of public policy." (NAS Report p. 5) In discussing the range of risks represented by current domestic and international regulations for EPA to consider, NAS noted that, while "there is a considerable body of analysis and informed judgment from which to draw in formulating a standard for the proposed Yucca Mountain repository," "EPA's process for setting the Yucca Mountain standard is presumably not bound by this experience." (NAS Report p. 39) Finally, NAS acknowledged that EPA was not constrained by its discussion of representative risks in selecting the peak compliance standard, concluding that "other starting points are possible, and of course the final rule could differ markedly from any of them." (NAS Report p. 3)

Because its concern was the determination of compliance at the time of peak dose, NAS did not explicitly consider whether compliance might be judged against different standards during the 1 million-year time frame, but implicitly acknowledged this possibility in its discussion of intergenerational equity (see also Section 9 of this document). We believe there is ample evidence that NAS recognized that the nature of the assessments changes and effectively becomes more stylized as the period covered by the assessment increases (see, for example, its many references to "bounding" approaches), although the committee did not address different assessment time frames. We believe it is reasonable to conclude that the nature of the compliance determination may also change as the assessment period grows longer. We find 10,000 years to be a reasonable transition time, as there is a considerable body of experience in conducting assessments for such periods. Further, as noted in Section 2, in his personal testimony before a Senate committee on March 1, 2006, Robert Fri, chair of the NAS committee, indicated that, in his opinion, a compliance standard changing over time would not necessarily be inconsistent with the NAS recommendation to assess compliance at the time of peak risk. He suggested that such an approach could be viewed as reducing "the risk of excessive conservatism." (Docket No. EPA-HQ-OAR-2005-0083-0380)

Commenters 0111, 0211.1, 0219, and 0367.1 question the "significant one-year increase in allowable exposure." They question why 350 mrem/yr would not be considered protective today, if it is protective for periods beyond 10,000 years. Commenter 0111 cites our "unprecedented" attempt to "set expiration dates for public health standards." Commenter 0223 similarly states that standards should be "degraded" only for "legitimate" and "performance based" reasons, and "not simply because a time limit has passed." The commenter urges us to establish a protective standard "which can always be reviewed over time." Our justification for the higher dose standard beyond 10,000 years is in part performance-based. We have discussed at length our concerns that modeling as a tool for decision-making has limitations over long time frames, and that these limitations are accentuated when significant uncertainty is present in the system being analyzed. In our view, the results of such analyses should not be considered to be accurate predictions, but rather estimates of performance given certain assumptions regarding the characteristics of the disposal system. (See NAS Report p. 71) We acknowledge that we cannot say exactly when these uncertainties become unmanageable or overwhelming. We assume the commenter is suggesting that, in the future, were we to identify a specific point at which the quality of projections renders them less credible, it would be "legitimate" to modify the rule to insert time-dependent standards for the longer-term. While we can re-visit regulations if necessary, we are not sure when this would be expected to happen. Our standards have a broader place in the regulatory structure, as demonstrated by the next comment.

Comment 0367.1-5 questions the difference in the two dose limits and how the higher proposed limit after 10,000 years is justified. In both the proposal and in selecting the final peak dose standard of 100 mrem/yr, we attempted to balance a number of factors, including the ability to reasonably model the disposal system far into the future, dose levels that would adequately protect the public, and the role of the compliance standard in the licensing process, to identify a level that would be appropriate for the entire period out to 1 million years. During the period immediately beyond 10,000 years, we anticipate that projected doses would not exceed the peak dose standard; however, an acceptable result will not by itself demonstrate that the disposal system is safe and will perform adequately. Should projected doses show a significant rate of increase during that period, NRC will make judgments as to whether that would indicate unacceptable degradation of the engineered barriers that will result in a less-than-reasonable expectation that the overall performance is acceptable.

As for the second part of the commenter's question, both the 15 mrem/yr and the peak dose standards refer only to doses caused by releases of radionuclides from the Yucca Mountain disposal system, as directed by the EnPA. Background radiation doses, or doses from other sources (such as medical applications), are not included in those standards. We have not derived the final peak dose standard from an analysis of specific estimates of background radiation. We note, however, that the 100 mrem/yr peak dose standard reasonably comports with an analysis from that perspective as well. For example, it is comparable to outdoor (unshielded) measurements of cosmic and terrestrial radiation in Amargosa Valley. When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally, and is within the difference between average estimates among counties in the State of Nevada. (Docket No. EPA-HQ-OAR-2005-0083-0387) This suggests that releases from the Yucca Mountain disposal system potentially leading to doses of 100 mrem/yr to the RMEI will result in *total* doses lower than those incurred by residents of other parts of the country from natural sources alone. Further, the projected doses would be incurred by only the RMEI, who is defined to be within the most highly-exposed segment of the population near Yucca Mountain. Most of the population would incur much lower doses, if any.

Commenter 0211.1 further asks "how DOE will demonstrate through performance assessment" that it complies, given the increased dose limit beyond 10,000 years. This commenter actually touches on another of the factors that led us to propose a higher dose limit for the long-term, which is its place in the licensing process. Consistent with the NAS recommendation to assess compliance at the time of peak risk, within the period of geologic stability, the compliance period for our standards will extend up to 1 million years. We believe it is likely that peak dose will occur sometime after 10,000 years, although we cannot say exactly when (we note that some commenters raise the possibility that the peak dose will actually occur earlier than 10,000 years). DOE's previously published performance assessments suggest that peak doses will occur sometime in the period between 200,000 and 500,000 years. We strove to establish a standard that would protect public health and safety and appropriately balance the factors important to regulatory decision-making over very long times, the relative confidence that can be placed in projections over different time frames, and the nature of the current generation's commitment to future generations, as well as how that commitment can be demonstrated.

We judged that the best approach would be to identify a level that balanced these factors for the entire period up to 1 million years, while maintaining the 10,000-year standard as a point of departure that focuses on the early evolution of the repository, when thermal stresses are most significant. Therefore, we have selected a standard that we believe is appropriate at any time up to 1 million years. The 10,000-year standard then gives NRC a basis for judging the overall appropriateness of DOE's projections of disposal system evolution over the longer-term, not just the results in comparison with the applicable standard. This may be most important during the period relatively shortly after 10,000 years. Should significant releases be projected during that period, NRC will have to judge whether such behavior indicates acceptable performance, even if the long-term peak dose standard is met. We note that NRC staff stated to NRC's Advisory Committee on Nuclear Waste (ACNW) that NRC would "look at the basis for – as we would have [in the 2001 rule], that if the dose went beyond 15 in just after 10,000 years, what in the performance assessment is causing that to occur, and why?" (Docket EPA-HQ-OAR-2005-0083-0376, p. 49). It may in fact be impossible for projected doses to exceed, or even approach, 15 mrem/yr within 10,000 years without also exceeding the peak dose standard at some other time during the compliance period. The 10,000-year standard would not, then, control projected doses during that period but would instead represent an explicit statement of the level of performance that is required to be achieved by the peak dose standard in that initial period. See Section 6 of this document for discussion of uncertainty in performance projections.

Several commenters (0175, 0177, and 0310) contend that our proposal would "doom" future generations and lead to "horrifying" cancer rates. They estimate a cancer incidence figure of 1 in 36 as resulting from a 350 mrem CEDE annual dose. Consistent with the direction of the EnPA and the recommendations of the NAS, our peak dose standard of 100 mrem/yr will protect public health and safety. The nominal annual risk associated with this standard, applying current risk estimates, is 5.75×10^{-5}, which is comparable to the range of risks represented by domestic and international standards NAS suggested that EPA consider, "all of which are consistent with recommendations from authoritative radiation protection bodies." (NAS Report p. 49 and Tables 2-3 and 2-4). When the extended time frames addressed by the peak dose standard are taken into account, with the attendant uncertainties, this is a reasonable level of risk. We conclude that our standards will protect public health and safety, as required by the EnPA. See Section 2, Issue H, and Section 5 of this document for discussion of radiation impacts.

Commenter 0271 questions the proposed higher dose limit because "the longer that the waste is buried there, the more deadly it will become over time." We assume the commenter means that over time it is more likely that *releases* from the repository will reach the accessible environment, and that for some period of time doses resulting from those releases will increase. After that period, however, doses will decrease. The commenter's statement could also be interpreted to suggest that early releases would be less "deadly" and therefore should be encouraged (the waste itself will over time become much less toxic). We do not believe it was intended in this way. Recognizing that some releases are inevitable, such an approach would be directly counter to the fundamental goal of geologic disposal to delay the period of release for as long as possible.

Other commenters also made statements requiring some interpretation. Commenter 0209.6 refers to regulations for nuclear power reactors in also concluding that our standard "fails to protect the public in the first 10,000 years." The commenter specifically cites 10 CFR part 50, Appendix I, Section 2A, which limits exposures to individuals in "unrestricted areas" (including members of the public) to 3 mrem/yr to the total body or 20 mrem/yr to any organ from calculated liquid effluents. It appears the commenter is using this restriction as an indication that our 15 mrem CEDE/yr standard for the initial 10,000-year period is not protective when compared to these effluent limits, and further objects that we have accepted the "false premise" that no waste package failures will occur within the first 10,000 years. However, the commenter fails to refer to Sections 2B and 2C of the same appendix, which contain separate limits on gaseous and particulate effluents, respectively. Taken together, and depending on the mix of radionuclides involved, the effluent standards cited do not differ significantly from the 15 mrem CEDE level. In addition, we do not believe that a standard for nuclear power operations can be reasonably compared to a standard for waste disposal applicable to the extreme far future.

Similarly, Commenter 0210.1 believes "the two-tier radiation standard is not stable" and asks how we can "be certain that the standards will protect people one million years in the future?" The commenter asks this question in recommending that further research be done on reprocessing of spent fuel and alternatives to geologic disposal. We are unsure what the commenter means by "not stable". We discussed earlier the application of NRC judgment at different times in concluding that the disposal system will perform adequately.

Similarly, we are not sure whether the question regarding protectiveness at "one million years in the future" is suggesting that humans may have developed more sensitivity to radiation over time, or that we can't be "certain" because we cannot independently verify that actual exposures at such times will be adequately represented by dose projections performed today. On the first point, we have taken the approach, as recommended by NAS and employed previously at WIPP and in various international standards (e.g., the French and Swedish standards referenced below), that it is not reasonable to project changes in human technology, society, or biology over long periods, as there is no basis for selecting one possible future over another. Therefore, we assume that the RMEI is representative of today's population in its response to radiation. On the second point, geologic disposal was never envisioned as a technology that would rely upon monitoring to confirm modeling projections. In fact, as we have stated before, it was understood to be a technology that must operate passively to protect public health independently of monitoring, maintenance, or even human knowledge.

In raising a number of points already addressed, Commenter 0267 charges that, in emphasizing uncertainties, we have avoided addressing certainties, and are instead relying on "wishful thinking" and "hope" that the worst will not occur. The commenter presents this view in terms of early failure of the engineered barriers, limitation of the human intrusion scenario, future geologic and climatic events and processes, harm resulting from actual exposures, and "that the future over which we have no control will present no surprises we haven't already imagined and taken into account."

However, we believe we have addressed these factors appropriately, and would argue against a "worst case" approach as inconsistent with the principle of "reasonable expectation." As we have mentioned before, assumptions regarding failure of the engineered barriers and the potential for early releases will be subject to NRC judgment, which will not focus exclusively on projected outcomes (doses), but which we expect to consider the overall approach to assessments (see EPA-HQ-OAR-2005-0083-0376, p. 45 for considerations in NRC's evaluation of "reasonable expectation"). The intrusion scenario is consistent with the NAS recommendation to test the "resilience" of the repository (if the intrusion is a deliberate attempt to disrupt the repository, there is no basis to judge the potential results); it assumes the intrusion will occur. The presumed scenario, exploration for water, must be considered to be conservative because water in the region is much more accessible at lower elevations and lower recovery costs. The assumption regarding use of current drilling technology is consistent with the overall NAS approach to human biology, society, and technology (we note that the French standard referenced below adopts the same approach to drilling technology). Regarding seismicity and climate change, DOE will consider highly disruptive seismic events using probability relationships derived from historic events. We did not specify how future climate should be represented, although we did state that it could be represented by constant (future) conditions for the period up to 1 million years. We believe this approach would capture the important aspects of climate change (flow of water through the repository) and is consistent with the NAS position. We also believe that arbitrarily imposing climate fluctuations, particularly the timing and magnitude of precipitation changes, adds an unnecessary speculative aspect to the dose projections (see the Yucca Mountain FEIS to see how such fluctuations affect dose projections). The timing and magnitude of such cycles is essentially unknowable, and we note that some researchers believe that future glacial cycles will be delayed and the current climate at Yucca Mountain is a better representation of future climate than cooler, wetter conditions. (See Section 8 of this document for discussion of climate-related comments.) As for potential exposures, the limit we have established for these long times is consistent with the overall public dose limit widely adopted as protective today (as stated earlier, however, it will not be possible to verify these projections with monitoring data). Finally, we have considered whether there might be fundamentally different processes or events in the far future than are known or expected today. We were unable to identify any such "surprises" (although perhaps by definition they would be unidentifiable), and do not believe there is a basis for speculating about the potential effects of unknowable influences on the disposal system.

Commenters 0180 and 0181 appear to accept that a higher peak dose standard is appropriate and offer an interesting suggestion to correlate the timing of the change in the dose standard to the failure of the engineered barriers, rather than specifying a point in time. The commenters correctly point out that "container integrity lifetime will be the primary determinant as to the protection afforded by the engineered barriers" and propose that the standard change "in that year or period after which the engineered barriers are expected to fail completely and when protection will be provided only by the natural barriers." In this approach, a "dose-based compliance standard should be applied up to the time when the peak package dose is expected to occur – risks after that point will decrease as a result of natural attenuation in the waste package." We are uncertain how to interpret this proposal. If a change in the dose standard would come after the engineered barriers "fail completely," this could be interpreted to mean that as long as a single waste package retains some of its contents, the initial dose standard would apply. As waste packages will probably fail over an extended period of time, this could be the case for close to 1 million years, when the natural barriers are already likely to have provided the only protection for the bulk of the radionuclide inventory for a very long time. It could also intend that an average time of failure should be estimated and used as the transition point for the dose standard. However, we are also uncertain how to interpret the reference to the "peak package dose." This could refer to the peak radionuclide inventory in the package, or possibly to the peak dose attributable to a single waste package. These are two very different things. While this comment presents an interesting approach, because of the uncertainties in determining when the "peak package dose" would occur, we do not see a clear way to formulate a safety standard using such an approach.

Several commenters again mentioned the compatibility of our proposal with international standards and guidance. Because we referred in our proposal to a number of international sources, both from bodies such as the IAEA and NEA and from specific countries, such as Sweden, as sources of general guidance or as examples of specific regulatory approaches, we are very interested in commenters' views on this topic. In general, we find few similarities in the details of the international approaches that are directly applicable, and no clear basis for comparing the different approaches. At the same time, we did find broad points of similarity in the overall approach to long-term projections.[8] Much of the guidance we cited is open to interpretation (some of it deliberately so, in order not to foreclose different approaches that may be crafted to comply with specific national legal or regulatory contexts). While we do not claim that our interpretation must be the only viable one, we believe our approach is reasonable and consistent with international guidance and approaches in their views of projecting and interpreting dose and risk for the extreme far future. Where we must depart from the common path is in our statutorily-directed mandate to establish a quantitative compliance standard. The more typical approach internationally is to require compliance with quantitative performance assessment for only a limited period of time (in some cases, less than 10,000 years). Longer-term dose projections may be compared to dose or risk targets or reference levels, but are viewed more as qualitative indicators of performance than as "accurate predictions of the expected behavior of a geologic repository" (NAS Report p. 71), to be weighed in conjunction with other qualitative arguments for confidence in the overall safety of the facility. At longer times, the weight given to quantitative projections typically decreases.[9] We must determine how

[8] "National programmes which have already established such criteria have generally found it possible to make cautious, but reasonable assumptions to extend the use of radiological limits already applied to contemporary activities for several thousands of years. The greater challenge lies in setting criteria for very long time frames, extending to a million year and beyond, for which safety analyses must account for high uncertainty and for which the understanding of the needs and impacts on future generations become increasingly speculative." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, 2007, pp. 20-21).

[9] The 2007 NEA document on "Consideration of Timescales in Post-Closure Safety of Geological Disposal of Radioactive Waste," which is based on surveys of NEA Member Countries, states "Calculated values of dose and risk are therefore viewed in regulations not as predictions but rather as indicators or measures of protection that are used to test the capability of the system to provide isolation of the waste and containment of radionuclides (the 'dose' that is being calculated is what radio-protectionists refer to as 'potential dose'). These indicators are to be evaluated on the basis of models that include certain stylized assumptions, in particular regarding the biosphere and human lifestyle or actions." (p. 38)

Similarly, ICRP Publication 81 contrasts the approach of "consideration of quantitative estimates of dose or risk on the order of 1000 to 10,000 years" with "consideration of quantitative calculations further into the future making increasing use of stylized approaches and considering the time periods when judging the calculated results. Qualitative arguments could provide additional information to this judgmental process." (Paragraph 71)

In its most recent recommendations, ICRP notes that "In Publications 77 and 81, the Commission recognized that both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered." (Publication 103, Paragraph 222)

The IAEA consensus document for geologic disposal ("Safety Requirements for Geological Disposal of Radioactive Waste," WS-R-4, 2006) states: "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Care needs to be exercised in using the criteria beyond the time when the uncertainties best to satisfy our statutory mandate, consistent with the NAS recommendations, while recognizing the uncertainties and complexities that lead to the view that longer-term projections are qualitatively different from relatively near-term projections.

With few exceptions, we received only statements that our proposal "would be the weakest standard in the world" or is otherwise inconsistent with international practices, without specific reference to points of disagreement or contrary examples. We disagree and will discuss international approaches in some detail.

Comment 0226-122 generally criticizes our "demonstrably false" statements that we "need not be consistent with international precedents, because those precedents do not address long time frames." However, we made no such statements. We have pointed out in our proposal, our final rule, and in some detail below, that the typical approach internationally is not to require compliance with a strict quantitative limit at very long times. This is the approach we adopted in our 2001 rulemaking, in which the regulatory authority considers projected doses in a more qualitative sense in the overall determination of disposal system safety. The appendix referred to in the comment (Docket No. EPA-HQ-OAR-2005-0083-0227) cites references in our proposal to NEA and UK sources as "selective and misleading," because the cited documents provide no justification for a different approach to assessments at 10,000 years. (70 FR 49035 and 49037, respectively) The commenter acknowledges that these sources recognize that at some point the underlying basis for the assessment may change, but points out that "radiological risk remains a key indicator" even over very long time frames. We believe the commenter is confusing two concepts, the conduct of dose assessments and the establishment of dose standards. We do not question that longer-term projections can provide useful information; as noted above, we required such projections in our 2001 rule. However, there is a significant difference between viewing such projections as "key indicators" and determining compliance against a quantitative dose limit. The commenter notes, as we stated in our proposal (70 FR 49033), that "the compliance criterion in the UK is a target not a limit, i.e., compliance with it is not absolutely required." The commenter then points out that the target applies for the entire assessment period, and seems to assume that long-term doses will be judged acceptable only if they exceed the target by only a limited amount. This assumption, however, represents exactly the problem we see with the "dose target" approach. Such conclusions regarding acceptable doses cannot be reached in advance of the actual assessment. Unless such considerations are established in regulation, there is no basis to assume that the projected dose can exceed the target by only a certain amount, or under specific circumstances or for specific reasons. Thus, we see no basis in the comment's assertion that "none [of these international approaches] permits the type of increase in risk" that the commenter sees with our proposed peak dose standard (the comments were, we note again, related to the proposed 350 mrem/yr peak dose standard). It cannot clearly be stated whether a dose target "permits" such judgments or not. (See also Section 9 of this document for additional discussion of this point as it relates to intergenerational equity.) Commenter 0368.3 offers a specific recommendation to consider the French standard for geologic disposal. The commenter describes this standard as requiring "reasonable best

become so large that the criteria may no longer serve as a reasonable basis for decisionmaking." (Paragraph 2.12) estimate characterization" in the short term, with "conservative or upper bound parameter characterizations, because you cannot do characterization, but you still have to meet the same [25 mrem/yr] dose limit." The commenter concludes that an appropriate standard for the long-term at Yucca Mountain would be an individual-protection limit between 10 and 25 mrem/yr with continued ground-water protection.

We disagree with the commenter's characterization of the French standard (Basic Safety Rule No III.2.f, "Disposal of Radioactive Waste in Deep Geological Formations," 1991, Docket No. EPA-HQ-OAR-2005-0083-0389). First of all, the standard is very clear that the 25 mrem/yr dose level is not viewed as "the same dose limit" throughout the entire period of disposal system evaluation. For the initial period, which is to last "at least 10,000 years…The limit of [25 mrem/yr] will be applied for determining the acceptability of the radiological consequences." However, "[b]eyond this period" when "uncertainty concerning the evolution of the repository increases progressively with time…Quantified estimates of the individual dose estimates must then be made. These may be supplemented, by more qualitative assessments of the results of these estimates, as regards the geological barrier evolution factors, so as to verify that the release of the radionuclides does not result in an unacceptable individual dose. In this verification, the same [25 mrem/yr] limit shall be used *as a reference value*." (Section 3.2.1, emphasis added) Thus, although the value is the same, 25 mrem/yr no longer "determin[es] the acceptability of the radiological consequences" (i.e., a strict compliance standard). This difference in wording is instructive, as it strongly indicates that doses that would be unacceptably high in the near-term would be acceptable at later times, as long as other arguments for the overall safety of the disposal system are considered valid. Regarding Yucca Mountain, we could conceivably have written our 2001 standard using similar language, e.g., that DOE should accompany its peak dose projections with a description of qualitative factors affecting those projections, and show a comparison to 15 mrem/yr "as a reference value." However, we doubt whether the commenter would have viewed such a statement as requiring DOE "to meet the same limit." Essentially, our 2001 standard as promulgated took the same broad approach as the French standard (and other international standards discussed below) by leaving NRC discretion as to how much importance to give quantitative dose projections, taking into account other qualitative information regarding the overall safety of the disposal system, over periods of hundreds of thousands of years.

It is useful to examine other aspects of the French standard for comparison to the approach we have adopted at Yucca Mountain, and more generally in 40 CFR part 191. The 25 mrem/yr standard in the French regulation applies only to "events which are certain or highly probable" (characterized by the commenter as "reasonable best estimate"). In other words, only the most likely evolution of the disposal system is judged against a quantitative dose limit, and that strict judgment applies only for the initial period after disposal. These "certain or highly probable" events do include some evaluation of climate and vertical movement (uplifting and subsidence). However, "hypothetical" situations involving "occurrence of random events" of natural or anthropogenic origin are evaluated separately. In addition to more significant climatic or seismic effects, these "hypothetical" situations include human intrusion and potential manufacturing defects in waste packages or other engineered barriers that might lead to early failure (Section 5.3.2).

In analyzing these "hypothetical" situations, "[w]hile consideration may be given to using the risk concept…to allow for the probability of occurrence of each situation giving rise to exposure…it can be expected to be difficult, if not impossible, to estimate the probabilities of the events which can result in exposure...Therefore, individual exposure expressed as a dose equivalent, associated with hypothetical situations for which allowance must be made in the design of the repository must be maintained well below *levels liable to give rise to deterministic effects*." (Section 3.2.2, emphasis added) Deterministic radiation effects are dependent not only on the radiation dose, but the time over which that dose is delivered. Levels resulting in deterministic effects are usually considered to be about 50 rem or higher, if the dose is delivered over a few hours, or at most, days (there are indications that some deterministic effects could result from acute doses of about 20 rem). However, it would be highly unusual to project such acute doses from a geologic disposal facility, where radionuclides must travel for extended periods through the natural geology before reaching a receptor. Conceivably, such acute doses could be incurred by an intrusion in which a person comes into direct contact with the waste layer itself, particularly early after disposal, when a significant inventory of short-lived fission products may still be present. However, the safety of geologic disposal has never been predicated on its ability to prevent an intrusion of this nature or to protect the intruder in such a situation. (NAS Report pp. 114-115) A cataclysmic volcanic eruption in which a significant quantity of waste is directly ejected onto the surface might be another situation leading to acute doses. In such an event, however, it is likely that the destructive nature of the eruption itself would be the overriding concern of the affected population. We note that the Finnish standard, discussed in more detail below, also includes such a reference to deterministic effects, characterizing such a level as "dose above 0.5 Sv [50 rem]". Again, for purposes of assessing the safety of the disposal system, such a dose would likely be calculated as an annual dose. A dose of 50 rem delivered over a year would not be expected to result in deterministic effects.

We note that the commenter's statement regarding "conservative or upper bound" analyses does apply to natural events such as extreme climate change or seismicity, where "the maximum earthquake physically possible shall be investigated on the basis of the tectonic context of the site". Climate change also requires that "[g]laciation…after 160,000 years with a conservative evaluation of the extension of ice shall be allowed for." (Appendix 2, Section 2) It is not clear what "conservative" means in this context, as a more limited extension of ice would probably permit different types of receptors to be considered. If ice is extensive, it may not be possible for human receptors to be present in an area affected by radionuclide release. This type of climate change effect is fundamentally different from that expected at Yucca Mountain and DOE will need to support its assumptions regarding early failures.

This overall approach has some significant differences from those applied at Yucca Mountain and WIPP. This is not to say that one approach is right and the other wrong, but the differences must be understood in order to appreciate how safety is demonstrated in each case. With the exception of the human-intrusion standard for Yucca Mountain, which was developed as a "stylized" scenario consistent with the NAS Report and conditions at Yucca Mountain, "hypothetical" situations are integrated through probabilistic sampling into the individual-protection analyses. At WIPP, intrusion scenarios based on historic rates of mining and drilling are drivers for the individual-protection standard, while under the French approach such scenarios might be assessed only as to whether the consequences might be extremely high. Similarly with seismic activity, where the "maximum earthquake physically possible" is assigned a probability of occurrence based on the observed historic record, rather than evaluated in a separate order-of-magnitude analysis. And although we have received a number of comments questioning DOE's estimates of waste package lifetime, consideration of the potential for early failure of packages or other engineered barriers caused by manufacturing defects have been incorporated into its individual-protection analyses for Yucca Mountain.

We believe this comparison is useful because it illustrates one of the fundamental concerns we expressed in our proposal, namely the emphasis that should be given to low-probability, high-consequence events as compared to more "expected" situations. It is not clear that evaluating a "worst case" seismic event in a separate analysis necessarily leads to a specific conclusion regarding the overall safety of the disposal system or the advisability of design changes to mitigate the potential effects of an event that has a very low probability of occurrence. Nor is it clear that such an analysis adequately captures the range of potential effects of lower-level (but not necessarily "limited and predictable") seismic events throughout the life of the disposal system, as will take place at a seismically active site such as Yucca Mountain, or that the effects from a combination of different events would be evaluated. We recognize, however, that similar questions regarding the probabilistic modeling approach also exist, in the sense that the full impact of a high-consequence event may not be appreciated if it is tempered by a low probability of occurring.

It is also instructive to consider the approaches taken by other countries. We discussed the Swedish approach in our proposal, but feel that certain aspects are worth emphasizing. Like the French standard, the standard issued by the Swedish Radiation Protection Authority (SSI, formerly the Swedish Radiation Protection Institute) (SSI FS 1998:1, "Regulations on the Protection of Human Health and the Environment in Connection with the Final Management of Spent Nuclear Fuel and Nuclear Waste," Docket EPA-HQ-OAR-2005-0083-0047) includes a numerical standard during the initial period after disposal and adopts a more qualitative approach at later times. Specifically, for the first 1,000 years following closure of a repository, "the assessment of the repository's protective capability shall be based on quantitative analyses of the impact on human health and the environment." (Section 11) Thus, initially the performance projections may be used to make decisions regarding the protectiveness of the disposal system. However, beyond the first thousand years, "the assessment of the repository's protective capability shall be based on various possible sequences for the development of the repository's properties, its environment and the biosphere." (Section 12) This indicates that, even for periods within 10,000 years, quantitative projections no longer form the basis for judgments regarding the overall safety of the disposal system, although they are still informative and will continue to be important in decision-making, as described below. An estimate of collective (population) dose over the first 10,000 years is also required (based on releases within the first 1,000 years), although no standard is given in the regulation.

In our proposal, we referred several times to draft guidance developed by SSI to supplement its standards (Docket EPA-HQ-OAR-2005-0083-0048). That guidance (now called "guidelines") is now final (SSI FS 2005:5, September 2005, Docket EPA-HQ-OAR-2005-0083-0388). In its discussion of the role of quantitative risk analysis in demonstrating disposal system safety, SSI notes that the final guidelines differ in some important respects from the proposed guidance, providing more specificity regarding inclusion of certain factors at different times in the disposal system's evolution. Thus, the final guidelines state that "The period of time of a thousand years should be regarded as the approximate time period for which a risk analysis can be carried out with high credibility with regard to factors such as climate and biosphere conditions." However, for longer periods up to 100,000 years, "Reporting should be based on quantitative risk analysis…Supplementary indicators of the repository's protective capability, such as barrier functions, radionuclide fluxes and concentrations in the environment, should be used to strengthen the confidence in the calculated risks." The important consideration for the timing of the analysis is whether the potential effects of large climate changes, such as glaciation, are captured.

Similarly, for periods beyond 100,000 years, the final guidelines state that "A strict quantitative comparison of calculated risk in relation to the criterion for individual risk in the regulations is not meaningful. The assessment of the protective capability of the repository should instead be based on reasoning on the calculated risk together with several supplementary indicators of the protective capability of the repository such as barrier functions, radionuclide fluxes and concentrations in the environment." Further, "[i]f the calculated risk exceeds the criterion" or other "substantial disruptions" are indicated, "the underlying causes of this should be reported on as well as possible measures to improve the protective capability of the repository." The draft guidance states only that, for hundreds of thousands of years, "the risk analysis may be based on a stylised description" of future events and "The intention should be to shed light on the protective capability of the repository and to provide a qualitative picture of the risks." Thus, while the overall approach is still to place less reliance on quantitative performance projections in assessing safety at longer times, and to supplement them with other arguments, both qualitative and quantitative, the final guidelines are more forceful in placing those quantitative projections at the center of the evaluation process.

The Finnish Radiation and Nuclear Safety Authority (STUK) has also issued regulations for "Long-term Safety of Disposal of Spent Nuclear Fuel" (YVL 8.4, May 2001, Docket EPA-HQ-OAR-2005-0083-0392). These regulations include two primary protection standards. The first is an individual-protection standard of 10 mrem/yr (0.1 mSv/yr), which applies to "an assessment period that is adequately predictable with respect to assessments of human exposure but that shall be extended to at least several thousands of years." (Section 2.2) Exposures are also to be assessed to a larger population, which may be affected by surface water releases, and for which the dose constraint is lower by a degree determined by the size of the exposed population.

The second protection standard, which is implied to cover periods beyond the time for which "human exposure" is "adequately predictable," is an activity release standard similar to that included in 40 CFR part 191 and applied at WIPP, although these releases are calculated on an annual, not cumulative, basis. This standard includes radionuclide-specific limits on releases to the environment "from the expected evolution scenarios," but that "may enter the environment not until after several thousands of years." These activity releases have been calculated so that "at their maximum, the radiation impacts arising from disposal can be comparable to those arising from natural radioactive substances," although the standard itself does not define either "natural radioactive substances" or the "radiation impacts arising" from them. We note this because we have received several comments claiming that it is inappropriate to use sources of natural radiation as a basis for assessing long-term impacts from disposal, and that our proposal was unique in discussing such considerations. Like the French and Swedish approaches, the Finnish standard also recognizes that "the importance to safety of such scenarios that cannot reasonably be assessed by means of quantitative analyses" should be considered, and that the significance of these "complementary considerations" "grows as the assessment period of interest increases." (Section 4.4)

Comments 0399-1 and 0401-1 wish to rebut comparisons to the Finnish standard by clarifying that the release limits in this secondary standard are based on maximum projected releases, and would be expected to lead to doses no greater than about 50 mrem/yr (the commenter also addressed several points that are outside the scope of our rulemaking, such as receptor and site characteristics). The commenter contrasts this with our proposal to use the median of the distribution of projected doses for comparison with the peak dose standard. We would point out, however, that it is not clear how the basis for definition of the release limits themselves is related to the demonstration of compliance with those limits. Stating that the limits are defined to represent the "maximum impact" is not the same as requiring that they be compared to the highest projected releases. For example, our cumulative release limits in 40 CFR part 191 were defined as a level that would result in approximately 1,000 excess health effects over 10,000 years, per 100,000 metric tons of heavy metal. Compliance with these standards, however, was not based on the maximum projections from performance assessments. More typically, compliance with our release limits would be assessed using the mean value of projections, as it is at WIPP. It is therefore difficult to directly compare the level of protection provided by the early individual-protection standard and the later-term release standard.

Finally, it is also instructive to consider the very different approach taken in "Protection Objectives for the Disposal of Radioactive Waste" developed by the Swiss Federal Nuclear Safety Inspectorate (HSK) (HSK-R-21/e, November 1993, Docket EPA-HQ-OAR-2005-0085-0055). Unlike the other examples discussed above, these guidelines contain no provisions for the use of "complementary considerations" or "supplementary indicators" in addition to individual dose or risk projections in determining whether the safety objectives have been met, nor is there a time constraint beyond which the objectives do not apply. There is, however, recognition that "[t]he further into the future predictions are, the greater the uncertainty…dose calculations for the distant future are not to be interpreted as effective predictions of radiation exposures of a defined population group. They are, in fact, much more in the nature of indicators for evaluating the impact of a potential release of radionuclides into the biosphere" but are still compared to the specified limits (10 mrem/yr to what is essentially an average member of the critical group from "reasonably expected" scenarios, with a risk from unlikely events not to exceed 10^{-6} per year). (Section 7.2) However, if a relatively small population would be affected, "the safety authorities reserve the right to set the permissible dose lower than the limit specified." (Section 7.5)

We continue to believe it is appropriate to specify a higher peak dose standard applicable between 10,000 years and 1 million years. We believe such an approach is consistent with the NAS recommendations and is the most appropriate approach in view of the language in the D.C. Circuit decision. The level we have selected for the peak dose standard, 100 mrem/yr, is consistent with the public dose limit recommended by ICRP and widely adopted internationally and nationally, and we conclude that it will protect public health and safety in the far future. Finally, we believe our interpretation of international guidance and approaches regarding the application of performance assessments over very long time frames is reasonable.

Section 4 Two-Tiered Standard

Issue B: Support use of a two-tiered standard

1. EPA has correctly noted that very long-term risks are now managed, and must be managed, differently from near-term risks, and thus we concur with EPA's decision to apply a different standard after 10,000 years than it does before 10,000 years. (Comment 0174-3)

2. We support EPA's new two phase radiation standard for Yucca Mountain because it is safe and realistic for the soon to be built nuclear storage facility. Clearly, we cannot what know today what advanced technologies our future generations will come up with to improve Yucca Mountain storage. Therefore, a different radiation standard for the "out years" in the future makes good sense. The 2-tier radiation standard selected wisely by the EPA is safe and fair. (Comment 0193-1)

3. Because of uncertainties associated with the incredibly long compliance periods, having a "two-tier" dose limit is justifiable. (Comment 0217-4)

4. The Department believes an approach with two compliance periods to regulate repository performance is appropriate because it embodies both good policy and good science. The factors that would be applicable in demonstrating compliance during the two periods, particularly uncertainty and its treatment, are sufficiently different that different compliance standards are warranted for the 10,000-year regulatory period and the period to time of peak dose. The 350 mrem/yr standard provides an acceptable level of protection both today and in the far distant future. Retaining a 15 mrem/yr standard for the first

10,000 years not only provides an acceptable level of protection but also ensures the use of robust engineered barriers to ensure compliance with that standard during the first 10,000 years. These barriers will continue to operate, to some extent, throughout the million-year period and, thus, keep exposure levels extremely low as long as possible. (Comment 0352-16)

5. While calculation of the performance of a repository system for a 10,000-year period is complex, it is unarguably much more difficult to do that calculation for a period 100 times longer with anything like the same degree of precision. Without specific guidance on how to adopt appropriate bounding of potentially disruptive processes, extending the performance assessment to the time of peak dose could introduce intractable speculation. Accordingly, EPA has acted reasonably to develop two compliance periods and separate calculational approaches for them. To do otherwise would ignore the limitations of bounding analyses, the greater uncertainties at time of peak dose, and the lessened precision in calculated results as time and uncertainties increase. (Comment 0352-17)

6. We find the two-tiered dose limits for before and after 10,000 years to be an appropriate recognition of the greater degree of uncertainty for the longer period. (Comment 0368.5-1)

Response to Issue B:

Several commenters agreed with our reasoning for applying different dose limits over different time periods, specifically with regard to uncertainty in projections. Commenter 0352 believes "the factors that would be applicable in demonstrating compliance during the two periods…are sufficiently different that different compliance standards are warranted" and that the 15 mrem/yr standard for the first 10,000 years "ensures the use of robust engineered barriers to ensure compliance with that standard." This commenter also states that "[w]ithout specific guidance on how to adopt appropriate bounding of potentially disruptive processes, extending the performance assessment to the time of peak dose could introduce intractable speculation" and that we have acted "reasonably" in proposing two different compliance standards.

We agree with the commenters. It is our judgment that the uncertainties involved during the unprecedented compliance period over which performance must be projected are significant enough that an approach involving two individual-protection standards is appropriate and, therefore, we have decided to retain it in the final rule. We are, therefore, establishing 1 mSv/yr (100 mrem/yr) as the individual-protection standard applicable beyond 10,000 years and up to 1 million years, which satisfies our EnPA mandate to protect public health and safety and is consistent with the recommendation of the NAS committee to establish a standard to assess compliance at the time of peak risk, within the limits of geologic stability of the site. We are also retaining, however, the 150 μSv/yr (15 mrem/yr) standard for the first 10,000 years, which is consistent with our overall risk management policies and past practices, and serves as a reasonable transition point to the projections of doses in the extreme far future. See Section 6 of this document for discussion of issues related to uncertainty in performance assessment.

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Section 5 Risk Level

1. EPA has now proposed to allow a highly dangerous and non-protective radiation exposure standard of 350 millirems per year for the period after 10,000 years at Yucca Mountain. Currently based on the NCRP recommendations, the cancer slope risk is about 6.4×10^{-4} latent cancer fatailities per rem. The actual slope from bomb survivor data is twice this value or about 1.3×10^{-3} LCF/rem. The most recent and reliable retrospective cohort study by Clemson University on DOE Hanford adult male workers shows a cancer slope risk of about 1×10^{-2} LCF/Rem!!! This would mean that background radiation would be expected to kill 17%-21% of the population. This is the vast majority of cancer deaths. So to sum up, EPA's radiaiton protection standard for Yucca Mountain in particular and for the all use in general should be changed to a single standard based on a 1×10^{-4} risk of cancer through out all time periods, and that level should be assesed on a full 70 year life span (neglecting only the last 5 years of life based on an inadequate time period to induce cancer), and based on the most restrictive cancer slope data (the Clemson study at $1 \times^{-2}$ LCF/rem) resulting in an allowable annual exposure limit of 0.14 millirem per year. (Comment 0091-1)

2. Using the standard 1×10^{-4} cancer fatality risk metric as the upper end of allowable risk from any one source, and based on a 70 year expsoure, the radiation standard for added exposure should be immediately reduced to 0.14 millirem/year. Even lacking the new Clemson data and lacking a change in the exposure duration to reflect real lifetime expsoures of 70 years, the EPA standard should be immediatley reduced to no more than 2.5 millirem per year. (Comment 0091-2)

3. EPA's estimates there will be 10 million cancer deaths over 1 million years that result from storing highly radioactive spent fuel in the mountain. (Comments 0103-5 and 0145-5)

4. EPA's proposal to allow 350 millirem per year radiation doses to people living downstream from the leaking dump -- the equivalent of 58 full chest x-rays per year -- would not only cause cancer, but also birth defects, genetic damage, and other maladies, and at alarming rates, and must be withdrawn. EPA's proposed double standard must be withdrawn. The proposal would protect people for the first 10,000 years to currently applied standards of protection, but would then doom future generations after that time to a 1 in 36 cancer rate (or even worse, up to a 100% cancer rate, due to EPA mathematical manipulation), and a 1 in 72 fatal cancer rate (or worse). Such proposed cancer rates and fatal cancer rates are horrifying, and EPA must withdraw such an unacceptable proposal. This is a complete violation of principles of inter-generational equity, as well as public health and environmental protection. (Comments 0133-1, 0135-1, 0137-1, 0141-1, 0144-1, 0146-1, 0147-1, 0148-1, 0150-1, 0157-1, 0159-1, 0160-1, 0161-1, 0163-1, 0164-1, 0170-1, 0189-1, and 0190-1)

5. Are you out of your minds? What you call an acceptable cancer risk is not acceptable at all. (Comment 0154-1)

6. A candidate probabilistic safety goal for a repository would be that the latent cancer fatality risk for the average individual located within the region of the repository would be a small percentage of the average fatality risk (for today's population and 0.1% of the annual health risk of death this implies a goal incremental risk < 1x10-5 per yr).
The appropriate size of the region should be based on the characteristic sizes of regions of high background radiation and low background radiation that exist naturally today (on the order of 100 to 500 miles). The smaller the region, the more conservative the criterion. In applying the safety goal, the degree of confidence required would be determined by the timeframe of the application. Thus, in the period of < 10,000 yr, a very conservative safety goal could be established and compliance with the goal could be achieved at a degree of confidence consistent with the mean value of the risk. In the period of >10,000 yr, a less conservative safety goal could be established and compliance with the goal could be achieved at a degree of confidence consistent with the median value of the risk. (Comment 0215-5)

7. On August 3, 2005, the Institute for Energy and Environmental Research (IEER) released a credible scientific report contending that EPA's federally allowed Maximum Contaminant Level ("MCL") level of drinking water contamination by plutonium-239 and other radioactive materials with similar properties is 100 times too high because it is based on obsolete, 1950s science. Nevada's expert Dr. M. C. Thorne was one of the peer reviewers of the study. The report, *Bad to the Bone: Analysis of the Federal Maximum Contaminant Levels for Plutonium-239 and Other Alpha-Emitting Transuranic Radionuclides in Drinking Water,* authored by Dr. Arjun Makhijani, president of IEER, is attached as Appendix F to these comments. Since plutonium-239 is one of the long-term risks posed by the Yucca repository, Nevada believes that the plutonium MCLs must be revisited by EPA before permitting the proposed Yucca radiation standard to go into effect. Plutonium and other alpha emitters will constitute the largest contributors to long term radiation dose to humans from the repository. The IEER study bases its conclusion on well-known advances over the past three decades in the scientific understanding of the behavior in the body of plutonium and other alpha-emitting, long-lived transuranic radionuclides. These radionuclides are now widely understood to concentrate near the bone surface and deliver a dose per unit intake that is far higher than previously estimated by EPA. Yet, EPA has thus far refrained from making more stringent its plutonium MCLs. (Comment 0226-117)

8. On page 3 of the document titled *The Swedish Radiation Protection Institute's proposed general guidance on application of the regulations concerning protection of human health and the environment in the final management of spent nuclear fuel and nuclear waste (SSI FS 1998:1)*, it is stated that the ICRP define the risk for the harmful effects per dose to individuals from the population to be 7.3% per sievert. As 1 sievert is 100 rem, then this risk is 7.3×10^{-4} per rad. For the initial time period of 10,000 years the expected annual dose can be as high as 15 millirem per year. This corresponds to a risk (from harmful effects) of 1.1×10^{-5} per year. If the RMEI were to reside in the Amargosa Valley for 50 years, then the attendant expected lifetime risk is about 5×10^{-4} , i.e., one half of one tenth of a percent. However, the proposed radiation standard after 10,000 years is 350 millirem per year and is based on the median value of dose. So the proposed regulation increases the

now median lifetime risk (i.e., the probability of exceeding this value is 0.5) is 1.3×10^{-2}. So the EPA considers it is being protective of health and wellbeing of future residents by proposing regulations that at the 50% confidence level about one in every eighty people in Amargosa Valley will die prematurely as a result of exposure to radioactive releases from the facility. I believe such a level of protection would be totally unacceptable for present day populations. When attention is focused on the mean value of dose (i.e., the expected value), this risk value based on the median is increased by a factor about 32 to provide an estimate of the expected lifetime (i.e., 50 year) risk of 0.4 – this means that almost half of the population is expected to die prematurely from the radioactive releases from the proposed repository. If the actual performance of the repository turned out to be at high end of the predicted distribution of dose then the risk would be even higher, where we might have four out every five of the population die prematurely from radiation exposure. Thus it can be concluded that the EPA considers the proposed post 10,000 year radiation standard to be protective of the health and safety of the future population when in reality it is expected to cause the premature demise of 4 out of every 10 members of the local population. It would appear the EPA is proposing to legislate in the favor of future genocide in the Amargosa Valley and justify it as being politically acceptable. With Federal Agencies looking after our wellbeing, who needs to worry about hurricanes, act of terror, and weapons of mass destruction? [Note the ICRP are considering reducing the risk value from 7.3% per sievert to 5.9% per sievert. However they are also considering introducing a hereditary risk factor i.e., the risk posed to the second generation from exposure of the parents.] (Comment 0263-19)

9. It appears that the USEPA not fully incorporate finding and conclusions of the National Academy of Sciences report on Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII report into their proposed new EPA radiation standard for YMP. The consequences of this report include the concepts that that there is no safe level of exposure to radiation—that even very low doses can cause cancer. Even exposure to background radiation causes some cancer; additional exposures cause additional risks. The committee also concluded that radiation can cause other health effects such as heart disease and stroke, and that further study is needed to predict the doses that result in these non-cancer health effects. The committee noted that it is possible that children born to parents that have been exposed to radiation could be affected by those exposures. The committee also concluded that risks from low dose radiation are equal to or greater than previously thought. However, it should be noted that in populations that receive several times the natural background dose or less, radiation is responsible for only a small fraction of the cases of cancer and other health effects…The committee stated that the Dose and Dose-Rate Effectiveness Factor which had been suggested in the 1990 BEIR V report to be applied at low doses, has been reduced from 2 to 1.5. That means the current estimate of the number of health effects at low doses is greater than the estimate used previously. This is extremely important since it may have an effect on the EPA radiation standard for YMP of 15mRem effective dose. While EPA used many times the phrase "calculated dose and or radiation," it is our opinion that instead of using the above phrase there is a need for experimental data to verify assumption used both by DOE and EPA. Finally, can the EPA provide recent experimental data including possible radiation bystander effects to justify the 15 mRem effective dose standard for YMP? (Comment 0270-5)

10. It is our opinion that the EPA should have taken a second look at epidemiology studies at Chernobyl accident and Three Mille Island concerning cancer risk before issuing their final radiation standard for YMP. (Comment 0270-8)

11. In a comprehensive review of published data available for assessing the risk of radiation induced cancer for radiation protection purposes, the UK Health Protection Agency calculated the risk of radiation-induced cancer at low doses and low dose rates and provided results of epidemiological investigations. The following is a short summary. 1. "Studies of the effects of exposure to background radiation and of environmental exposure are subject to the influence of confounding factors and generally lack sufficient statistical power to detect small increases in risk." 2. Epidemiological studies thus indicate an approximately 40% increase in the risk of radiation-induced cancer in childhood following exposures in utero at doses of low-LET radiation of about 10–20 mGy. (Comment 0270-9)

12. EPA does not discuss the increased risk to human health and safety from the higher levels of exposure at the 10,000-year mark, despite the director of EPA's Office of Radiation and Indoor Air's acknowledgement that the risk to public health increases at the higher level. EPA does not assume that humans are somehow better able to handle doses of radiation in the future. Rather, EPA admits that the 350 millirems number is not based on public health, which is not EPA's concern. In an attempt to craft a standard that DOE can meet rather than one based on sound science, EPA has ignored its most basic responsibility, the protection of public health and safety. (Comment 0293-6)

13. 350 millirem per year over 70 years (EPA's standard assumed lifetime) is a cancer risk of 1 in 36 (i.e., 2.8%). That is 288 times higher than EPA's outer limit of its acceptable risk range (10^{-4}) and 28,800 times higher than its preferred point in the risk range (10-6). Even assuming only a 30 year exposure time – unreasonable in the scheme of things – yields a risk of roughly 1 in 100, 100-10,000 times higher than EPA's acceptable risk range. These figures are based on the National Academy of Sciences just-released BEIR VII report. The BEIR reports, produced every decade or so, form the basis for all government risk estimates; the Federal Guidance 13 estimates were derived largely from BEIR V. BEIR VII increases risk estimates for cancer incidence by approximately third from the Federal Guidance 13 levels. BEIR VII's new figure is 1.14×10^{-3} cancers per rem. (Comment 0296-2)

14. For EPA to now propose a 350 millirem/year exposure limit, albeit for future generations, is unconscionable and vastly outside what even the current EPA rules suggest is dangerous to public health. A dose of 350 millirem/year over one's lifetime, according to the recent National Academy of Sciences report on radiation risks, will cause cancer in approximately one out of every 36 people exposed. This is vastly outside the 1-in-10,000 to 1-in-a-million risk range EPA has used as a basis for establishing radiation exposure limits. (Comment 0301-3)

15. EPA's general position for decades has been to regulate exposures to keep the risk to the public at one cancer in one million people. In some circumstances, EPA has allowed workers to be exposed to a higher risk of cancer – one in one thousand. According to a recent National Academy of Sciences report on radiation health risks, 350 millirems per year over one's lifetime will cause cancer in approximately one out of every 36 people exposed—a risk 3 to 5 orders of magnitude greater than the range that EPA has always used before. (Comment 0302-13)

16. Under the EPA's rule, there is no upper limit of dose for the half of the exposures that would be above the median. In other words, under the EPA standards, significant numbers of people could legally be exposed to doses that would produce a statistical 100% chance of inducing a cancer in the exposed individuals. (Comment 0302-15)

17. We are opposed to your proposed standard of 350 millirem/year radiation exposure of the public downstream of the proposed Yucca Mountain high-level radioactive waste site in Nevada after the first l0, 000 years. The numbers of cancers, congenital and genetic effects that would result for future generations are totally unacceptable from the standpoint of public health and environmental health protection, as well as ordinary morality. This proposed rule equates to premeditated murder and must be withdrawn. (Comment 0308-1)

18. The proposed peak dose limit would pose a lifetime cancer incidence risk of 1 in 36 for the general population and 1 in 30 for women. EPA has previously stated that even 1 in 250 lifetime risk is unacceptable from a single facility. (Comment 0314.1-5)

19. The 350 millirem per year dose limit is 14 times higher than the dose limit contained in NRC regulations governing the disposal of low-level radioactive waste and more than twenty times higher than the dose limit previously proposed by the EPA as being protective of the public health (i.e. 15 millirem per year). Using the risk factors from the National Academy of Sciences BEIR VII report, we find that the excess cancer risk for an individual that would be exposed to 350 millirem per year over a 70 year lifetime would be more than 1 in 36. The risk to women from this level of exposure would be even greater, approximately 1 in 30. These risks are unacceptably high. As discussed in section three below, the EPA's choice of the median dose for determining compliance with the 350 millirem per year dose limit means that the upper bound doses actually received could be significantly higher. (Comment 0314.1-9)

20. The higher level radiation standard may seriously impact the health of Las Vegas' citizens. NAS's recommended acceptable range of radiation exposure, which the EPA previously recognized, is 2 to 20 millirem per year . The level of human exposure after 10,000 years permitted by the new rule far exceeds this range. This higher level will result in additional cancer deaths over time. In fact, the State of Nevada's health and safety consultant concludes that exposure to a 350 millirem additional annual dose for just three years would create a 4.8 percent increase in cancer risk. (Comment 0341-2)

21. It is unfortunate NAS did not have available the deliberations of…NAPA…The principles developed by NAPA suggest that when looking exceedingly far into the future, the major concern should be to avoid the possibility of catastrophic consequences. Basing the level of protection at time of peak dose on consequences that would be catastrophic in a global sense in the context of events over the course of one million years, or at least catastrophic on a regional or even individual level, would require consideration of the levels at which health effects from radiation have been actually observed. In the proposed rule, EPA noted: "The BEIR [Biological Effects of Ionizing Radiation] VII report reaffirmed that evidence exists that even the smallest radiation dose may convey some risk of incurring a cancer, and the risk increases proportionally to the dose…." The Department believes that this does not correctly reflect the conclusions of the BEIR VII study. The study cited no evidence proving actual effects at small doses. Furthermore, the study considered 100 mSv (10 rem) to be "low dose." This is not "the smallest radiation dose," or even a small dose, by regulatory standards. The study's conclusion was that "...current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans." Neither did the study find that "evidence exists" that risk increases proportionally to dose. The report states: "The Committee judges that the balance of evidence from epidemiologic, animal and mechanistic studies tend to favor a simple proportionate relationship at low doses between radiation dose and cancer risk. Uncertainties on this judgment are recognized and noted." The statement of considerations for EPA's final rule should reflect that the BEIR VII report reaffirmed the appropriateness of assuming, for regulatory purposes, that small radiation doses may convey some risk of incurring cancer, and that risk increases proportionally to dose, while recognizing uncertainties with this assumption. (Comment 0352-22)

22. Has EPA done the calculations to estimate occurrences of cancer due to exposure from Yucca Mountain? (Comment 0367.1-6)

23. What is the standard of what is safe for my body – today or in the future? (Comment 0367.1-12)

24. We strongly oppose EPA's proposal. … double standard .. extremely dangerous and it is immoral. These proposed regulations are completely unacceptable and should be immediately withdrawn. For the first 10,000 years, people exposed to … a lifetime cancer rate of one in 835 people. Then it dooms future generations to a new radiation standard of one in 36 cancer rate. …. This is a complete violation of EPA's responsibility to protect public health and the environment. A standard based on a one in 36 cancer rate is not a standard. It is a death sentence. This proposal to allow 350 millirem per year radiation doses to people living downstream … would cause cancers, birth defects, and genetic damage. (Comment 0368.1-1)

25. I really urge you to do that (consider BEIR VII) because it's quite different from the BEIR 5 report in many important respects that I'm sure you already know. The risks to children are shown to be much greater than the risks to grown-ups. The risks to women are shown to be overall much greater than men. For the first time, cancer incidence risks have been published and I believe you should go according to cancer incidence risks and protect to standards like one in 10,000 for cancer incidence, not cancer fatalities because fatality rates are changing all the time, fortunately coming down due to improved medicine. Now, I think that the question of protecting pregnant women should also be part, the question of protecting developing fetuses and embryo. (Comments 0368.3-8 and 0368.4-3)

26. EPA's general position for decades has been to regulate exposures to keep the risk to the public at one cancer in one million people. According to the recent BEIR 7 report on radiation health risks, 350 millirems per year over one's lifetime will cause cancer in approximately one out of 36 people exposed. This is a risk three to five orders of magnitude greater than the range the EPA has always used before. (Comment 0368.6-4)

Response to Section 5:

Many of the commenters in this section have made reference to the risk estimates that EPA uses for assessing the impacts of radiation exposure. The comments were generally phrased in relation to the proposed peak dose standard of 3.5 mSv/yr (350 mrem/yr). We are not establishing the proposed 350 mrem/yr level as our final peak dose standard; instead, we are establishing 1 mSv/yr (100 mrem/yr) as the standard to apply for the period beyond 10,000 years and up to 1 million years. Because the comments addressed fundamental issues involved in estimating risks from radiation exposure, however, we are responding to the comments on this topic.

Comment 0091-1 supports a lifetime risk-based standard at 10^{-4} and refers to a study of workers at DOE's Hanford facility showing that the risk of radiation-induced cancer may be 50 times higher than current EPA estimates. Our Yucca Mountain standards are dose-based at the direction of Congress. We are unfamiliar with the study cited by this commenter (which was neither submitted nor adequately referenced), but find the suggested risk coefficients to be implausible and contradicted by the current body of peer-reviewed epidemiological studies of radiation workers, as summarized in Chapter 8 of the BEIR VII report (Docket No. EPA-HQ-OAR-2005-0083-0430).

Comment 0091-1 also says, "Currently based on the NCRP recommendations, the cancer slope risk is about 6.4×10^{-4} latent cancer fatalities per rem. The actual slope from bomb survivor data is twice this value or about 1.3×10^{-3} LCF/rem." Our adjustments to its risk coefficients account for increased repair at low doses and dose rates. Our understanding of radiogenic cancer risk relies heavily on the ongoing studies of the Japanese atomic bomb survivors. Because the doses that this group received occurred over a very short time period, an adjustment to the Japanese data is commonly made when using the Japanese data to estimate the risk from radiation exposure at lower doses and dose rates. (See BEIR VII, Docket No. EPA-HQ-OAR-2005-0083-0430, Chapter 6, for discussion of Japanese survivor studies.) The 1993 report by the United Nations Scientific Committee on the

Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation* (Docket No. EPA-HQ-OAR-2005-0083-0406), and the 1994 EPA report, *Estimating Radiogenic Cancer Risks* (Docket No. EPA-HQ-OAR-2005-0083-0405), have recommended a dose and dose rate effectiveness factor (DDREF) of 2 when acute doses are less than 20 rem and the dose rate is less than 10 mrem per minute. The commenter is suggesting that it is inappropriate for us to apply a DDREF to our estimates of cancer mortality risk at Yucca Mountain because the total doses from the site will also be high dose exposures. In fact, releases from Yucca Mountain resulting in an RMEI dose at the peak dose limit of 100 mrem/yr would easily meet the criteria for applying the DDREF. We believe that it is appropriate to continue to apply a DDREF of 2 for its cancer risk coefficients, as described on pages 173-174 of Federal Guidance Report 13 (Docket No. EPA-HQ-OAR-2005-0083-0072).

Comment 0091-2 recommends that the dose limit for Yucca Mountain should be 0.14 millirems per year for any time period, cited as the results of a Clemson University study of DOE Hanford workers (see above response to 0091-1), or no more than 2.5 mrem/yr, based on a 1 in 10,000 risk limit for 70 years of exposure using current risk estimates. These suggested dose limits are below any dose-based limits currently in force in the United States today. The farther out in time the analyses go, the more uncertainty there is in the dose projections. Restricting doses in the extreme far future to levels that are well below what are regulated today would be unreasonable.

Comments 0103-5 and 0145-5 say that EPA estimates 10 million cancer deaths from Yucca Mountain over 1 million years. There is no reference given for this assertion, but it is perhaps a reflection of another comment (0324-5) that references the following language from our 1985 final rulemaking for 40 CFR Part 191 that “estimates of the risks from unmined ore bodies ranged from about 10 to more than 100,000 excess cancer deaths over 10,000 years. Thus, leaving the ore unmined appears to present a risk to future generations comparable to the risks from disposal of wastes covered by these standards” (50 FR 38083, September 19, 1985, Docket No. EPA-HQ-OAR–2005–0083–0064). Comment 0324-5 then makes the erroneous assumption that the upper end of this estimate (10 excess cancer deaths per year world-wide) equates to what EPA would consider an acceptable risk for releases from Yucca Mountain over each of the next one million years. Comment 0324-5 is also addressed in Section 3, Issue F, of this document. All these comments are based upon a misreading of EPA’s text and are incorrect. The release limits in 40 CFR Part 191 were scaled to a level estimated to result in 1,000 excess fatal cancers over 10,000 years from disposal of 100,000 metric tons of heavy metal. The individual peak dose standard is not based upon or related to the risks from uranium ore bodies. Our role at Yucca Mountain is to establish public health and safety standards with which DOE must demonstrate compliance.

Comments 0133-1, 0135-1, 0137-1, 0141-1, 0144-1, 0146-1, 0147-1, 0148-1, 0150-1, 0157-1, 0159-1, 0160-1, 0161-1, 0163-1, 0164-1, 0170-1, 0189-1, 0190-1, 0154-1, 0263-19, 0293-6, 0296-2, 0301-3, 0302-13, 0302-15, 0308-1, 0314.1-5, 0314.1-9, 0341-2, 0368.1-1, and 0368.6-4 state, in various ways, an opposition to the risks from radiation exposure at 3.5 mSv per year and many of them reference a 1 in 36 risk of excess cancer at this exposure level. Using a conversion factor of 5.75×10^{-7} fatal cancers per mrem, our final long-term peak dose standard of 1 mSv/yr (100 mrem/yr) represents a nominal annual risk of fatal cancer of 5.75 x 10^{-5}, or 5.75 in 100,000. This is comparable to the range of risks represented by domestic and international regulations that NAS suggested EPA consider, and which NAS stated were “consistent with recommendations from authoritative radiation protection bodies” (Comments 0196-1 and 0198-4 appear to refer to the low end of the NAS suggested starting range in their references to “one in a million per year”). (NAS Report p. 49 and Tables 2-3 and 2-4) EPA does not consider this level of risk to be excessive in the context of a standard applicable for the period from 10,000 years to 1 million years, given the increased uncertainty in dose projections and the questionable assumption that current risk estimates can be applied to the extreme far future. Risk correlations at any time cannot be considered absolute and precise, particularly when applied in a prospective manner to the behavior of a disposal system that will operate passively for hundreds of thousands of years (we note that NAS applied a smaller conversion factor of 5 x 10^{-7} fatal cancers per mrem). When time frames on the order of 1 million years are considered, it is reasonable to view the nominal risk associated with the 100 mrem/yr peak dose standard as a reasonable level of risk. We are focusing discussion of the risk associated with the peak dose standard on annual risk, as this was the metric considered appropriate by the NAS committee, although it did not recommend a particular risk level. The Agency has determined that this standard will protect public health and safety. Comment 0341-2, referring to a State of Nevada consultant’s report, claims that exposure to 3.5 mSv/yr for 3 years would result in a 4.8% increase in the cancer rate. This statement is unfounded and seems to be a misinterpretation of the Nevada consultant’s statement [Appendix A, Mike Thorne and Associates Limited, External Memorandum, page 7, Docket No. EPA-HQ-OAR-2005-0083-0227] that exposures at *3 times this level (i.e., 10.5 mSv/yr)* over a lifetime would increase a person’s risk of cancer by 4.8 %. It is important to note that these estimates of cancer incidence relate to the proposed dose standard. Our 100 mrem/yr standard applies only to the hypothetical reasonably maximally exposed individual, who is defined to be among the most highly exposed members of the population.

Comment 0215-5 discusses the relationship of the safety goal for Yucca Mountain with the degree of confidence in the target risk value, stating that “In the period of >10,000 yr, a less conservative safety goal could be established and compliance with the goal could be achieved at a degree of confidence consistent with the median value of the risk.” We have set the peak dose standard at a level higher than for the first 10,000 years in part because of the uncertainties involved in projecting doses in the far future. Our final standards include both a more stringent peak dose standard and specification of the arithmetic mean as the statistical measure of compliance.

Comment 0226-117 presented information and an assessment of health effects and risk estimates for ingestion of an isotope of plutonium. While this comment may have potential relevance to risk assessment in general, we believe that this level of detail is outside the scope of comments since it pertains to the ground-water protection standards which are not part of the amendments to 40 CFR part 197. The information mentioned in this comment is more relevant and could be considered in the context of the periodic re-examination of

dose/risk factors for specific radionuclides by the scientific radiation risk assessment community.
Comments 0270-5, 0368.3-8, and 0368.4-3 encourage EPA to implement the findings and recommendations of the recently released BEIR VII report. In fact, it will take us the next few years to incorporate the BEIR VII recommendations and make necessary updates to its risk assessment methodology. However, the overall risk estimates of the BEIR VII Committee are compatible with our current risk estimates. One notable change in the BEIR VII report is the recommended value for the dose and dose rate effectiveness factor (DDREF). The DDREF is used to adjust the slope of the observed dose response curve at high acute doses when extrapolating down to the low dose and low dose rate region of interest. The BEIR committee recommended a change in the DDREF from 2 to 1.5. However, ICRP's most recent recommendations still support using a value of 2. (Publication 103, Docket No. EPA-HQ-OAR-2005-0083-0423) Both organizations acknowledge that the range of experimentally observed DDREF values makes its selection a matter of judgment. Therefore, the value of the DDREF is still an unsettled issue, and we will continue to follow the debate on this issue.

Comment 0270-8 encourages EPA to take a second look at the results from epidemiological studies of populations exposed from the Chernobyl accident and from the accident at Three Mile Island. We do not believe there is any evidence of increased cancer incidence from the Three Mile Island accident, which had very low off-site doses. Current epidemiology shows a significant and increasing risk of thyroid cancer among those exposed as children from the Chernobyl accident. Reports of anecdotal, but as yet not statistically significant increases in other cancers among responders and other highly exposed groups are being followed closely by EPA. However, at present, the Chernobyl data and our risk estimates are consistent, so we see no need to change our estimates, but would do so if significant increases were noted. See the 2003-2005 report of the Chernobyl Forum, Docket No. EPA-HQ-OAR-2005-0083-0419.

Comment 0270-9 quotes some findings of the UK Health Protection Agency regarding (1) the inability of epidemiological studies to detect small increases in risk as a result of variations in background, and (2) the increased risk of cancer in children following *in utero* exposures of 10 to 20 milligray (mGy). We consider the peer-reviewed scientific literature, such as the data reported here, when assessing changes to its risk assessment methodology. We agree with the statement about variations in background. However, doses in the range of 10 - 20 mGy (1 - 2 rad) are much higher than our long-term dose rate limit. We believe that the *in utero* doses from Yucca Mountain releases, even at the level of our peak dose standard, will fall within the current safe guidelines for exposure of the fetus as recommended by the ICRP and NCRP (ICRP Publication 60 (Docket No. EPA-HQ-OAR-2005-0083-0421) and NCRP Report 116 (Docket No. EPA-HQ-OAR-2005-0083-0407), respectively). The same study was referred to by Comment 0226-5 in Section 2, Issue H of this document.

Comment 0352-22 takes issue with how EPA characterized the BEIR VII report's recommendation regarding the application of a linear dose response relationship at low to very low doses. The commenter encourages us to be more explicit about the uncertainty associated with this assumption and to make it clear that the linear dose model is a regulatory tool. We will examine our representation of the uncertainties surrounding the dose response curve at low doses, but overall, we stand by our interpretation of the BEIR VII recommendations that they were unequivocal in their support for using a linear no-threshold model.

Comment 0367.1-6 asks if EPA has calculated the excess cancers from exposure to Yucca Mountain. We have not calculated projected excess cancers because our authority and role is solely to set the public health standards; it is DOE that has the authority and role to project potential doses resulting from the performance of the Yucca Mountain disposal system. However, as noted above, using our current cancer risk coefficients, we estimate that members of a population who receive an extra 100 mrem/yr would have an additional annual cancer mortality risk of 5.75×10^{-5}, or 5.75 in 100,000. This is comparable to the range of risks represented by domestic and international regulations that NAS suggested EPA consider.

Comment 0367.1-12 asks what a safe level of radiation is today or in the future. What is "safe" is very much an individual value judgment, but we believe that our final standards are protective of the residents living near the Yucca Mountain site now and in the extreme far future. Using our current risk estimates, potential radioactive releases in the extreme far future will present a 4×10^{-3} risk of fatal cancer (0.4%) above the current baseline risk of 22% for the projected RMEI, assuming a dose rate of 100 mrem/yr for 70 years.

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Section 6 Uncertainty

Issue A: Higher uncertainty should not be addressed by using a higher dose limit

1. EPA's proposed rule offers no reasonable basis for diverging from the NAS's recommendation and from its own past practice, or for using one compliance measure for the pre-10,000-year period and another for the post-10,000-year period. Primarily, EPA cites uncertainties about Yucca Mountain and perceived "over-conservatisms" in DOE's modeling. These uncertainties and supposed over-conservatisms, EPA claims, call into question the higher values in DOE's modeling, and suggest that a performance measure that devalues those higher values is appropriate. These explanations lack any logic or rationality. [U]ncertainty provides no reason for creating a more lax standard, whether that laxity is achieved through a higher numeric standard or a more permissive statistical measure. Similarly, conservatism provides no reason for selecting the median rather than the mean, because conservatism, if it actually existed (the reverse is the case), would be a reason for DOE to fix its modeling, not for EPA to adjust its standard. (Comment 0226-15)

2. Moreover, it defies logic and common sense to use uncertainty about Yucca's future performance as a rationale for a *looser* standard. If DOE is highly uncertain about whether its chosen site and systems will be safe, that uncertainty provides more reason for retaining a conservative, protective standard through peak dose, not a looser one. (Comment 0226-24)

3. Even if EPA were correct that Yucca's long-term performance after 10,000 years is qualitatively more uncertain, its proposed rule fails to explain how that uncertainty justifies a more lax standard. (Comment 0226-26)

4. Such an explanation would be extraordinarily difficult to provide, for the reasonable response to uncertainty about the safety of an engineered system would be to demand greater protection, or preclude that system from being deployed at all. Reasonable regulators never would evaluate the safety of bridges, for example, against less stringent safety standards simply because engineers were able to predict their performance only over the short-term. That uncertainty should only make regulators more conservative, not less. (Comment 0226-27)

5. Consistent with that principle, EPA (and other federal agencies) have until now reacted to anticipated uncertainty by adopting *conservative* assumptions and standards. In fact, Nevada has confirmed that, when faced with uncertainty, EPA uses conservative assumptions and adopts conservative standards in all areas of health-based regulation except, now, for Yucca. EPA does not explain why it departs from these sensible precedents. (Comment 0226-28)

6. For example, EPA adopted conservative values of parameters or standards when there were uncertainties when it regulated underground injection of hazardous materials under a regulatory regime (40 C.F.R .Part 148, especially 40 C.F.R. § 148.21(a)(5)) requiring that there be no migration of the wastes for so long as they remain hazardous, 69 Fed. Reg. 15328 (March 25, 2004); when it developed a methodology for deriving air quality criteria to protect health, 65 Fed. Reg. 66444 (November 3, 2000); when it regulated pesticides to protect health, 64 Fed. Reg. 37022 (July 8, 1999) ("the greater uncertainty in the data associated with the assumptions, the more conservative (i.e., unlikely to underestimate exposure) the assumptions should be"), and 68 Fed. Reg. 15945, April 2, 2003 ("uncertainty was addressed in the screening level assessments…with conservative assumptions for model inputs"); when it increased the cover standards to limit emissions from uranium mill tailings because of uncertainty in long-term (1000 year) projections, 48 Fed. Reg. 45926 (October 7, 1983); when it set water quality standards for toxic pollutants, 64 Fed. Reg. 61182 (November 9, 1999); when it developed a policy regarding persistent, bio-accumulation of new chemicals, 64 Fed. Reg. 60194 (November 4, 1999) ("given…the uncertainty…due to lack of data, the TSCA new chemicals program is and must be conservative by nature"); when it set emission standards for locomotives and locomotive engines, 63 Fed. Reg. 18978 (May 14, 1998); when it adopted principles for estimating neuro-toxicity in risk assessments, 59 Fed. Reg. 43260 (August 17, 1994); when it regulated hazardous wastes using the 90th percentile Monte Carlo risk curve, 63 Fed. Reg. 42110 (August 6, 1998); when it regulated food additives, 56 Fed. Reg. 7750 (February 25, 1991) ("in addressing uncertainties [in quantitative risk assessment] however, EPA generally uses conservative assumptions to ensure that risks are not underestimated."); when it protected drinking water, 56 Fed. Reg. 3526 (January 30, 1991); and when it listed hazardous wastes under RCRA, 55 Fed. Reg. 11798 (March 29, 1990).

Other federal agencies use similar approaches. For example, OSHA used the 95th percentile (as opposed to the central tendency) value in risk assessments used to derive safety standards for workers' exposure to toxic chemicals, 62 Fed. Reg. 1494 (January 10, 1997) (standards for methylene chloride). And HHS uses conservatisms in addressing health effects, 61 Fed. Reg. 33511 (June 27, 1996) ("a conservative (i.e., protective) approach to address these uncertainties in health effects"). (Comment 0226-29)

7. While EPA repeatedly emphasizes "uncertainty" as a core justification for its proposed rule, its discussions of uncertainty are hopelessly vague. EPA uses the term "uncertainties" generically. It rarely specifies either the particular uncertainties with which it is actually concerned, or their likely effects, and it never coherently explains how it believes specific types of uncertainty might justify a more lax or a two-tiered standard. This is especially important when one considers that the most obvious source of potential uncertainty, climate change, as well as others, are eliminated from consideration. This is a crucial failure. It precludes Nevada and others from knowing which uncertainty sources EPA considers important, and why EPA believes those sources might justify a higher standard. Indeed, EPA's failure to specify the relevant uncertainties suggests that EPA may not even know which uncertainties matter, or what the implications of particular sources of uncertainty actually are. Indeed, as noted earlier, premising a rule on uncertainties in the licensing analysis before the licensing analysis is even done is itself speculative to the point of being useless. (Comment 0226-31)

8. The reason you offer, that uncertainties allow such a large limit is simply outrageous. You claim to be protective by increasing the allowable doses just because there's more uncertainty in predicting releases. That doesn't give you a justification for increasing the dose limit. Quite to the contrary, if there's such great uncertainty you should have stricter limits or at least the same limits as before - not raise the limits because you're afraid that you can't meet them. If you can't meet them then the Yucca Mountain dumpsite is simply unsuitable. (Comment 0260-1)

9. EPA claims that "rising uncertainties justify adopting a different (higher) dose level" after 10,000 years. But in its study, NAS concluded that the uncertainty for one million years is manageable because of the known geologic processes affecting the site, clearly contradicting EPA's statements. Thus, EPA's reasoning for increasing the dose after 10,000 years is not substantiated. (Comment 0302-8)

10. EPA holds that "the rationale for the 350 additional millirem from 10,000 years and, beyond deals with the amount of uncertainty that we're faced with in projecting out 10,000 years . . ." This is a quote from an Associated Press article dated October 10, 2005, attributed to EPA, spokesman John Millett. My simple question is, if uncertainty increases over time, shouldn't the regulations be strengthened, not weakened, to accommodate for that?! EPA seems, in its proposed rule, to largely think that "conservatism" is a bad or dirty word. When it comes to protecting human health and human lives and the environment, the most conservative, protective standards need to be applied. (Comment 0324-13)

11. EPA states in column 1, page 49021, that "realistic analyses are preferred over conservative and bounding assumptions, to the extent practicable." But how "realistic" can federal agencies be when predicting out 10,000 or 1,000,000 years into the future?
Not being conservative in this case is an, unacceptable retreat, and sacrifices the public's right to health and environmental protections from the one agency in the federal government charged with that mandate, the EPA. EPA states on page 49025, column 1 that "it is `reasonable' to consider approaches for uncertainties in calculations at several hundred thousand years that may differ from the approach for uncertainties considered within 10,000 years after disposal...". By weakening the regulations?! Shouldn't EPA *STRENGTHEN* the regulations, given such large uncertainties and the long-lasting deadliness and hazard of high-level radioactive wastes? Such uncertainties require MORE conservatism, not less! (Comments 0324-20, 0324-22, 0324-26, and 0324-30)

12. Currently, the general consensus of national and international scientific community is that radiation doses above background should not exceed 100 mrem/yr effective dose for continuous or frequent exposure from radiation sources other than medical exposures. In the U.S., the accepted apportionment for radioactive waste management is 15 mrem/yr This, 15 mrem/yr, all pathway and the Safe Drinking Water Standard have been deemed by our society as the allowed dose (risk). While Citizen Alert would like to see more stringent standards, at the very least, these should be upheld through the period of peak risk; otherwise, the integrity of the EPA will be undermined. How are we to know when the EPA is developing a sound scientifically protective standard or just bending to special

interests? Relaxing the standard to accommodate greater uncertainties is not justifiable, and outside of the responsibility of the EPA. The preamble contends that since the results of performance assessment past 10,000 years are highly uncertain and that a higher allowed dose limit is necessary to satisfy a "reasonable expectation" of the goals of the standard. The REASONABLE EXPECTATION is that the EPA will act as an independent agency and advance protection standards that do just that, " . .. protect human health and the environment." It is not the role of the EPA to cater to the "needs" of the Dept. of Energy (DOE) to have a standard that will a priori allow Yucca Mountain to be licensed. (Comment 0328-9)

13. Uncertainty does not justify the application of different levels of protection. (Comment 0368.10-2)

Response to Issue A:

A number of comments stated that uncertainty did not justify a two tiered standard (Comments 0226-15, 0226-31, and 0368.10-2), or an apparent relaxation of the 15 mrem/yr standard (Comments 0226-24, 0226-26, 0260-1, and 0324-13), and in fact uncertainty should lead to tighter standards (Comments 0226-24, 0324-20, 0324-22, 0324-26, and 0324-30) or even the elimination of the Yucca Mountain site as a potential geologic repository (Comment 0260-1). Some comments stated there was no, or insufficient, rationale connecting questions of uncertainty and dose limits (Comments 0226-26, 0226-27, 0226-28, 0226-31, and 0302-8). Similar points are touched on in Section 2 of this document, Issue F. We also refer readers to Section 18, where we address comments on the related topics of implementability and reasonable expectation.

We do not agree with these comments for several reasons. Making dose projections for a geologic repository over the time frames involved – upwards of 1 million years - requires the extrapolation of information about the characteristics of the site and the performance of the engineered and natural barriers well beyond the ranges of practical experience with these materials. Significant uncertainties are involved and unavoidable when projecting the expected performance of any potential deep geologic repository to such time frames, and these uncertainties must be considered in setting standards and judging compliance assessments against such standards. NAS also "recognize[d] that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs increases." (NAS Report p. 56) These uncertainties, and the ability of the performance assessment techniques to distinguish between credible alternative models of the disposal system performance, represent the scientific limits of the technology to make projections of future performance.

In setting standards for the 10,000-year period, EPA believes that uncertainties in projecting performance are more manageable than at much later times, i.e., over the 1 million-year period of geologic stability. While NAS recommended that safety assessments be performed over the period of geologic stability and expressed its belief that bounding analyses were possible as a way to manage longer-term uncertainties, the committee made no recommendations about risk limits for compliance decisions. Rather, it acknowledged that such decisions should be made in the public rulemaking process. We believe that these very long-term assessments can be made, but we also believe that quantitative safety assessments should not be the only factor when making regulatory decisions for these very long time frames, and that the limitations of such assessments should be considered in setting a standard. We believe its frequent references to "bounding" approaches indicates a recognition by NAS that there are inherent uncertainties in characterizing the disposal system that cannot be eliminated, i.e., limits to the ability of the technology to make definitive "predictions" of disposal system performance in the very long term. This reasoning is the basis for having a two-tiered standard: an "early" time frame standard when uncertainty is relatively low that is consistent with established practice for regulating geologic disposal systems, and a later time frame standard when the confidence in quantitative assessments is unavoidably lower (Comments 0226-15, 0226-31, and 0368.10-2,), as explained further below.

We see a changing role for quantitative safety assessment as the compliance period is extended from 10,000 years to as long as 1 million years. Initially, greater confidence can be placed in the characterization of the site and other components of the disposal system, and the idea that site evidence from the relatively recent past (thousands of years) can be used to support near-term projections (10,000 years). When looking farther out in time (as long as 1 million years), however, confidence in the individual factors affecting performance and their interplay will be lessened as the disposal system evolves from its original state in ways that are not entirely predictable from a knowledge of current conditions at the site. By extension, confidence in dose projections from that evolving system will also be lessened. At all times, a regulator should have confidence that an applicant has sufficient understanding of the system and the factors affecting its performance. Numerical projections for comparison with specific criteria are not the only way, or always the best way, to demonstrate such understanding. The joint IAEA-NEA Peer Review of the Total System Performance Assessment – Site Recommendation (TSPA-SR, Docket No. EPA-HQ-OAR-2005-0083-0062, pp. 23-24) addressed this point directly:

> [T]he IRT has observed a tendency for more focus to be given to the demonstration of numerical compliance with the proposed regulatory requirements than on developing and presenting an understanding of repository performance…In this regard, there is an emerging international consensus that building confidence in repository performance is of comparable importance to demonstrating compliance with criteria.

For periods on the order of 10,000 years, there is a body of experience in conducting and interpreting assessments of dose and risk, such that greater reliance can be placed on them to demonstrate system understanding. Conservatisms can be more easily identified and quantified, and sensitivities and uncertainties can be more easily bounded and their influences examined. At much longer times, however, when the system has evolved from its initial conditions, the methods and assumptions used to construct the assessment take on greater significance, since the site's characteristics and the processes operative under these changed conditions, are more uncertain. In our view, it would be reasonable to give less weight to peak dose assessment results when considering overall system safety, as compared to assessments covering the initial 10,000 years. Extending the same dose limit throughout the period of geologic stability would not adequately recognize this shift over time. (66 FR 32098, June 13, 2001, Docket No. EPA-HQ-OAR-2005-0083-0042)

The approach we have included in our final rule is to specify a dose standard for the initial 10,000 years, as well as a second, higher, dose standard for the time of peak dose beyond 10,000 years. The context for these two standards in the rule is identical. Each must be met for NRC to issue a license. However, we believe a higher peak dose standard is an appropriate and effective way to address the concerns outlined above regarding the use of projections at very long times. DOE's peak dose projections will be examined in detail in the licensing review. While making its licensing decision, we do not believe that NRC will focus on just the projected doses. Rather, NRC will consider a number of factors in determining whether there is a reasonable expectation that the standard will be met (e.g., Docket No. EPA-HQ-OAR-2005-0083-0376, p. 45). DOE will be required to explain and defend its assumptions, data, and methods. We see a higher standard as providing the appropriate recognition of the limitations in performance projections over very long time periods and encouraging a more thorough exploration of the implications of changes in the assumptions, data, and methods, as well as the role of conservatism and uncertainty in constructing robust assessments. For these reasons, we do not believe the approach suggested by commenters to incorporate more conservatism or rely on bounding approaches is appropriate. (Comments 0226-28, 29, and 0324-20, 0324-22, 0324-26, and 0324-30)

Our conclusion that a higher peak dose standard is appropriate does not directly tell us what that standard should be. One thing is clear, however, whatever the standard is, it must be protective of public health and safety. We believe that data used in quantitative safety assessments becomes more uncertain as time progresses. The characteristics of the site will vary over time as a consequence of natural processes at and around the site, which are occurring at different rates. As a result, the performance of the natural barrier components have associated uncertainties, both in defining their characteristics as they may vary over very long timeframes and in projecting their combined effects on performance. Similarly, the engineered barriers will inevitably degrade and also change the characteristics of the natural barriers around the wastes. Degradation of the engineered barriers involves multiple elements, each with its own failure mechanisms and rates. The drip shields and double-layered metal containers would fail from various corrosion mechanisms, whose presence or absence and rates will vary as the physical and chemical conditions in the emplacement drifts vary over time. The cladding around the fuel pellets could fail by different mechanisms and rates (stress induced failures, corrosion processes) than the drip shields and container. Finally, the fuel pellets themselves will undergo degradation that will vary as functions of the age of the pellets and the chemical environment surrounding them before and after the containers are breached and ground water enters. Thus, degradation of the natural and engineered barriers results in the release of radionuclides in ways that are not completely predictable quantitatively. While considering how our peak dose standard might appropriately reflect these uncertainties, we turned to two sources of insight, approaches used in other disposal programs and our own technical assessments. (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429)

The international radioactive waste community has grappled with the question of increasing uncertainty and the use of quantitative safety assessments in regulatory decision making. As discussed in the preamble to the proposed and final rules, international organizations and disposal programs abroad have suggested that exposure levels in the very long-term in the range of background radiation levels could be considered acceptable. As discussed in the preamble for the final rule, we have set a 100 mrem/yr peak dose limit during the stability period, rather than the limit in the proposed standard. The rationale for this selection is also discussed in Section 3 of this document.

Our approach for the extreme far future differs from the international practice primarily in that we are establishing an explicit, numerical peak dose standard against which assessment results will be compared, whereas the preferred approach internationally is to emphasize other non-quantitative factors influential to safety. In that approach, numeric assessment results are considered more for what they indicate about overall performance rather than their strict conformity with specific dose or risk criteria.

The second approach we have used is our own technical analyses. EPA has done some technical modeling studies of the site to examine the implications of the very long time frame for the geologic stability period on the reference dose limit of 10,000 years proposed in the standard. (Docket No. EPA-HQ-OAR-2005-0083-0386) This dose limit is the only established and implemented marker for acceptable repository performance. It was established in 40 CFR part 191 on a generic basis for any disposal system, and implemented for the WIPP facility certification. As such it represents the level of exposure the society is willing to accept as acceptable health risk from a deep geologic repository for a 10,000-year period. Our technical analysis examines the propagation of uncertainty as reflected in dose projections over the very long-term and estimates the variations in doses that could result for a hypothetical disposal system under the conditions at Yucca Mountain. To do this analysis, we constructed a hypothetical situation where the number of failed waste packages necessary to deliver a mean dose of 15 mrem/yr at Yucca Mountain dose was calculated, and then the release projections from this fixed number of packages was followed to peak dose, under the range of conditions expected for the site. The resulting peak doses calculated were in the range of several hundred mrem/yr at peak dose, for various approaches to the computer simulations. The analyses looked at the effects of uncertainty, as reflected by the spread in site data used in the modeling, on the very long-term performance of this hypothetical system. It should be understood that this represents a hypothetical disposal system and is not intended to represent the actual expected performance of the site, since we deliberately constructed a disposal system that was at the "edge of compliance" at 10,000 years, i.e., it was set to produce a mean dose of 15 mrem/yr at 10,000 years. Results of the analyses showed that the uncertainty (reflected by the difference between the 5th and 95th percentiles of the calculated doses) from the initial starting point, the "edge-of-compliance" hypothetical system at 10,000 years, and at peak dose, increased by approximately two orders of magnitude. The uncertainties reflected in these results concern the behavior of the natural barrier over time relative to the hypothetical "edge-of-compliance" disposal system examined. These results support our position that uncertainties in projecting doses into the very long-term do increase significantly. The increasing spread in dose projections limits the ability of numerical performance assessments to distinguish between possible alternative assumptions and conceptual models that could be proposed for the disposal system, and makes performance assessments in the very long-term a less reliable tool for projecting doses with confidence. We also examined uncertainties and alternate conceptual models of how the disposal system's performance is assessed, both in terms of the engineered and natural barriers (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429). The results in these documents illustrate the complicated interplay between uncertainties in the natural and engineered barrier performance and the decreasing ability of the performance assessment tool to distinguish between alternative conceptual models that produce dose estimates within the observed limits of data and model uncertainties. Consequently our assessments show that less confidence can be placed on the results of such very long-term projections in compliance decision-making, as highly confident "predictions" of performance into the very long-term. The decreasing confidence on the reliability of numerical dose projections over very long time frames is supported by these analyses, and supports our decision to look to other contexts as a framework for selecting a peak dose limit.

We believe, considering the results of our modeling, that the peak dose standard should not be viewed as a less strict or "loosened" standard, but rather as reasonable (Comments 0226-24, 0226-26, 0260-1, and 0324-13). Moreover, as established elsewhere, the peak dose standard is protective of public health and safety. See Sections 2 and 10 of this document for additional discussion of the protectiveness of the peak dose limit. We have established standards that are protective of public health and the environment, meaningful, implementable, and provide a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation. In our view, an unchanging 15 mrem/yr standard would not present a reasonable test and would not be appropriate (Comments 0226-24, 0324-20, 0324-22, 0324-26, and 0324-30).

Comment 0226-15 mentioned that uncertainty is not a reason for changing the standard but rather for DOE to fix its modeling, while other comments claimed that uncertainty affecting the peak dose standard argues for rejecting the site (Comment 0260-1). As described above, the peak dose limit for the period of geologic stability appropriately recognizes the limitations of modeling over very long times and is reasonable and protective of public health. The implications of the standards for DOE's modeling is a question for DOE to address relative to its modeling efforts and the licensing process. Final licensing or denial of a license is the purview of the NRC (Comment 0260-1).

Comment 0226-27 likened setting two dose standards for different times as akin to setting two different engineering standards for a bridge on the basis of uncertainty. The comment questioned why, in the light of uncertainties over long time periods, a stricter standard for later times was not the more appropriate course of action to compensate for uncertainties. While this analogy is appealing on the surface, it fails to capture the substantial difference between the two situations. A bridge can and would be maintained through its entire functional lifetime, in contrast to the disposal system at Yucca Mountain which is intended to be a passive system, i.e., it must perform as expected without human intervention over the compliance period. Over long time periods at Yucca Mountain, the engineered barriers will inevitably degrade and uncertainties about the slower evolution of the natural barrier around the repository cannot be eliminated. Therefore in the very long-term, the confidence that can be placed in performance projections must inevitably decrease. We recognized this in selecting a peak dose limit higher than the 15 mrem/yr limit for 10,000 years, but which is still a protective limit for the reasons explained elsewhere in this document and the preamble to the final rule. For the bridge and repository situations to be analogous, one would have to assume that the bridge receives no maintenance over an equivalent functional lifetime (hundreds of thousands of years). Assigning the same performance expectations to an un-maintained bridge over such a time span, or even a few decades, would not be reasonable.

Comment 0226-29 presents a long list of references to other regulatory actions involving some degree of uncertainty, lack of applicable data, and conservative assumptions, taken by the regulatory agencies in response to these situations. These cited examples are fundamentally different from the case of deep geologic disposal of radioactive wastes. The cited examples concern areas where institutional controls are assumed to operate to monitor and address adverse effects, collect necessary information to improve health effects assessments as necessary, and thereby assess the impact of "conservative" assumptions taken in prior regulatory decisions. For deep geologic disposal, the intent of the effort is to develop a system that will perform acceptably without the need for human intervention. Indeed, with consideration of the time frames over which the disposal system operates (as long as 1 million years under the regulatory framework), it must be assumed that the operative time frame is far too long to assume that any active institutional controls can operate. For the disposal system, uncertainties must be identified and assessed during the operational period prior to repository closure, and regulatory decisions made using that understanding. In contrast to the examples posed by the comment, we believe that uncertainties should be reflected in a cautious, but reasonable, approach to setting the standard, so that a protective standard can be developed and regulatory decisions made with full knowledge of the inherent uncertainties in the disposal system affecting such decisions.

Section 6 Uncertainty

Issue B: Recognizing the uncertainties is reasonable

1. Protecting people and the environment is one responsibility, balancing risk is another. To base a judgment about a repository's level of protection in comparison to natural exposure levels demonstrates a healthy level of rationality. The uncertainties in projecting repository performance out to 1,000,000 years are such that modeling can not really show that release limits of a few 10s of millirems are met and that to pretend it can is ridiculous on its face. The EPA has proposed a radiation exposure limit in the period beyond 10,000 years that is not so low that it flat out dooms Yucca Mountain to failure. A rationale that compensates geologic uncertainty with a larger exposure limit is responsible. (Comment 0185-2)

Response to Issue B:

We agree with the thrust of this comment (Comment 0185-2), in terms of the risk management approach we have used in setting the peak dose standard, and the degree of confidence that can be placed on quantitative dose projections in the very long-term. We believe that the standards we have set are a responsible balancing of risk and public health protection, and recognize the limits of confidence in quantitative modeling over the geologic stability period as reliable predictions of potential exposures.

Section 6 Uncertainty

Issue C: General uncertainty comments

1. The Supplementary Information contains many discussions to the effect that uncertainties in projecting the performance of waste disposal systems increase with increasing time. Other reports by the IAEA and NEA, for example, are cited to support this assertion. It may be true that uncertainties generally increase with increasing time in the far future. However, it must be understood that assertions about this in IAEA and NEA reports are based on an important assumption, namely that uncertainties in future biospheres and human behaviors are important factors in determining uncertainties in projected doses at far future times. IAEA and NEA reports have assumed that future biospheres and human behaviors are largely unknown and that their uncertainties are largely unquantifiable. What I am asking here is that EPA consider revising its discussions of uncertainties and how they change over time to properly account for assumptions that are implicit in discussions of this issue in other reports but are not relevant to EPA's regulations, given that the biosphere and human behaviors at future times are fixed by rule at Yucca Mountain. EPA should also consider whether an assumption that uncertainties increase with time is reasonable at Yucca Mountain. (Comment 0186-15)

2. I would also note that it may not be true that uncertainties in projected doses at Yucca Mountain increase with time out to one million years. It seems to me that uncertainties are likely to be largest during the period when waste containers fail and the uncertainty in the distribution of container failures over time is likely to be an important contributor to the overall uncertainty in projected doses. Once all containers have failed, it seems to me that uncertainties will decrease even though projected doses are increasing. I also note that, as indicated in the Supplementary Information, this perspective on when uncertainties are the greatest was presented in the NAS report on Technical Bases for Yucca Mountain Standards (Docket No. OAR-2005-0083-0076). EPA's arguments to dismiss the point of view in the NAS report are unpersuasive. I am also not persuaded by EPA's arguments on this issue in Section II.C .2 of the Supplementary Information. (Comment 0186-17)

3. A different perspective on the important issue of uncertainty that I believe is more relevant, … is this. The important issue is not whether uncertainties in projected doses increase with time over one million years (or, at least to the time of peak annual dose). Rather, the important issue is that the uncertainty in whether the Yucca Mountain facility will be in compliance with standards clearly increases out to the time of peak annual dose

(and perhaps beyond, if projected annual doses are not decreasing substantially with time). That is, the issue is one of uncertainty in regulatory decision making, not uncertainty in projected doses, although the two are linked. For example, large uncertainties in projected doses are unimportant if upper credibility limits are well below applicable dose criteria. (Comment 0186-18)

4. You talk a lot about uncertainties. And that really is quite a smoke screen. There is not that much uncertainty. Department of Energy has done computer simulations, they show us what they expect doses to be. And they're right out there within that range. And you've met what their expectations are by having the median used for your calculation mark and by having 350 millirem. (Comment 0209.14-6)

5. The core justification EPA offers for numerous components of its proposed rule—its lax, two-tiered standard; its use of the median rather than the mean; and its attempts to pre-set modeling parameters, among others—is increased "uncertainty" after 10,000 years. But the EPA and DOE studies relied on by EPA show no qualitative increase in uncertainty after 10,000 years, and there is good reason to believe that the uncertainty after 10,000 years will in fact be less. Therefore, uncertainty provides no foundation for EPA's proposed rule. This contention is set forth in great detail in a report prepared for Nevada by Dr. M. C. Thorne, *The Role of Uncertainties in Defining the Proposed Standard* (Nov. 10, 2005), attached as Appendix C. Moreover, as the Court has already pointed out, EPA's uncertainty rationale is inconsistent with the NAS's findings and recommendations. (Comment 0226-23)

6. EPA's discussion of uncertainty is terminally vague, and fails to specify not only the logical link between uncertainty and a looser standard but also the types of uncertainty upon which EPA bases its logical leaps. Had EPA actually considered specific sources of uncertainty, it would have found that no source provides a basis for rationalizing a looser standard. (Comment 0226-25)

7. In fact, EPA's abandonment of its longstanding approach to uncertainty has the effect of protecting humans in Nevada less than fish, for NOAA used conservative assumptions when confronted with uncertainty in protecting fish populations, 59 Fed. Reg. 7647 (February 16, 1994); 57 Fed. Reg. 3952 (February 3, 1992). (Comment 0226-30)

8. Just as the Army Corps of Engineers should not measure levees against lax safety standards because it cannot predict exactly when Katrina-esque hurricanes will strike, Yucca Mountain should not be held to a looser standard simply because DOE cannot project when exactly the engineered barriers will fail. They will fail, and radionuclides will escape, at some time. EPA's standard must protect against that threat even if EPA and DOE are uncertain whether it will occur in 400 or 400,000 years. The particular sources and types of uncertainty that exist at Yucca Mountain do have implications for regulatory decision-making. Some uncertainties imply that the site should be more carefully studied. Others imply the need for better engineering, or for a different site. *None* of these types of uncertainty provide any basis for a looser standard, or for taking a different approach to assessing post-10,000-year compliance. The report by Dr. Thorne [Appendix C] establishes this fact. On a regulatory policy level, uncertainty about potential flaws in DOE's engineering barriers provides a reason for demanding better-engineered systems or, perhaps

more realistically, for locating a site where geologic systems provide containment and thus mitigate the impact of the engineered barriers' inevitable failure, as is the case with DOE's WIPP repository site, for example. But it defies logic to suggest that DOE is entitled to a looser safety standard because it cannot say for certain whether its engineered systems will work. (Comment 0226-32)

9. The NAS was clear that reasonable predictions of the performance of the natural systems can be made within the period of geologic stability. But here too, DOE is not entitled to a looser safety standard simply because it is uncertain how its chosen site will behave because it stopped its site investigation program before all of the data were in. Also, some natural systems at the site will change in the future—for example, climate will vary, earthquakes may occur, and volcanic eruptions may disrupt the repository—and some uncertainties do exist with respect to such changes. The NAS considered possible uncertainties in natural system behavior and specifically concluded that they did not preclude assessments of performance at peak dose. It repeatedly rejected any suggestion that these parameters change and become more unpredictable at 10,000 years, noting that "earth scientists are accustomed to dealing with physical phenomena over long time scales." *Id.* at 71. But again, such uncertainties, even if they were more than NAS assessed, are no basis for setting a laxer standard. If Yucca were a better site, with much longer geologic containment, these uncertainties would matter much less or not at all. A poor site is no justification for a lax standard. (Comment 0226-33)

10. The NAS noted one specific restriction on that conclusion—its determination that future *human* scenarios were too uncertain to model—but otherwise adhered to the consistent conclusion that uncertainties did not preclude meaningful assessments of long-term compliance with a numeric standard. *Id.* And it expressly rejected any suggestion that 10,000 years represents a significant crossover point at which uncertainties render long-term compliance assessment less meaningful, finding that "there is no scientific basis for limiting the time period of an individual-risk standard in this way." *Id.* at 6. The NAS report thus contains an unequivocal rejection of the notion that uncertainties are somehow more unmanageable in longer-term compliance projections. (Comment 0226-34)

11. In addition to being inconsistent with the findings and recommendations of the NAS, EPA's conclusions about steadily increasing uncertainty are wrong. Even if DOE is correct in its optimistic assumptions about short-term performance of the waste canisters, its current modeling graphs indicate that the range of modeling results rises initially but then *decreases* as time passes. *See* Appendix C. And if those engineering assumptions are acknowledged to be major sources of uncertainty, the highest levels of uncertainty are likely to occur even earlier. (Comment 0226-36)

12. Rather than acknowledging, let alone avoiding, this conflict, EPA attempts to mask it through disingenuous discussion of the NAS report. EPA quotes the NAS stating, "[b]ecause there is a continuing increase in uncertainty," and suggests that this carefully selected excerpt indicates that the NAS clearly agrees with EPA's view that "uncertainties generally increase with time, at least to the time of peak dose." 70 Fed. Reg. at 49025. But the entire NAS quote states: "Because there is a continuing increase in uncertainty about

most of the parameters describing the repository system farther in the distant future, it might be expected that compliance of the repository in the near term could be assessed with more confidence. *This is not necessarily true.*" NAS Report at 72 (emphasis added). The NAS then explained why "this is not necessarily true," pointing out that many site parameters (like geologic parameters) do not change with time, and that others are more significant during the short term. *Id.* (Comment 0226-37)

13. EPA's FEPs also undermine the key rationales for EPA's creation of a higher numeric standard in the post-10,000 year period, and for EPA's position shift to require use of the median, rather than the mean, for projecting compliance. EPA proposes to justify both its 350 millirem/year standard and its use of the median primarily on the rationale that both are necessary to manage long-term uncertainties in performance assessment. EPA's theory appears to be that a combination of uncertainty and compounding conservative assumptions will unavoidably skew DOE's modeling, and that, rather than expecting DOE to fix those perceived modeling problems, EPA must for some reason compensate for that skewing by using a commensurately skewed higher standard and a less conservative statistical compliance measure. The use of predetermined FEPs undercuts EPA's uncertainty rationale. By specifically defining future states for crucial FEPs, such future climate states, EPA manages uncertainty out of the modeling process. Having taken that step, it is inconsistent to *optimistically* adjust the end-goal to account for negative uncertainties that the modelers have been required to remove. Essentially, this methodology double-counts the perceived uncertainty. The use of FEPs also thoroughly undercuts EPA's predetermination that DOE's modeling process will be overly conservative. As shown in the mathematical example above, arbitrary exclusion of FEPs can inherently skew the modeling process toward optimistic outcomes. (Comment 0226-95)

14. In the proposed regulations the EPA discusses uncertainty in predicted performance, especially the speculated increase in uncertainty after 10,000 years. However, each of the physical and chemical processes occurring in the release and transport of radionuclides is not particularly complicated especially once the thermal excursion, due to the heat of radioactive decay, has passed. There are uncertainties associated with many of the parameters required to numerically generate a solution to the defined set of release and transport equations. These uncertainties are quantified by using the techniques of probabilistic risk assessment where they provide a predicted distribution of results. This expected distribution, which includes the composite effect of all uncertainties considered, is compared to the proposed standard to establish whether or not a reasonable degree of compliance has been achieved. If the distribution of predicted results becomes unacceptably wide (or skewed) as the simulation time increases then it is fair to infer that either the performance of the repository is unacceptable or our understanding and modeling of the processes governing performance are unacceptable. In the case of the latter eventuality, if we cannot reasonably predict repository performance with some acceptable confidence at all times, we have no right to place waste in Yucca Mountain. (Comment 0263-1)

15. If the proposed regulation is to specify how compliance will be assessed, then the method must be applied in a consistent and logical manner to the probabilistic predictions of repository performance. As long term performance has not been predicted in recent years by DOE, the EPA's (a priori) approach must be meaningful for all combinations of performance results. The EPA position of stating that there is very large uncertainty at late time has no basis and is speculation. Two examples of potential suites of results are discussed. The EPA's final methodology must allow sound regulatory decision making on both of these stylized examples. (Comment 0263-12)

16. EPA concludes that current activities constitute the least arbitrary scenario to use in calculating human exposures, but when confronted with a similar type of uncertainty in modeling geologic conditions, EPA concludes that at a certain point the uncertainties of the analyses eliminate credibility altogether, but fails to state why 10,000 is the magic dividing line. (Comment 0311.1-11)

17. The standard should recognize that the uncertainties in the estimated doses will increase with time and that the uncertainties beyond 10,000 years will become very significant. In this regard, therefore, we propose that the EPA adopt the French approach to waste repository standards in which the doses beyond 10,000 years are calculated using scientifically reasonable, but highly conservative choices for the important parameter values in order to increase confidence that the ultimate impacts from the repository will be less than those predicted. (Comment 0314.1-8)

18. EPA goes on "Such a conclusion would be inconsistent with any concept of permanent disposal, which necessarily requires examination of time frames and events that cannot be predicted with certainty,". This is not true. Yucca's geology is fractured and fissured and entirely unsuitable for high-level radioactive waste burial. But other geologic settings within the United States could very well be much more geologically stable and reliable for radiation isolation than Yucca's earthquake-plagued volcanic tuff EPA should not paint Yucca critics as complete nay-sayers to geologic disposal. This is an unfair and inaccurate characterization. (Comment 0324-31)

19. Emphasis on "long time" misleading – issue is how well DOE understands the site. (Comment 0367.1-17)

20. There is too much uncertainty involved in ensuring the facility can meet its limits. (Comment 0367.2-26)

Response to Issue C:

A number of comments made reference to the NAS statements about uncertainty possibly decreasing over very long time frames and being potentially more manageable than at earlier times (Comments 0186-17, 0226-33, 0226-34, 0226-36, and 0226-37). NAS made statements that it believed uncertainties would increase for some aspects of the site but that these uncertainties were boundable within the geologic stability period. We agree with this assessment, but offered cautions in our writing that bounding analyses could become overly conservative in terms of the assumptions used with the net effect that the actual expected performance of the site could be poorly represented by overly "pessimistic" assessments.

A number of comments stated that our approach to integrating uncertainty considerations into the proposed standards conflicts with the NAS positions on the role of uncertainties in setting standards (Comments 0186-17, 0226-23, 0226-33, 0226-34, 0226-36, and 0226-37), differs from other approaches to uncertainty in regulatory matters (Comment 0226-30), or is too vague on the subject of uncertainty and regulatory decision making (Comments 0226-25 and 0263-12). We believe our approach does take proper account of uncertainties as NAS suggested. Comment 0226-37 takes issue with our excerpt of a statement by NAS regarding "continuing increase in uncertainty," implying that we have removed it from its context and disregarded the remainder of the statement. We note that the entire statement is included in the preceding paragraph (70 FR 49025). The commenter is correct that our basic position agrees with NAS that "uncertainties generally increase with time, at least to the time of peak dose." The committee stated that position directly in discussing its recommendation for a peak risk standard: "We recognize that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs increases." (NAS Report p. 56) We agree with this general statement because the Earth is not a static system and over time changes in the natural barrier around Yucca Mountain should be expected.

The NAS also pointed out that some major uncertainties, specifically those arising from the degradation of the engineered barrier components, would decrease after these barriers degrade to the point of ineffectiveness, and in some respects that could make projections of very long-term performance less uncertain than projections when the engineered barriers are actively degrading and releases occurring as functions of how the barriers fail and at what rate, particularly if this occurs during the early thermal pulse period when short-lived radionuclides decay and generate considerable heat. Comments 0186-17 and 0226-36 did not find persuasive our argument that this tends to downplay the uncertainties in one of the more significant factors in the timing and magnitude of peak dose. Overall, we agree that system uncertainty would be less if the engineered barriers were intended to provide containment for only a few thousand years, rather than function for tens to hundreds of thousands of years. However, although the assessment may be bracketed by periods of relative certainty in the behavior of the engineered barrier (initially, all containers and barriers are intact; at some later point, none or very few are), the assessment results reflect the period of relatively rapid change in between, when waste packages are failing not only across time but spatially within the repository. From very long time periods the gradual evolution of the characteristics of the natural barrier add uncertainty to dose projections using characteristics defined by present-day conditions.

Regarding the "manageability" of long-term uncertainty, NAS also made the point that it believed uncertainties could be addressed by bounding analyses. We disagree with commenters who interpret such statements as "rejecting" the idea that uncertainties, and their impact on assessments, become more problematic to evaluate over time. NAS emphasized that its recommendations were scientific in nature. The committee recognized that "the objective instead is a reasonable level of confidence in analyses" and "the level of confidence for some predictions might decrease with time." (NAS Report p. 71) The committee further emphasized the policy aspects involved, such as the standard itself, the compliance period, and what would constitute a "reasonable level of confidence" in analyses. We believe that NAS recognized that performance assessments would effectively become more stylized as the assessment period increased (as a result of using bounding assumptions to address some uncertainties that prove difficult or impossible to define more precisely), and that this is reflected in its frequent references to "bounding" approaches as a way to manage uncertainties in making compliance assessment "feasible." (NAS Report p. 55) Thus, while Comments 0226-33 and 0226-34 are correct that NAS made no specific statements regarding 10,000 years in this regard, we believe it recognized that a compliance standard applicable for periods approaching 1 million years might differ in some ways from its recommendations.

On the role of bounding assessments, we have been more cautious, as described in our preamble to the proposed standards (70 FR 49042). We believe that bounding analyses have value, but it can be compromised if the analyses are excessively conservative in terms of both the assumptions in the analyses and the spread of parameter values chosen for the analyses. While conservative assumptions commonly used in bounding analyses are to be expected, and a degree of conservatism is desirable, we cautioned against putting heavy reliance on assessments that contain many, and perhaps extreme, conservative assumptions for bounding assessments. Such overly conservative analyses tend to present an unnecessarily pessimistic picture of performance, and can mask a lack of understanding of how the site will actually function. Neither of these alternatives is desirable. To the latter point, we agree with part of the statements in Comments 0226-32 and 0367-17 that uncertainties should be reasons for more investigation of the site to lower uncertainties where it is practical and productive to do so with additional studies. However, we also recognize that the impetus for more studies in any particular area to lower uncertainties should be balanced against the overall uncertainties in projecting performance of the disposal system as a whole, so that resources are targeted to lower uncertainties associated with significant factors determining long-term performance and dose estimates.

To assess the uncertainty in projecting performance over the period of geologic stability, we have performed some limited site-specific modeling, examining the range of parameter values projected for the site as described in our supporting documents (Docket No. EPA-HQ-OAR-2005-0083-0386, EPA-HQ-OAR-2005-0083-0414, and EPA-HQ-OAR-2005-0083-0429). The modeling work is described in detail in these documents, and summarized below as it relates to the comments. To examine the question of increasing uncertainty over very long time periods, it is necessary to begin the analyses from a well defined starting point. The starting point for our analyses is a hypothetical disposal system, functioning at the "edge-of-compliance" at 10,000 years, i.e., we used the simplified site model described in this report to determine how many waste packages to fail within 10,000 years (under the assumptions of the analyses which differ from the actual expected performance of the Yucca Mountain repository design) to produce a mean dose of 15 mrem/yr at 10,000 years as the reference case (Docket No. EPA-HQ-OAR-2005-0083-0386). This reference case also reflected the uncertainty in natural barrier performance for the period up to 10,000 years in defining the mean dose to the RMEI. We then continued the analyses out to projections of peak dose and examined the growth of uncertainty in the dose projections, as illustrated by the spread between the 5th and 95th percentile values of the projected doses, without allowing any additional waste package failures to contribute to doses (i.e., no additional radionuclide inventory was introduced after 10,000 years into the disposal system modeled). With this model construction we were examining the effects of uncertainties in calculating the natural barrier performance contribution to estimates of the peak dose projections for the hypothetical disposal system we addressed. As a matter of definition for our unique analyses, we considered the engineered barriers to be the metallic waste containers, the spent fuel cladding and the drips shields. Without eliminating additional waste package failures from contributing to releases, we would not be able to isolate the effects of natural barrier uncertainties (from whatever source, e.g., uncertainties in laboratory measurements or field tests) on the calculated dose projections from uncertainties due to the engineered barrier performance. The spread in dose projections for the peak dose estimates in these calculations increased approximately two orders of magnitude relative to the reference case at 10,000 years, illustrating a quantitative increase of uncertainty over the long-term. It should be noted that these calculations are relevant to the reference case we defined. Other conceptual models for the disposal system, involving other assumptions, would give different results, potentially with less or greater changes in the range of calculated dose projections. The intent of our analyses was to assess the relative changes in dose projections for a defined disposal system over the time to peak dose, as an illustrative example of the uncertainty levels in the dose projections for relatively short (10,000 years) and long time periods (to peak dose). This objective was focused primarily on addressing the questions of whether uncertainties could be shown to increase over very long periods out to peak dose, and we believe that our analyses show this for the natural barrier portion of the disposal system.

We also examined uncertainties in both the natural and engineered barrier performance to identify processes that play a dominant role in the peak dose calculations and examine their likely behavior over long time frames and the ability of performance assessments to distinguish between alternative conceptualizations of the disposal system. (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429) Our conclusions indicate that performance assessments have limitations in distinguishing between alternative conceptualizations where the peak doses differ by tens of mrem/yr, and that uncertainties in the rates and magnitude of some processes can produce divergent results under some conditions. For example, differences in corrosion rate assumptions can produce dramatic differences in peak dose values, but assumptions about roof fall in the emplacement drifts and the consequent intrusion of ground waters can have marked effects on peak dose, either increasing or decreasing it significantly. These general observations indicate that uncertainties, and the assumptions used in modeling, over the very long time frames involved in assessments have an important role in the assessment results and the degree of confidence that can be placed in them as reliable projections of future behavior.

Comment 0209.14-6 expressed an opinion that uncertainties are not large. We disagree with the comment. These analyses support our premise that uncertainties in making dose projections over very long time frames limits and lessens the degree of reliance that can be placed on these numerical assessments for regulatory decision-making, both in terms of setting standards and making compliance decisions against standards. The effect on regulatory decision making of increasing uncertainties over time lies in the problem of being able to meaningfully distinguish among alternative assumptions about the behavior or characteristics of components of the disposal system and their effects on dose projections. We have also examined engineered and natural barrier uncertainties and alternative conceptualizations of the disposal system on dose projections to gain insight on how these issues affect the confidence that can be placed on dose projections. The effects of different assumptions about the behavior of specific processes, or changing site characteristics, for example, can easily be overwhelmed by increasing uncertainties in the disposal system performance as a whole. In our modeling we see that different corrosion rate assumptions for the waste packages can lead to dramatic changes in the time and magnitude of the peak dose (an engineered barrier uncertainty). However assumptions about the extent of roof collapse can also dramatically affect the peak dose estimates, illustrating the complex interplay of processes involved in natural barrier and engineered barrier performance. The results of our assessments show that as uncertainties increase in the long-term, therefore, the ability of dose projections to critically distinguish between alternative representations of the disposal system in numerical models diminishes, under the larger envelope of uncertainties in performance of the total integrated disposal system. As our analyses show, the long-term uncertainties in calculating the natural barrier performance increase significantly over time, supporting our rationale for considering other strategies for setting the peak dose limit, as explained in the preamble to the final rule and other places in this document. (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429)

We agree with the comments that stated the most uncertain time is when the repository engineered barriers are breaking down. Indeed, this is the most complex period for realistically quantitatively describing the performance of the disposal system. However, this is also the period when doses are moving upward from minute levels to higher levels. After the engineered barriers have degraded sufficiently that their containment capabilities are largely gone, the radionuclide inventory within the waste packages is obviously far more accessible for transport out of the repository and into the natural barrier. Uncertainties in the natural barrier at that time would play a more significant role quantitatively in dose projections than they would when the engineered barrier is still providing significant containment. Our uncertainty analyses addressed the growth of uncertainties in the natural barrier for the hypothetical limited-inventory system we modeled during the time when the natural barrier performance is most important.

Comment 0226-36 refers to DOE dose projections rising with time as the engineered barrier degrades and a decrease with time thereafter. This decrease at long times is due to radionuclide decay in the waste packages creating a lower radionuclide inventory after they are breached rather than a decrease in uncertainties in the very long term. DOE dose projections show an approximately two order of magnitude spread in dose estimates during this post-peak time frame (when most of the waste packages have been breached and are releasing radionuclides). This corresponds with the two order of magnitude increased spread of dose assessments relative to the reference case in our modeling for the hypothetical disposal system with a fixed number of failed waste packages (Docket No. EPA-HQ-OAR-2005-0083-0386).

Our assessments were used to examine the range of uncertainty in site conditions and parameter values, and in this way we believe we have considered uncertainties in setting the standards as the NAS intended. That is, we have considered the potential effects of uncertainties and the limitations they impose on the confidence that can be placed on very long-term dose projections as well as the ability of performance assessments to meaningfully distinguish between alternate conceptualizations of the disposal system. We believe these analyses provide a quantitative means of describing increasing uncertainty in projecting doses over the period of geologic stability. We believe the peak dose limit we have established is protective and provides a reasonable test of the disposal system performance, appropriately considering the uncertainties that exist for the site (Comments 0226-32, 0226-33, and 0367.2-26). See the discussion in Issue A of this section for more details on this technical work.

Comment 0186-15 suggests that our discussion of international positions on uncertainty is misleading because we do not highlight the fact that much of this uncertainty is related to biosphere and human behavior assumptions (Comment 0226-34 makes a similar point in connection with the NAS recommendations). The commenter believes we have significantly reduced, if not eliminated, this source of uncertainty by specifying characteristics of the RMEI. The commenter points out that "IAEA and NEA reports have assumed that future biospheres and human behaviors are largely unknown and that their uncertainties are largely unquantifiable." We acknowledge the commenter's point, and agree that the inability to project human behavior as far into the future as some other factors is a significant source of uncertainty, but do not believe it affects our position regarding uncertainty in dose assessments. The NAS committee stressed the impossibility of predicting future human behavior and recommended that we should define a receptor consistent with current population patterns and lifestyles (NAS Report p. 122). We believe this approach is generally consistent with the growing acceptance internationally of the concept of "reference biospheres." For example, the IAEA has made this suggestion, but recognizes that such assumptions create a more stylized calculation: "While it may be possible to make general predictions about geological conditions, the range of possible biospheric conditions and human behaviour is too wide to allow reliable modelling. The emphasis of assessment should therefore be changed so that the calculations relating to the near-surface zone and human activity are simplified by assuming present day communities under present conditions. Such calculations can therefore only be viewed as illustrative and the 'doses' as indicative. The use of reference biospheres will likely become a principal tool in this time frame." ("Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," TECDOC-767, 1994, Docket No. EPA-HQ-OAR-2005-0083-0044, p. 19) We also note that the French Basic Safety Rule III.2.f states, "The characteristics of man will be considered to be constant (sensitivity to radiation, nature of food, contingency of life, and general knowledge without assuming scientific progress, particularly in the technical and medical fields)" (Docket No. EPA-HQ-OAR-2005-0083-0389, Section 3.2). Similarly, guidance issued by the Swedish Radiation Protection Authority (SSI FS 2005:5, "Biosphere conditions and exposure pathways", Docket No. HQ-OAR-2005-0083-0388) states:

> "Unless it is clearly unreasonable, however, today's biosphere conditions at the repository and its surroundings should be evaluated, i.e., agricultural land, forest, wetland (mire), lake, sea or other relevant ecosystems…the selection of [exposure paths] should be based on an analysis of the diversity of human use of environmental and natural resources which can occur in Sweden today."

Regarding the agreement of biosphere and climate, we addressed in our proposal the idea that the RMEI characteristics could change with climate, in the sense that other lifestyles might be expected to become more prominent in a cooler, wetter climate (70 FR 49023). However, we continue to believe that the RMEI would represent a reasonably conservative scenario, particularly in its use of ground water, even under changed climate conditions. Historical evidence suggests that Yucca Mountain would not be expected to undergo glaciation such as has occurred in Northern Europe, which would significantly affect the biosphere and human behavior (Viability Assessment of a Repository at Yucca Mountain: Volume 3, Total System Performance Assessment, DOE/RW-0508). (See also Sections 2 and 8 of this document.)

Comment 0226-95 criticized our inclusion of specific instructions for the treatment of some features, events and processes (FEPs) and eliminating them from consideration in compliance assessments as undercutting the treatment of uncertainties. We believe that the particular details we have included in the final standards do not eliminate necessary FEPs from consideration, but merely remove areas of unresolvable and, therefore non-productive speculation from the safety assessments. More specifically, our stipulations on the assessments of climate change in safety assessments do not remove the need to consider significantly increased precipitation during long-term climate cycles over the period of geologic stability. Rather, by allowing averaged values of precipitation (or other appropriate climate-related parameters) estimated for such cycles to be used in the assessments, we remove an unresolvable question about the exact timing and extent of individual "spikes" in precipitation. The need to consider increased precipitation is not removed from the assessments, and the effects of the increased precipitation are still fully included in the assessments. What are removed are the purely speculative aspects of projecting exact timing and magnitude of future climate changes. (See Section 8 of this document for more discussion of climate change and Section 16 of this document for discussion of FEPs.)

Comment 0226-25 suggests that EPA describe various types of uncertainty. We believe that the discussions of uncertainty in the technical support document ("Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessment," Docket No. HQ-OAR-2005-0083-0085) provide a thorough discussion of the uncertainties in assumptions built into DOE modeling approaches (such as choices in corrosion mechanisms), and uncertainties in data used in safety assessments (corrosion rate data for example). Our analyses examining various types of uncertainties in disposal system performance assessments provide detailed discussions of the uncertainties, their behavior over time and implications for performance assessment analyses and dose projections. (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429)

Comment 0263-1 stated that the spread of results in safety assessments over time is a measure for the acceptability of the repository site. We believe that this outcome of the assessments is the product of increasing uncertainty in the data base used in safety assessments, and taken alone it should not be the deciding reason for rejecting the site. While the implications of uncertainties should be understood and evaluated, we believe that the compliance decision that NRC will make should not be based on quantitative projections alone for such extended periods, but also with due consideration to the principle of reasonable expectation in evaluating the overall character of those projections. The compliance decision NRC will make will be based upon its regulations, since NRC has the responsibility for granting the license to operate the disposal system. (See Docket No. EPA-HQ-OAR-2005-0083-0376, p. 45 for discussion of NRC considerations in determining "reasonable expectation.") In line with these statements, we agree with the points raised by Comment 0186-18, i.e., that uncertainty in projecting doses with time is a contributor to uncertainty in regulatory decision making and must be factored into the regulatory process that NRC will execute. Our description of the "reasonable expectation" concept (see Section 17 of this document) provides some additional insight on the role of this concept in regulatory decisions.

Comment 0311.1-11 contends that EPA failed to explain why 10,000 years is an appropriate time for the evaluation of uncertainties. Contrary to the commenter's statement, we have not viewed 10,000 years as a "magic dividing line" where uncertainties "eliminate credibility altogether." We emphasized in our proposal that uncertainties do not become unmanageable immediately after 10,000 years, but will become progressively greater over long time frames. However, there is a body of experience that suggests uncertainties associated with this shorter time frame can be effectively addressed in a regulatory setting, where no such experience exists for periods as long as 1 million years. The 10,000-year component is directly comparable to the level of protectiveness provided in 40 CFR part 191 and adopting it for Yucca Mountain maintains consistency with other applications of deep geologic disposal (WIPP in particular). We believe that this requirement forces the development of a disposal system that will provide at least as protective a situation as would be mandated if 40 CFR part 191 were applied to Yucca Mountain. We believe this will lead to a more robust disposal system when combined with the peak dose standard beyond 10,000 years, which we are establishing in response to the NAS recommendations and the D.C. Circuit ruling.(Docket No. EPA-HQ-OAR-2005-0083-0414)

Comment 0324-31 misinterpreted the statement in the preamble to the proposed rule. We were discussing the uncertainty involved with determining performance of any repository out to time frames on the order of 1 million years. The commenter is incorrect if he meant to imply that uncertainty would vanish if a different repository site were selected. That is not the case. Projecting disposal system performance, including the natural barrier, over very long time periods is uncertain by its very nature for any potential situation. The Yucca Mountain site has been selected through the process mandated by law and it is not EPA's mandate to judge the merit of the site relative to other potential disposal sites. Further, EPA's task, as outlined in the NWPA, was to set generally applicable environmental radiation protection standards. Our task under the EnPA is to set site-specific public health protection standards for Yucca Mountain. We believe that we have done so. It is NRC's responsibility to implement our standards by revising its licensing requirements to be consistent with our standards and using them in the decision on the acceptability of the Yucca Mountain disposal system. The DOE is responsible for siting, building, and operating an underground geologic disposal system for SNF and HLW. It is also DOE's responsibility to show that a proposed disposal system will meet the standards put in place by EPA and implemented by NRC. It is NRC's responsibility to evaluate uncertainties involved in DOE's site description and dose assessments in its decision making (Comment 0186-18). The process executed to select the Yucca Mountain site from among other alternatives also examined the relative uncertainties of the individual sites and reached the conclusion that the site was sufficiently understandable to proceed with site characterization.

One comment (comment 0314.1-8) suggests we should adopt the French approach to dose assessments, i.e., the use of "scientifically reasonable, but highly conservative choices for important parameter values." We find this description contradictory in that it is difficult to call a parameter value selection scientifically reasonable, implying a realistic approach to parameter value assignment, while also being highly conservative, which implies a departure from any attempt to perform realistic modeling. We believe it is DOE's responsibility to determine the approach used for disposal system performance assessments for licensing (e.g., to decide upon the degree of conservatism in their dose projections), and NRC's responsibility to evaluate their choices in the context of the licensing process. Therefore we do not believe it appropriate to mandate any particular approach to selecting parameter distributions for DOE's performance assessments. More discussion of the French and other international approaches may be found in Section 4 of this document.

We do not believe the analogy Comment 0226-30 draws between the treatment of uncertainties for the Yucca Mountain situation and the treatment of uncertainty in regulatory activities aimed at managing fish populations is appropriate. The wildlife management situation deals with an active system that can be monitored and modified over the regulatory time frame, whereas the potential Yucca Mountain disposal system is a passive system that requires a realistic recognition of the nature of the system's uncertainties and the limits they impose on performance projections over the compliance period.

Section 6 Uncertainty

Issue D: Cohen uncertainty report

1. EPA assumes that DOE's models will be overly negative in their predictions of repository performance, and that EPA must therefore create a lax rule to accommodate or balance out that negativity. The first major problem with EPA's over-conservatism rationale is that EPA never explains it. EPA never describes the logical link between an overly conservative analysis and a more lax, second-tier standard. Nevada infers that EPA believes the standard must be lax to accommodate perceived weaknesses in the modeling, but EPA itself has never specified this or any other rationale. But even this rationale, if expressed, would be unreasonable, for the proper remedy for flawed modeling is to fix the modeling, not to weaken the standard. If EPA intended to say that, because of inevitable increased conservatisms after 10,000 years, a 350 millirem/year standard is the equivalent of 15 millirem/year, it has failed to support its premise. In fact, the opposite premise is the more supportable one. (Comment 0226-39)

2. EPA cites a 2005 report prepared by its contractor, Cohen and Associates. But that report cannot support any proposition about the degree of conservatism in DOE's analysis. To evaluate whether DOE's past modeling was overly conservative, the report would have needed to determine which assumptions were conservative and which were optimistic. It would then have needed to quantitatively assess the relative importance of those assumptions to determine whether the overall results were shifted toward conservatism or optimism. Because some degree of conservatism normally is considered desirable in a risk projection—particularly where, as EPA repeatedly states is the case, there is some uncertainty about the projections—EPA would also need to determine whether any resultant shifting of the projections was excessive. (Comment 0226-40)

3. The Cohen report contains no such analysis. Instead, it provides a qualitative and almost totally one-sided discussion. It summarizes almost every assumption that could conceivably be characterized as conservative, sometimes even double-counting the same assumptions. With the exception of a handful of pages in chapter 5, however, the report does not even consider whether optimistic assumptions have been made. Also, nowhere does the report perform any quantitative analysis of the effects of the assumptions it identifies, let alone quantitatively address the effects of the optimistic assumptions it ignores. The report is like a legal analysis that addresses only one side of an argument; it is completely unbalanced and provides no basis for EPA to conclude that DOE's modeling is overly conservative. Moreover, the Cohen report fails to support the actual rule proposed by EPA which eliminates many uncertainties and potential conservatisms from the analysis. (Comment 0226-41)

4. EPA's conservatism rationale also fails to explain why conservatism is inappropriate. To the extent conservatisms are unnecessary, and can be replaced by more realistic analyses, this is the appropriate solution – not weakening the standard. By premising the rule on alleged conservatisms after 10,000 years, the rule has the effect of discouraging DOE and NRC from doing more realistic analyses, lest the premise for application of EPA's rule is

found lacking and the licensing process be thrown into confusion. To the extent the state of scientific knowledge does not permit realistic analyses, then bounding assumptions and analyses are inevitable, but we have no way of knowing how such bounding assumptions and analyses are conservative. It defies scientific logic to give credit for “conservatisms” when it cannot be established whether the conservatisms actually exist. EPA traditionally considers conservatism an important and necessary response to this kind of uncertainty. Such conservatism is particularly important for Yucca Mountain, because EPA's standard and NRC's licensing process will likely be the only opportunities to "test" the safety of the repository design. If DOE, EPA, and NRC eschew conservatism in their approval process and allow the construction of a repository with only a moderate probability of success, they will create a major risk for future generations—without giving those future generations any tools to manage that risk. Those future generations may not have any ability to undo repository failures, or even to know that the repository exists. A conservative standard now will be the primary protector of their safety. (Comment 0226-42)

5. The greatest uncertainty in the performance of the repository relates to the timing of the peak dose, which is itself entirely dependent on the lifetime of man-made waste packages. If DOE's optimistic assumptions about container life are wrong, then DOE's entire performance evaluation becomes extremely non-conservative. EPA itself has noted the importance of this issue, which, if DOE's assumption is wrong, has led modelers to vastly overestimate the ability of the repository to contain waste. (Comment 0226-43)

6. There is no disagreement that DOE's waste containers eventually will inevitably fail, and that Yucca's geology will permit leaking radionuclides to reach the accessible environment. The timing of that failure is uncertain, for DOE is proposing to employ engineered systems that have never been tested on anything approaching the time scales over which DOE hopes they will provide protection. (Comment 0226-44)

7. Finally, there is no genuine dispute that the resistance—or lack thereof—of the containers to corrosion is the crucially important determinant of the timing of peak dose. In its recent report, EPA's contractor provided a detailed discussion of DOE's lack of knowledge about when its containers will fail. Initially, the Cohen report noted that DOE's proposed system is unique. "Unlike most concepts adopted by other nations," it stated, "the proposed Yucca Mountain repository exposes the metallic waste packages and drip shields to sustained oxidizing conditions." Cohen at 5-1. It then noted that the performance of that unique system was difficult to predict. "Engineering experience," the report stated, "with passive metals is extremely short (i.e., approximately 100-150 years) compared with the timeframe of repository performance projections. Extrapolation of present knowledge to the longer timeframe is thus highly uncertain." *Id.* at 5-13 (parentheses in original). It later added that "[t]he failure, to date, to identify clear natural or archeological analogs for long-term passive metallic behavior seriously limits confidence regarding the stability of passive films in providing extremely long-term corrosion resistance." *Id.* at 5-15. (Comment 0226-45)

8. In drawing these conclusions, the Cohen report cited, and followed, the conclusions of leading corrosion experts. In 2001, an expert panel considered corrosion risks to the Yucca Mountain containers. That panel "called attention to how little is presently known about the nature of passive film on Alloy 22," and it considered a series of ways in which the containers might fail. *See id.* at 5-15 to 5-16 (quoting Sagues, 2002). The Cohen report also emphasized the threat of unanticipated modes of corrosion. "[U]nexpected modes of alloy deterioration often emerge when service conditions deviate (even on a microscopic scale) from anticipated regimes," it wrote, and it concluded that "the possibility of other unexpected but potentially severe deterioration mechanisms developing into the far future cannot be dismissed easily." *Id.* at 5-13 (parentheses in original). The expert review on which the Cohen report relied similarly identified a series of potential failure modes that would merit further study. In addition to being highly uncertain, the corrosion resistance of the casks is critically important. The Cohen report notes that "the choice of corrosion rates for the performance projections is a major factor in both estimating the magnitude and time of peak dose projections." Cohen at A-20. EPA similarly emphasizes that corrosion is "exactly the critical element in estimating timing and magnitude of peak dose." 70 FR 49026. This importance exists for an obvious reason; because water always is percolating through Yucca Mountain, radionuclide transport will begin as soon as radionuclides are released, and corrosion rates therefore will determine when releases take place. The effect of those corrosion rates on repository performance is so great that EPA's own economic impact analysis suggests that there is little value in attempting to reduce any other sources of uncertainty. Cohen at A-20. EPA's own documents indicate (1) that the rate of corrosion is of enormous importance; and (2) that EPA and DOE have very little certainty about how quickly corrosion will occur. Nevertheless, DOE's models, to date, consistently have assumed that no corrosion-related failure will occur during the first 10,000 years of the repository lifetime, and, indeed, that robust corrosion resistance will continue for additional thousands of years. *DOE thus has assumed the certain performance of one of the most uncertain aspects of the repository system*. This assumption undermines EPA's theory that DOE's modeling will be "overly conservative." DOE has made highly optimistic assumptions about the single most critical variable affecting repository performance, notwithstanding the "various sources of worse-than-anticipated performance of the WP that have not been sufficiently investigated, or, in some instances, would be very difficult to evaluate in a short research period." Cohen at 5-16. That assumption leaves DOE's analysis as optimistic as a safety assessment of the Titanic that assumed the ship certainly would not collide with icebergs, or an analysis of the Hindenburg's safety that ignored the potential proximity of sparks. (Comment 0226-46)

9. Corrosion assumptions are just one of many potential sources of optimism in DOE's proposed modeling. Neither DOE nor EPA has done a comprehensive analysis of optimistic assumptions and their potential consequences, but several other assumptions and modeling techniques could similarly skew the analysis. For example, EPA's proposed exclusions of criticality events, EPA's ratification of DOE's assumption of the nonexistence

of manufacturing defects, EPA's exclusion of natural events it considers "unlikely," and EPA's exclusion of localized corrosion and other potential engineering problems all would skew DOE's modeling toward potentially excessive optimism. *See* discussion *infra* on FEPs. That excessive optimism vitiates any attempt by EPA to rely on supposed "over-conservatism" as a justification for a lax second-tier standard. (Comment 0226-47)

Response to Issue D:

The purpose of the technical support document referred to by the commenter ("Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments," prepared under contract to EPA by Sanford Cohen & Associates, Docket No. EPA-HQ-OAR-2005-0083-0085) was to provide a framework for understanding the safety analyses that have been performed for the Yucca Mountain site, and provide some insight necessary for the Agency to evaluate the effects of uncertainty in the far future.

Most of the comments make reference to the connection between uncertainty and performance projections for the site particularly in connection with the longevity of the metal containers (Comments 0226-43, 0226-44, 0226-45, 0226-46, and 0226-47), conservatism in the DOE performance assessments (Comments 0226-40, 0226-41, and 0226-42), and the connection between uncertainty in general and the two-tier standard (Comments 0226-39 and 0226-47). These comments were made in the context of the proposed peak dose limit of 350 mrem/yr. and imply a connection between that limit and our examination of assumptions and conservatism in past DOE performance assessments of the Yucca Mountain site. We have not adopted the 350 mrem/yr peak dose in the final rule. In proposing the 350 mrem/yr limit, as well as setting the 100 mrem/yr peak dose limit in the final rule, the assumptions, either conservative or optimistic, in DOE's assessments were not the basis for the decisions. The intent of our examination of the assumptions and conservatisms in DOE performance assessments was to understand the processes operative in the disposal system and their interplay in long-term dose projections and we believe the report provided this insight. The comments received concerning specific aspects of these processes and performance analyses are welcomed and add to the insights provided in the report.

On the general topic of conservatism, Commenter 226 states that we have overcompensated for perceived conservatisms in DOE's modeling, while at the same time given too much credence to DOE's non-conservative assumptions regarding waste package performance. The commenter concludes that we have "premis[ed] the rule on alleged conservatisms after 10,000 years," which "has the effect of discouraging…more realistic analyses" (Comment 0226-42). The commenter states that the legitimate way to address excessive conservatism in modeling is to "fix the model," rather than change the standard. Here again, we did not base standard on the information in the critiqued report.

We do not believe we have prejudged the amount of conservatism in DOE's modeling, nor have we concluded that conservatism is inappropriate or that the total system assessments are overly conservative. Our assessments of the assumptions and conservatisms in the DOE assessments were performed to provide us with some insight into the behavior of the disposal system under various conditions and performance scenarios. The degree of conservatism and its relation to uncertainties in projecting long-term performance are a major part of the NRC's task in evaluating the site's projected performance and making a compliance decision relative to our standards. To construct a standard that is a reasonable test of the disposal system performance we need to understand how the disposal system is anticipated to perform. The referenced report was intended to provide such insights. We recognize that introducing conservatism is a common, and generally accepted, way to help address the effects of uncertainty. In our proposal, we stated that "conservatism in long-term performance projections may be unavoidable in practice" (70 FR 49042) but "realistic analyses are preferred over conservative and bounding assumptions, to the extent practical" (70 FR 49021). We note that some comments disagreed with this position, suggesting that increased conservatism is warranted for assessments covering longer time periods (see Issue C in this section).

We did caution strongly against the use of excessive conservatism in either the models or in developing the parameter value distributions, and do not agree with the implication of many commenters that a more conservative approach is preferable to more realistic analyses whenever possible. Excessively conservative assumptions for various aspects of the modeling are not desirable and can lead to assessments based on a system that is unlikely to exist. The decisions that follow from such assessments would then be focused on extreme situations. We recognize that it may be very difficult to identify and characterize conservatisms over very long time periods, as the characteristics of the disposal system evolve over the long-term in ways that are not completely predictable. However, we believe DOE's assessments should reflect the best understanding of the site and the evolution of the disposal system over time. Transparency in identifying such conservatisms as are deemed necessary and appropriate in assumptions and parameter values, and the uncertainties associated with them, will aid NRC in determining with "reasonable expectation" that the dose assessments will or will not comply with the standard. NAS expressed a similar view in stating that "transparency in the use of assumptions is critical to evaluating the calculated risk." (NAS Report p. 69) Similarly, we noted in our proposal that the IAEA-NEA Peer Review of DOE's TSPA-SR model recommended that DOE present "analysis based on a realistic or credible representation" as well as "complementary analyses with different conservatisms, in order to place the best available knowledge in perspective" (70 FR 49028). As an example of the need for transparency of assumptions, an independent evaluation of DOE's assumptions for igneous scenarios concluded that those assumptions led to calculated doses that were nine orders of magnitude higher than "realistic" assumptions ("Evaluation of the Igneous Extrusive Scenario," Presentation to the Nuclear Waste Technical Review Board, September 20, 2004, Docket No. EPA-HQ-OAR-2005-0083-0074). In many cases, there may be no clear line between "conservative," "realistic," and "optimistic" assumptions. In some cases, assumptions or parameter values may be labeled as conservative when there is insufficient evidence to support that claim, meaning they may actually be seen as realistic if more information were available. We believe it is the consistent reliance on conservatism when choices present themselves that should be viewed with caution. Application of the principles of "reasonable expectation" should ensure that the analyses do not rely on extreme assumptions or parameter values, whether conservative or optimistic. Instead, the full range of reasonable and defensible parameter values will be emphasized in the performance assessments and considered in reaching a compliance determination.

The commenter also cites, we believe incorrectly, several "optimistic" assumptions that our proposal would allow (Comment 0226-47). With the exception of a criticality event, which we concluded would not be significant at very long times (Docket No. EPA-HQ-OAR-2005-0083-0082), the examples cited by the commenter are related to the probability screening threshold established for inclusion of features, events, and processes (FEPs) in the analyses. Without dwelling on the interpretation of "unlikely" vs "very unlikely" FEPs, our individual-protection standard allows FEPs to be categorically excluded only if they have an annual probability of occurrence less than 1 in 100 million (10^{-8}). This equates to a 0.01% chance of occurrence over 10,000 years, and only 1% chance of occurrence over 1 million years. We view this as casting a very wide net for potential FEPs, and hardly one that would lead to "optimistic" assumptions. In fact, FEP screening is not connected to the nature of assumptions used in modeling disposal system performance for the FEPs included in the modeling. The choice of optimistic or pessimistic assumptions about the processes included in the site conceptual model are determined by the analysts (using the information gathered during site characterization and from laboratory testing) after the FEPs have been screened for inclusion or exclusion on the basis of probability. "Unlikely" FEPs, as defined by NRC, may be excluded from the human-intrusion and ground-water protection analyses (40 CFR Part 197.36(b)). Further, this probability threshold also applies to FEPs affecting the engineered barriers, including "manufacturing defects" and "localized corrosion and other potential engineering problems" (as well as criticality events). Thus, we have neither "ratified DOE's assumptions" nor "excluded" these potential FEPs. Localized corrosion is recognized as a process that could be initiated relatively early in the disposal period, when temperatures are high. Our standards require that FEPs operating for the initial 10,000-year period continue operating throughout the period of geologic stability, so that FEPs that are influential at early times are in no way excluded from the longer-term analyses. Localized corrosion differs from general corrosion in its early significance for waste package failure, whereas general corrosion operates over a much longer time period and eventually causes waste package failures at longer times, which is why we explicitly included general corrosion in our proposal. As with all FEPs, DOE will have to defend its assumptions regarding waste package failure mechanisms. More detailed discussion of FEPs may be found in Section 16 of this document.

As the comments point out correctly (Comments 0226-43, 0226-44, 0226-45, 0226-46, and 0226-47), corrosion of the metal barriers (the waste containers and the surrounding drip shields) is a critical process in determining the range of potential releases from the repository, both within the 10,000-year period and through the remainder of the period of geologic stability, and is a significant issue for long-term performance (Comments 0226-40, 0226-41, and 0226-42). We agree with the commenter's observation about the importance of corrosion rate assumptions and dose projections. This observation is also confirmed by our modeling examining the interplay of major "driver" parameters controlling the timing and magnitude of the peak dose (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429). Variations in assumed corrosion rates caused the peak dose to move beyond the stability period for some assumptions or move forward in time and increase significantly in size relative to a defined reference case. Variations in the amount of ground water entering the emplacement drifts can also act to counterbalance the effects of increased waste package failure rates or increase doses dramatically for given corrosion rate assumptions.

As noted above, NRC will evaluate DOE's assumptions regarding engineered barrier performance. Alternative assumptions may result in projections of significant early releases, as well as potentially dramatic changes in the timing and magnitude of the peak dose. To gain insight into the interplay of process in the natural and engineered barriers over the compliance period, we performed some modeling to examine the contributions of various processes, and the contributions of various types of uncertainty, to peak dose projections. (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429**)** Using a less elaborate site model than that used for DOE's total system analyses (TSPA), we gained some insight into the possible behaviors of the disposal system. The potential corrosion resistance of the metal barriers alone, or uncertainty in any other components of the disposal system, is not a basis for setting any particular peak dose limit, as the comments correctly point out. However, it does provide insight into the implementability of the standards and how to construct a reasonable test of the disposal system performance which was not the purpose of the Cohen report, but the peak dose limit was not determined using that document (Comments 0226-39 and 0226-47).

EPA has performed some analyses to determine the implications of extending the regulatory time period past 10,000 years, the limit in previous applications for deep geologic disposal, and out to time frames as long as 1 million years ("Modeling Uncertainty Effects on a Reference Dose Level," December 2006, Docket No. EPA-HQ-OAR-2005-0083-0386). These analyses look specifically at the range of uncertainty in projecting the peak dose if the Yucca Mountain disposal system were to be at the "edge of compliance" at 10,000 years, i.e., if, hypothetically, a sufficient number of waste packages had failed and were releasing radionuclides into the natural barrier such that the RMEI would experience a dose of 15 mrem/yr at year 10,000. The Agency performed modeling using a site-specific model (although less detailed than the TSPA models used in previously published DOE assessments), which was modified to address the corrosion issue by removing the drip shield totally from the analyses and deliberately failing waste packages until a 15 mrem/yr dose was produced at 10,000 years. By eliminating the containment capability of the engineered barrier system and thereby fixing the source term for releases into the natural barrier, a major component of uncertainty was removed from the hypothetical disposal system, essentially removing the "optimistic" perspective on corrosion rates mentioned in some comments from the analyses (Comment 0226-47). This system, with the fixed number of failed waste packages, was then modeled to explore the range of potential doses for the range of potential values for important site parameters (and their uncertainty) that determine dose levels. This analysis indicated that the hypothetical system at the "edge of compliance" at 10,000 years (showing a mean dose of 15 mrem/yr), the existing limit for an acceptable disposal system at 10,000 years, would produce a range of exposure values at peak dose over a million years of several hundred mrem/yr, for various choices of modeling options. The variation in dose levels at 10,000 years for the hypothetical system (the difference in dose levels between to 5 and 95 percentile of the dose distributions at 10,000 years and at peak dose) increased approximately two orders of magnitude from the starting point at 10,000 years, reflecting an increase in uncertainty over that time period due to variations in the natural barrier site conditions. (Docket No. EPA-HQ-OAR-2005-0083-0386) This technical analysis supports our belief that long-term projections should be viewed as qualitatively different from shorter-term projections in the context of decision-making. Extensive descriptions of these analyses are presented in the referenced reports in the docket.

We disagree with the comment that the peak-dose standard is a "relaxed" standard (Comment 0226-47). The modeling described briefly above sheds some insight into this question. Results of our modeling to examine "driver" parameters controlling the peak dose (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429) show that a hypothetical disposal system giving a 15 mrem/yr mean dose at 10,000 years would produce peak doses in the range of several hundred mrem/yr under the site conditions at Yucca Mountain for a scenario where the number of waste package failures was kept at a fixed level. Other simplified modeling we performed (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429) leads to the conclusion that a peak dose limit in the low hundreds of mrem/yr constrains the disposal system to keep releases well below 15 mrem/yr for periods well in excess of 10,000 years in order to meet a 100 mrem/yr peak dose limit. We have set the peak dose limit at 100 mrem/yr for reasons not based on our modeling results, but these results and the insights they provide to the Yucca Mountain disposal system behavior, indicate that the 100 mrem/yr limit appears to impose significant constraints on the disposal system to minimize releases for periods of many tens to hundreds of thousands of years after repository closure. Therefore the addition of a peak dose standard at 100 mrem/yr provides more protectiveness than a 10,000-year standard alone. We do not agree that the standard is weakened by the addition of a peak dose limit of 100 mrem/yr. (Comment 0226-31) We believe that the peak dose limit we have established is an appropriate and protective health protection standard for periods approaching 1 million years, and that it provides a reasonable test of the disposal system consistent with the NAS recommendations, D.C. Circuit decision, and principles of reasonable expectation.

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Section 7 Use The Mean Or Median?

Issue A: Prefers the mean or median

1. This proposal is in contrast to use of the mean (i.e., arithmetic mean) of a probability distribution of projected doses at times up to 10,000 years. Of all the statistical measures … that EPA might have chosen for comparison with a dose criterion, I believe that the median clearly is the least appropriate. The fundamental problem with using the median …, rather than the mean or some other percentile above the median, is that the median is insensitive to uncertainties in projected doses. In representing a probability distribution by a single number (measure) that is to be compared with a specified dose criterion, it is essential that the chosen measure of a probability distribution of projected doses be sensitive to uncertainties. Furthermore, the measure of a probability distribution of projected doses to be used in compliance demonstrations must increase as uncertainties increase. The mean of a probability distribution has this essential property when the mean exceeds the median, which will always be the case in performance assessments at Yucca Mountain, but the median does not. It is important to note that projected doses will not resemble normal distributions, for which the mean and median are the same. … EPA has argued that the arithmetic mean should not be used because the mean is too greatly influenced by extremes in a probability distribution. EPA's arguments are weak and, it seems to me, without merit. It is precisely because the mean is sensitive to upper tails of probability distributions of projected doses at Yucca Mountain, which clearly are of greatest interest in evaluating overall safety of the facility, that the mean is a valid and useful measure of a probability distribution in judging compliance with dose criteria. (Comment 0186-9)

2. There are two reasons why use of the mean does not unreasonably distort probability distributions of projected doses. First, as EPA's discussion makes clear, projected doses toward the upper end of probability distributions are weighted by their probability of occurrence, and those probabilities generally will be low. Second, related to the concept of "reasonable expectation" is the important point that NRC should have the authority to judge whether the highest projected doses that influence the mean of a probability distribution are reasonable, i.e., whether they represent reasonable outcomes. It is not, (and it should not be), EPA's responsibility to try to eliminate by regulation possible difficulties in compliance demonstrations that might result from a few unusually high projections of dose. (Comment 0186-10)

3. I have two further arguments against EPA's proposed use of the median. First, when the median of a probability distribution of projected doses is used at times beyond 10,000 years but the mean is used at earlier times, the difference between the dose criteria in the two time frames is not presented realistically. In reading the regulations and Supplementary Information, it would be easy to conclude that the proposed dose criterion at times beyond 10,000 years is a factor of 3.5/0.15 = 23 less restrictive than the dose criterion at earlier times. However, when probability distributions of projected doses are taken into account, the degree of relaxation in the dose criterion beyond 10,000 years probably will be much

greater. Suppose, for example, that at times beyond 10,000 years when projected doses are the highest, the 90% credibility interval spans three orders of magnitude (i.e., the 95th percentile of the probability distribution is a factor of 1,000 higher than the 5th percentile); DOE calculations I've seen indicate that this probably is a low estimate of uncertainty. If probability distributions of projected doses are approximately lognormal, which should be the case, the mean would be about 9 times higher than the median, and the degree of relaxation of the standard would be about a factor of 23 x 9, or about 200. The actual uncertainty could be well in excess of three orders of magnitude, in which case the degree of relaxation of the standard would increase greatly. If the uncertainty is four orders of magnitude, for example, the mean would exceed the median by a factor of about 50, and the degree of relaxation of the standard would be a factor of about 23 x 50, or more than a factor of 1,000. If EPA believes that an annual dose of 0.15 mSv represents an upper bound of an acceptable dose at times up to 10,000 years, it is very difficult to justify that annual doses in the range of about 30-200 mSv would be acceptable at times beyond 10,000 years. Thus, a major shortcoming of EPA's argument in favor of using the median dose at times beyond 10,000 years is that EPA has not acknowledged the large relaxation in the degree of protectiveness in their standards that the change from a mean to a median probably involves. (Comment 0186–11)

4. My second argument against use of the median is similar to EPA's argument against use of the geometric mean, which is that projected doses of zero, or close to zero, would determine the geometric mean. Suppose, for example, that 51% of all calculated doses in a probability distribution are either zero or very small, as in EPA's discussions of very small but meaningless doses. In this case, use of the median would lead to the absurd result that the "best estimate" of the dose is zero, even though almost half of the doses are greater than zero and, indeed, could be quite large. Does EPA seriously believe that this is a reasonable interpretation of the calculated probability distribution in this case? This example clearly illustrates why the median is a very poor representation of a probability distribution for purposes of compliance demonstrations. (Comment 0186-12)

5. The standard is an average dose rather than a maximum permitted dose. Large numbers of people will get doses far higher than this average dose with proportionally higher risks. Half the radiation scenarios will result in doses higher than that. There is no upper limit for the half of the exposures that would be above the median. Let's be clear about this. There is no upper limit to the dose at all. Dozens of the 300 or so exposure scenarios that DOE would run would result in doses above the 350 millirem or 1,000 millirem doses. In other words, under the EPA standard, significant numbers of people would be exposed to doses that would produce a statistical 100 percent chance of inducing cancer in exposed people. A hundred percent risk of cancer is unacceptable. (Comment 0209.12-6)

6. [Use of the median] is a highly significant shift; DOE's current modeling predicts that at peak dose, mean values will be approximately *three times higher* than median values, and a 350-millirem median standard is thus the equivalent of an approximately 1000-millirem mean standard. (Comment 0226-11)

7. Because EPA proposes to continue using the mean, which it accurately describes as a "familiar and well-understood statistical concept," for its 15 millirem pre-10,000 year period, *see* 70 Fed. Reg. at 49042, its post 10,000-year standard will be almost *seventy* times higher than its pre-10,000 year standard. This shift may be (and appears calculated to be) outcome-determinative; DOE's TSPA modeling suggests that Yucca could just barely meet a median-based standard, but would grossly fail a standard based on the mean. (Comment 0226-12)

8. EPA's shift from the mean to the median also marks a dramatic departure from EPA's prior approach. In its prior rulemaking, EPA initially proposed to use the *higher* of the mean or median, and eventually settled on the mean as its chosen compliance measure. In the 1999 proposed rule for Part 197, EPA stated that: "As a result of the performance assessment there will be a distribution of the highest potential doses incurred by the RMEI [Reasonably Maximally Exposed Individual]. We are proposing that the mean or median value (whichever is higher) of that distribution be used by NRC to determine compliance with the individual protection standard." 64 Fed. Reg. 46988. In the June 2001 Final Rule, EPA [confirmed use of the mean]. 66 Fed. Reg. 32125 (emphasis added). EPA went on to consider many of the rationales it now offers for selecting the median, but it rejected them, concluding instead "that, in the case of Yucca Mountain, the mean is an appropriate measure." *Id.* In its June 2001 Responses to Comments in its prior rulemaking on Part 197, EPA similarly made clear that it would employ the mean rather than the median (pp. 4-7, 7-3, 7-4, 7-5, and 7-6). (Comment 0226-13)

9. [B]ecause no model run outcome is assumed to be more likely than any other modeling run, the mean, which treats each run as equally important, is more appropriate than the median, which treats higher, more dangerous outcomes as less important outliers. In contrast, the median artificially discounts high dose realizations (the distributions tend to be positively skewed) simply because they are high, with no justification in sound science, and notwithstanding that the doses are already weighted by their associated probabilities. Put another way, use of the mean violates the principle that all realizations are presumed to be of equal weight, absent some actual investigation of particular outliers that would raise questions about their scientific validity… EPA's selection of the median is based on a basic misunderstanding of statistics. EPA repeatedly states that the median avoids placing "undue" emphasis on extreme events. [A] statistical measure specifically designed to throw out the higher numbers introduces a pronounced, non-conservative, and irrational skewing effect. But the mean is not skewed, as EPA implies, by those higher outcomes; in the averaging process, the results are treated as equally likely and important. No other approach is rational. (Comment 0226-14)

10. The selection of the median is statistically inappropriate for another reason. By selecting the median, which considers only the number, but not the magnitude, of "bad" (i.e. above-the-median) outcomes, EPA has declined to consider the degree of harm threatened by each of those bad events. Use of the median will discourage any investigation of high dose calculations since those high doses will have little or no effect on compliance. Indeed, use of the median will permit a finding of compliance notwithstanding hundreds of dose calculations showing lethal doses of radiation, because the median is insensitive to the

actual magnitude of the approximately 42% of the dose calculations above it. As a hypothetical example, if 149 realizations (calculations) showed Yucca Mountain would destroy all of the nearby Nevada residents, but 151 of the realizations showed a dose of less than 350 mrem, the EPA approach would pass the repository. The reality is that for any safety evaluation, the magnitude of any potential bad outcomes does matter, and the mean takes that magnitude into account whereas the median does not. In fact, as Dr. Thorne points out (see Appendix C), the median has no well defined relationship to health detriment, so that EPA's proposed use of the median effectively severs the dose standard from the actual harm it is supposed to prevent. Such a standard is not even health-based, as required by law. (Comment 0226-16)

11. EPA fails to explain why focusing on "bad" outcomes is inappropriate for a safety analysis. Indeed, the typical goal of nuclear safety analysis is to focus precisely on the potential bad outcomes. The core purpose of a health and safety analysis is to figure out what will happen if things go wrong. No one would ever criticize levee builders for focusing on performance during extreme weather events rather than on routine sunny days. (Comment 0226-17)

12. Finally, by discounting the effects of high dose calculations, use of the median also reduces the very uncertainty EPA relies on for its choice of 350 millirem. (Comment 0226-18)

13. At times after 10,000 years, EPA is proposing to raise the radiological exposure standard of 15 millirem to 350 millirem, i.e., an increase in acceptable dose by a factor of about 23. In conjunction with this increase, the metric to determine compliance will be changed from the mean value of dose of a number of realizations to the median dose value of those realizations. For typical assessments of the repository at Yucca Mountain the median value of dose is between one and two orders of magnitude higher than the mean value of dose. Taking this difference between mean and median to be one and a half orders of magnitude (i.e., a factor of about 32 which is the geometric midpoint of the two limits) implies that the proposed late time radiological dose standard is about 740 times higher than the initial 10,000 year standard when compared on a consistent statistical basis. This proposed massive relaxation of radiological standards at 10,000 years by the EPA illustrates their lack of regard for future generations as demanded by the NWPA. (Comment 0263-6)

14. For a statistical distribution, the mean provides an unbiased estimate of the expected value. This fact is used in the field of probabilistic risk assessment to provide the estimate of the expected value of the outcome of a model with one or more uncertain inputs. The model results are used to make decisions regarding the expected outcome and the range of outcomes. The assessment of the performance of the repository is no different. The mean of the set of realizations should be used at all time to gauge compliance with regulatory limits. The median value, while being some measure of location, does not provide an estimate of expected outcome. In fact for repository performance the median of a set of realizations is lower than (or much lower than) the mean or expected value. (Comment 0263-9)

15. The EPA erroneously attempts to statistically justify the use of the median of a set of realizations rather than the mean for compliance because of the possibility that a few probabilistic results (i.e., of low probability as each realization is attributed an equal probability of occurring) may be large and thereby "distort" the mean or expected value. If the model is correctly set up and validated these high results are meaningful and their numerical magnitude cannot be discarded as occurs by using the median. (As an historical aside, would the mean or median have been the best measure of evaluating probabilistic risk in the following engineering ventures, (i) the Titanic, (ii) the Hindenburg, and (iii) the Tacoma Bridge? In all cases these ventures were considered extremely sound at the 50% confidence level, i.e., from the use of the median of predicted outcomes. Please do not put EPA in the position of being responsible for a future addition to the list.) In fact the whole probabilistic risk community understands the occurrence of the occasional high values and for this reason always considers (as is done in the present 10CFR63) "reasonable expectation." As discussed in item 8 [See Comment 0263-10 in Issue C of this section], the IPR expressed concern of the diametrically opposite effect of artificially reducing (by dilution) the mean prediction in an attempt to ensure conservative input parameters (the IRT used the expression that increased ignorance of the system results in an improved prediction of performance). When expected performance is dictated by a few high consequence outcomes (as with a reactor PRA) the median provides a totally false sense of security and safety over the use of the expected value (i.e., the mean value). The EPA should reevaluate its position in an unbiased manner on the measure to be used to determine compliance. (Comment 0263-11)

16. The EPA must refrain from using the median value of a set of probabilistic realizations and use the more statistically meaningful mean (i.e., expected) value. In addition the EPA must establish a sensible criterion for proposed standard for mean dose value that is based on current protective health and safety rationales. (Comment 0263-20)

17. Another significant and inconsistent change proposed for 40 CFR 197 is how calculated doses are compared to the standard…The inconsistency is not well explained…The reasoning here does not mesh. Why not use the same method for all times? It appears as though your agency is trying to be consistent with the National Academy of Sciences recommendation on one hand, which clearly states; "We recommend that the mean values of calculations be the basis for comparison with our recommended standards."(1995 NAS Report p. 123), and on the hand satisfy the "needs" of the DOE to allow higher doses for compliance after 10,000 years. By using the median, the bar of what DOE must demonstrate is lower; by as much as 300 mrem/yr from the 2001 calculations. What is the EPA up to? (Comment 0268-3)

18. EPA has exhausted its bag of tricks to justify this outlandish standard by employing twisted logic to convince us that the better way to determine compliance with the standard is through use of the median rather than the mean. In fact, the public – those whose health EPA is supposed to protect – generally believes that a dose limit is what the dictionary says it is: “An amount or quantity established as the greatest permissible.” The public would most likely not approve of using the mean either, but to use an even less protective method of calculation is careless and an affront to those whom the Agency is supposed to serve. (Comment 0294-3)

19. The 1 in 36 risk figure may significantly understate true risks. EPA, in addition to proposing a new standard 23 times more lax than the previous 15 millirem standard, has proposed changing the way the dose is calculated. The prior rule relied upon the mean; the new rule proposes switching that to the median. Based on prior computer runs by DOE, this would further relax radiation standards significantly, by something on the order of three-fold. Thus, what EPA is proposing is not really 350 millirem/year, a 23-fold increase over the previous standard, but on the order of 1 rem per year, a 75-fold increase, which carries with it a risk of about 1 in 10. But because the proposed standard is a median, that results in permitting half of the exposure scenarios to yield doses in excess of the median, with no upper limit. So, true peak doses to the public could be far, far higher than 350 millirem/year. (Comment 0296-3)

20. We endorse EPA’s decision to specify the use of median dose as the compliance measure beyond 10,000 years. Whether to use the median of the output distribution, or any other measure, is clearly a regulatory prerogative that is within EPA’s discretion. There is no standard statistical approach stating whether the mean (whether arithmetic or geometric) or the median is a more appropriate measure of the central tendency of the distribution. We agree, as EPA asserts, that the median is less affected by extreme values, and therefore is considered more useful when there are outliers or extreme values that range over orders of magnitude. In the context of Yucca Mountain, this aspect of the median clearly has utility. Past Yucca Mountain performance assessments have often shown mean values near the 95 percentile of the output distribution - clearly an indication that extreme values are greatly affecting the mean. (Comment 0298-16)

21. Using the method of mean dose distribution during the first 10,000 years means that large numbers of people would receive doses far higher than 15 millirem/year, with proportionately higher risks for cancer. To make matters worse, in the period beyond 10,000 years, when the EPA switches from the mean dose distribution to assess regulatory compliance to a median dose distribution, half of the radiation scenarios could result in doses vastly exceeding 350 millirem/year. In fact, using the median dose distribution method, the EPA introduces a ‘sky is the limit’ formula for half of the people above the median where there is no maximum upper limit for exposure. This median dose distribution method for risk assessment is so flawed that it has been rejected by scientists worldwide. Under the new EPA rules, the median dose analysis method would allow significant numbers of people to be exposed to doses that could statistically produce a 100% chance of inducing cancer. (Comment 0301-5)

22. The use of the median to set a dose limit from a combined distribution is inappropriate. The best estimate of the mean dose (give all uncertainties) would be considerably higher than the median. The 95^{th} percentile dose of about 2 rem per year would create a lifetime fatal cancer risk for women of about 1 in 10 and a cancer incidence risk of about 1 in 5. This would make the proposed standard statistically about like Russian roulette rather than a radiation protection rule at least for some people.

The EPA has justified the use of the median by saying that it does not want the high values of dose to affect what it calls the "central tendency" of the distribution. Specifically, it notes that "In fact, for early occurrences of disruptive events (human intrusion or igneous intrusion), DOE assessments show that at some periods of time the arithmetic mean of the projected doses can exceed the 95th percentile of the distribution of TSPA [Total System Performance Assessment] results."

However, what the proposed rule dose not accurately take into account is that over the time periods of actual interest to the standard (i.e. less than 10,000 years and between 100,000 and 1 million years) the projected dose distributions are well behaved with the 95th percentile larger than the mean which is, in turn, larger than the median of the distribution. Specifically, for times less than 10,000 years the peak 95th percentile dose for the proposed action is more than seven times higher than the peak mean dose while for times out to one million years the peak 95^{th} percentile dose is more than four times higher than the peak mean dose. Reading off the graphs of projected doses in the DOE Final EIS, we can also estimate that the peak median dose at long times will be about a factor of three or four less than the mean.

The well behaved nature of the distributions of projected doses over both short and long times is due to the fact that the peak doses are not dominated by "disruptive events," but by the natural processes of water infiltration, waste package corrosion, and radionuclide transport to the biosphere. There is thus no scientific justification for accepting the use of the mean for times less than 10,000 years as representative while rejecting the mean dose at very long times. This conclusion is supported by the ICRP's *Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste*, which states that

> As general guidance, the Commission considers that its recommendations on the estimation of exposures in Publication 43 [*Principles of Monitoring for the Radiation Protection of the Public*] apply. **The Commission therefore continues to recommend that exposures should be assessed on the basis of the mean annual dose in the critical group**, i.e. in a group of people representative of those individuals in the population expected to receive the highest annual dose, which is a small enough group to be relatively homogeneous with respect to age, diet, and those aspects of behaviour that affect the annual doses received.

In making use of different statistical measures for the dose limits, the proposed rule increases the disparity between the level of protection provided to distant generations compared to the present generation. Already the 350 millirem per year dose limit for times greater than 10,000 years is more than 23 times the 15 millirem per year dose limit for times less than 10,000 years. Taking into account the additional difference introduced by the choice of statistical measures would make the long-term dose limit about 70 times or more greater than that which is considered acceptable today. We recognize that the process of calculation is probabilistic and, therefore, there cannot be guarantees for everyone in the literal sense. But, if a statistical approach is used for the long-term, there is a strong case to be made that, whatever the value of the standard, the part of the probability distribution for the dose limit should not be the median or even the mean, but the 95th or 99th percentile, so that the vast majority of the population can be assured of protection. We recognized that the DOE projections of dose estimates are the result of Monte Carlo realizations and do not directly represent doses to fractions of the population. However, if the median of such realization is 350 mrem per year, the uncertainties in the parameters will create a significant likelihood that a large portion of the population will be exposed to more than that, and some exposed to much more. Given that the uncertainties at the high end of the doses are significant, the mean exposure could be much higher, perhaps several times higher, that the median. Hence, while considerably less than half the exposed population would be expected to be exposed to levels several times higher than 350 mrem/year, the risks to them would be very high indeed.

The large uncertainties at the high end can be interpreted as representing a significant chance that a small proportion of the population would be exposed to high levels or that there is a small chance that large numbers of people could be exposed to them at the time that the highest doses would occur. The interpretation would depend on the specifics of the scenarios that are being run. For instance, a 95 percentile value of peak dose of about 2 rem per year, which can be inferred from official DOE and contractor estimates, could create great risk a small minority of exposed people. For women exposed to this level of radiation it would create lifetime fatal cancer risks would 1 in 10 and incidence risk would be about 1 in 5. This would make the proposed standard statistically about like Russian roulette rather than a radiation protection rule at least for some people. On the other hand, it can be interpreted as a small chance of creating very large risks for large numbers of exposed people, which is also unacceptable. (Comment 0314.1-6)

23. To make matters worse, EPA's 350 mrem/yr figure is not a maximum permitted dose to the public, but rather a median dose, meaning that 50% of doses would, be higher than 350 mrem/yr. Large numbers of people would, under this proposed rule, get doses far higher than 350 millirem/yr. EPA, proposes changing from the mean dose (add all the individual doses and divide by the total number of doses to arrive at the average, or mean dose, thus including very high doses in the mean) after 10,000 years to a median dose (the middle dose value, with an equal number of dose values above and below it - meaning that very high doses are simply disregarded, no matter how high they are) .
According to Dr. Robert Gould, chair of the security committee of Physicians for Social Responsibility, “the sky’s the limit” as to how high doses could go, for incredibly there is no upper limit for the half of the exposures that would be above the median. These higher doses would carry proportionately higher health risk. (Comment 0324-3)

24. In DOE's Yucca Total System Performance Assessment for Site Recommendation, at the time of peak dose (after the waste packages corrode and fail), the mean dose of the many computer simulations is about 600 mrem/yr, whereas the median dose is about 200 mrem/yr. Yucca would not meet a standard that required the mean to be less than 350 mrem/yr, but would if the median were used. EPA's use of a 350 mrem/yr median dose

limit is thus a transparent attempt to keep Yucca "licensable," despite its clearly unsuitable geology. A median of 350 mrem/yr results in doses of 2,000 mrem/yr (2 rem/yr) to the 5% of people most exposed; over a lifetime of such exposures, one in five women would contract cancer from Yucca's leaking wastes. This is nightmarishly unacceptable. (Comments 0324-4 and 0324-27)

25. Just as with the magnitude of the dose, the EPA has chosen to require the arithmetic mean expected dose of ensemble calculations for periods up to 10,000 years, but after which the median expected dose is to be used. The inconsistency is not well explained; the reasoning here does not mesh. Why not use the same method for all times? It appears as though your agency is trying to be consistent with the National Academy of Sciences recommendation on one hand, which clearly states; “We recommend that the *mean* values of calculations be the basis for comparison with our recommended standards.” (1995 NAS Report p.123), and on the hand satisfy the “needs” of the DOE to allow higher doses for compliance after 10,000 years. By using the median, the bar of what DOE must demonstrate is lower; by as much as 300 mrem/yr from the 2001 calculations. What is the EPA up to? (Comment 0328-2)

26. EPA should refine their median criteria to further address low probability uncertainties and inherent conservatisms that exist in DOE and NRC dose projection methodologies. (Comment 351-5)

27. The Department agrees that for projections to time of peak dose, it is appropriate and sensible to use a measure of repository safety based on the central tendency in the distribution of calculated doses that is not strongly influenced by high- or low-end projections that represent low probability situations. The Department considers that the choice of the median instead of the geometric mean is a policy consideration, clearly within EPA's scope, and the Department supports its use. (Comment 0352-32)

28. It is well understood that the arithmetic mean is very sensitive to the largest values (the extreme values) of the data set it is used to represent and thus can give a very distorted picture of what is really happening if the distribution under consideration is skewed to the high side. In such cases, one or a few very large data points can effectively dominate the value of the arithmetic mean. This is precisely the situation with very long-term projections of repository performance…Lognormal distributed data are biased toward extreme values and, accordingly, these extreme values have the potential to dominate the estimate of the mean. This is easily seen in plots of the dose rate… where the results are clearly lognormal, and span 5 to 10 orders of magnitude. In a Monte Carlo realization, each realization has the same probability of being correct…Consider, for example, a point in time on such a curve where the upper and lower extreme values are 1,000 mrem/yr and 0.001 mrem/yr respectively. These points have an equal probability of being correct; however, if an arithmetic mean is used as the measure of compliance, the upper extreme has nearly one million times the influence on the value of the arithmetic mean as does the lower extreme…The geometric mean is the statistically correct measure of central tendency for lognormally distributed data. Unlike the arithmetic mean, the geometric mean mitigates the dominating effect of high extreme values. It simply is not possible to use the statistics of an

arithmetic distribution, that is, the arithmetic mean, to deduce meaningful insight about the central tendency of any data that are lognormally distributed…EPA argues that undue influence on the geometric mean by very small calculated doses is a basis for using the median instead. However, small or zero results do have statistical meaning, and can be accommodated in a number of ways for purposes of determining a geometric mean…In any case, the use of a median value as proposed by EPA is a more realistic measure of central tendency than is the arithmetic mean for lognormally distributed information and accomplishes the aim of defining a measure of central tendency for lognormal results. It is a reasonable substitute for the geometric mean for these types of distributions, since it insulates the measure used for compliance purposes from the undue effects of extreme values in the same way as the geometric mean. The Department considers that the choice of the median instead of the geometric mean is a policy consideration, clearly within EPA's scope; and the Department supports its use. (Comment 0352-33)

29. The Department also concurs with the use of the arithmetic mean for the 10,000-year standard. The Department notes that EPA chose the arithmetic mean rather than the median for the original 10,000-year standard because it was the more conservative of the two measures. While it might be appropriate to use a more conservative measure for the initial 10,000 years, such conservatism is unwarranted at the time of peak dose. Use of the median instead of the geometric mean as the compliance test for dose at time of peak risk is clearly consistent with EPA's emphasis on the importance of reasonable expectation as the standard of proof of compliance…The extreme values result from realizations in which many of the parameter values are drawn from the extreme tails of the probability distributions. Yet the tails are often the part of the distribution about which there is least confidence, so that a measure such as the mean, which can be dominated by such extreme values, is a more uncertain measure than the median. (Comment 0352-34)

30. Failure to use an appropriate measure of central tendency to describe results of simulations involving lognormally distributed parameters would not be consistent with EPA's direction to use realistic approaches to model the site performance. (Comment 0352-35)

31. In issuing the final rule, EPA should clarify that the statement made in promulgating Part 197 in 2001, "…the fundamental compliance measure consistent with a literal mathematical interpretation of [reasonable expectation] would be the mean value of the distribution of calculated doses," is not applicable at the time of peak dose. (Comment 0352-37)

32. The result of calculating the 350 millirem/year standard using the median is that it is 70 times less stringent than the 15 millirem/year standard which is calculated using the mean. The radiation rule will affect thousands of generations into the unknown future. We don't know the future, but the farther out in time we go, the more conservative we should be.

EPA argues that because it is such a long time, a weak standard is better than none. We believe that because the future is unpredictable, it is important that the standard contain conservatism so that the repository system can be judged based on its ability to contain the waste in thousands of years. The way to do that is to adopt a standard that contains that conservatism. Revising the radiation standard by switching from the mean to the median is less conservative, is less protective, and is not acceptable. (Comment 0353-8)

Response to Issue A:

Most comments on this topic opposed our proposal to use the median of the distribution of results as the statistical measure of compliance for the peak dose between 10,000 and 1 million years, primarily because it is expected to be lower than the arithmetic mean (Comments 0186-9, 0186-10, 0186-11, 0186-12, 0226-11, 0226-12, 0226-13, 0263-6, 0263-9, 0263-11, 0263-20, 0268-3, 0294-3, 0296-3, 0301-5, 0314.1-6, and 0353-8). We also received some comment supporting our proposal as an appropriate way to address the difficulties in projecting doses for periods up to 1 million years (Comments 0298-16, 0352-32, 0352-33, 0352-34, 0352-35, and 0352-37). We proposed to use the median for the period between 10,000 and 1 million years as a way to acknowledge the greater uncertainties in dose projections over that time frame and to lessen the potential for a small number of very high projected doses to have a disproportionate effect on the overall outcome, which is more likely to be seen when using the arithmetic mean. We wanted the statistical measure to reflect the “central tendency” of the dose projections, which we believed would be a fair representation of disposal system performance over the time frames in question. We considered the relative merits of the arithmetic mean, geometric mean, and median in meeting this goal, and proposed the median as the best of the three. See 70 FR 49041-49046 of the proposal for this discussion.

After further consideration of comments and the NAS Report (see Issue B of this section), however, we are changing our approach to the determination of compliance for the post-10,000-year standard at Yucca Mountain. We will require NRC to use the arithmetic mean of the distribution to determine compliance at all times. Thus, while there are substantive issues raised by commenters concerning use of the geometric mean or median as the appropriate statistical measure to determine compliance, given that the Agency, consistent with the recommendation of the NAS, has adopted the arithmetic mean as the appropriate statistical measure, we find that the technical bases of those comments do not require response.

Section 7 Use the Mean or Median?

Issue B: NAS recommendation of the mean

1. For several reasons, this shift to the median is flawed. First, the NAS expressly recommended the use of the mean. Second, using the median is inconsistent with EPA's own past and present statements and practice, and EPA has offered no rational explanation for the shift. Third, EPA's approach is scientifically and statistically unsound. Finally, use of the median would allow a grossly unsafe site to be licensed; though DOE's current

modeling projects that the median dose will be below 350 millirem/year, 42 percent of the modeling runs appear to exceed that number. *See* Appendix A, at 8. No site that has a 42 percent chance of failure can ever be considered adequate. [T]he NAS could not have been more clear: "We recommend that the *mean* values of calculations be the basis for comparison with our recommended standards." NAS Report at 123 (emphasis added). Since EPA's rule must be based upon and consistent with the NAS's findings and recommendations, that recommendation mandates the use of the mean. Yet EPA has not only failed to implement that recommendation; it has pretended it doesn't exist. EPA falsely claims that "NAS in its recommendations did not speak explicitly to any particular performance measure to be used in determining compliance with regulatory standards." 70 Fed. Reg. at 49043. That obviously is not true. In proposing to use the median rather than the mean, EPA also would deviate from the practice of the NRC, which in its prior Yucca Mountain rule also specified that the mean would be used. In responses to comments, the NRC explained why the mean was the appropriate measure. 66 Fed. Reg. at 55752 (November 2, 2001). (Comment 0226-10)

2. The Technical Basis for Yucca Mountain Standards, on page 75, explicitly recommends that mean values of calculations be the basis for comparisons with recommended standards. Despite the court's ruling that the NAS recommendations be followed, the EPA has deliberately elected to disregard this recommendation at times greater than 10,000 years where the median value is being proposed for comparison to the standard. Will EPA justify its position on ignoring the NAS recommendation on the use of the mean value? (Comment 0263-8)

3. Although NAS did recommend use of the "mean values of the calculations" we find that use of the median for longer term calculations would not be inconsistent with those recommendations. NAS recognized the need for EPA to apply policy judgments in matters such as these, stating "We acknowledge that determining what risk level is acceptable is not ultimately a question of science but of public policy." Consistent with this philosophy, EPA should use its discretion, as a matter of policy, to assure that the mathematical determinant of risk is calculated in a manner that is not overly subject to extreme values. EPA's specification of use of the median value for calculations beyond 10,000 years is an appropriate use of agency discretion. (Comment 0298-17)

4. The NAS "recommended the mean values of calculations to be the basis for the comparison with our recommended standards." The mean gives equal weight to all scenarios, and gives the best estimate of the expected dose. The scientifically appropriate way to weigh uncertainty is to select scientifically based distributions of the uncertainties of the most significant individual parameters used in the modeling, and then sample these uncertainties using well known modeling techniques. It is scientifically unsound to skew the final results by using the median dose as a benchmark for comparison against a regulatory limit. (Comment 0311.1-9)

5. It is appropriate for EPA to address the fact that the Committee report recommended use of the mean as the test for compliance…In the absence of any clearly stated scientific or technical basis in the Committee report for use of the arithmetic mean, that recommendation should be viewed as a policy suggestion rather than as the kind of technically based finding or recommendation that the Energy Policy Act of 1992 was seeking from the Committee, and should not constrain EPA's ability to establish policy for the protection of public health and safety. The Committee's statement is in a section comparing the Committee recommendations with the 10,000-year standard at 40 CFR Part 191. It is important to note that the report contains no discussion of the technical issues concerning the choice of the measure of central tendency to use for compliance comparisons, or, more importantly, crucial recognition of the inherently skewed or lognormal nature of the peak dose performance assessment results that has so much bearing on the choice of the appropriate measure. EPA proposed rule is correct in concluding that a different measure is appropriate for assessing performance at time of peak dose for technical reasons. Further, much of the discussion of the use of the mean in the proposed rule concerns homogeneity in assessing mean group risks. If these data were lognormally distributed, then the geometric mean would be the appropriate statistical measure for assessing central tendency there as well. (Comment 0352-36)

Response to Issue B:

Comments 0226-10, 0263-8, and 0311.1-9 focused on a statement by the NAS committee: "We recommend that the mean values of calculations be the basis for comparison with our recommended standards." (NAS Report, p. 123) After consideration of these comments and further review of the NAS Report, we agree with the commenters that specification of the arithmetic mean as the appropriate statistical measure by which to determine compliance with the radiation protection standards at Yucca Mountain is consistent with the language in the NAS Report. We did receive some comments making the case that our proposal to use the median could be consistent with the NAS statement, in the sense that the committee recommended the same compliance measure used in 40 CFR part 191, which covered only 10,000 years, but did not show any appreciation that technical or policy considerations might come into play if the distribution of projections covering hundreds of thousands of years differed in significant ways from those shorter-term projections (e.g., if projections are extremely skewed or otherwise suggest the arithmetic mean would not be representative of expected performance) (Comments 0298-17 and 0352-36). These comments also suggested that the median could be consistent with use of the term "expected value" as used by the NAS committee because the committee intended that the compliance assessment not be overly driven by a limited number of high-end results. Given the express mandate of the EnPA, however, that our standards must be "based upon and consistent" with the recommendations of the NAS, we decline to adopt this reasoning.

Section 7 Use the Mean or Median?

Issue C: Other mean/median comments

1. Discussions in Section II.C.5 about normal distributions seem to me to be largely irrelevant, because I don't see how projected outcomes of waste disposal at Yucca Mountain will be normally distributed if reasonable probability distributions of input parameters are used. It seems to me that projected outcomes will closely resemble lognormal distributions. (Comment 0186-24)

2. There are two major problems with the proposed metrics, the mean and the median: a) these metrics have been shown by numerical experiments to usually under predict the actual dose to the public, and b) using current state of the art methods, these metrics are unstable and cannot be reliably predicted. On the whole, the peak of the mean metric chosen by EPA tends to underestimate the actual received dose. The median metric provides even lower estimates of risk than the mean and is thus even more problematic. Other, easy to regulate metrics such as the mean of the peak of each realization, for example, are more stable and provide a more accurate prediction of the actual received dose. Please revise the regulation to use more stable and robust predictors than the mean or median of the realizations. EPA should not mislead the public by stating that a metric which can be reliably predicted is desirable and then turn around and choose metrics (mean and median) which are demonstrably unpredictable using current state of the art methods and which tend to underestimate dose. (Comment 0202-1)

3. However, the International Peer Review (IPR) of the Yucca Mountain Project expressed concern that even using the mean value of a set of realizations could be subject to systematic underestimation of the real expected value due to the phenomenon of risk dilution. If such risk dilution is considered a problem with the use of the mean value by the IPR, then it must be a much more serious compliance problem with the use of the median. The EPA should only use the mean value as a measure of compliance to ensure future generations are protected. In addition, the EPA should acknowledge the possibility of risk dilution and mandate how the effect will be mitigated (or explicitly direct the NRC to do so). (Comment 0263-10)

4. The EPA claims it is retaining the FEP cut-off probability of 10^{-8} per year in the post 10,000 year standard. This is incorrect if the median is used as a measure of compliance. Consider a low probability event with a potentially large consequence such a volcanic eruption through the repository. Ignoring the dilution due to the finite duration of the consequences (as discussed in 10b), for the event to be considered using the metric of the median value of the realizations would require that at least half of the probabilistic realizations include the event, i.e., the expectation of having no events over the million years must be less than 0.5. Using Poisson statistics, this implies that events with a rate of less than 6.9×10^{-7} per year automatically cannot influence the median (i.e., fewer than 50% of realizations would, on average, include the event) and as such are effectively screened out at a much higher probability level (6.9×10^{-7} per year) than 10^{-8} per year as claimed. The EPA needs to propose an alternative to the use of the median such that the required

low probability events are taken into account. This could be done be replacing the median (i.e., the 50%ile) by the mean value or the 99%ile (or possibly, with lots of arm waving, at the 95%ile) of all realizations. Such a replacement would be in line with normal statistical inferences where results subject to uncertainty are given at the 99% (or 95%) confidence limit. (Comment 0263-17)

5. EPA should refine their median criteria to further address low probability uncertainties and inherent conservatisms that exist in DOE and NRC dose projection methodologies. A possible way would be to set the post 10,000 year criteria to a 25% probability and median dose at two or more times the standard dose criteria. Although such an approach has not been used before, neither have numerical standards ever been required beyond 10,000 years before. (Comment 0264-6)

6. . . . with respect to the specific questions posed by EPA on elements of the proposed standard (*e.g.*, median vs. mean; treatment of features, events, and processes; Reasonably Maximally Exposed Individual) Duke endorses the comments provided by NEI on the behalf of the nuclear industry. (Comment 340-2)

Response to Issue C:

Several comments on this topic were technical in nature and raised points that are not necessarily obviated by use of the mean instead of the median. We will address them only briefly here. Comment 0263-10 raises the issue of "risk dilution" and urges us to explicitly direct NRC how to address this potential. "Risk dilution" in this sense refers to the possibility that uncertainty in parameter value distributions may be addressed by deliberately making those distributions broader to increase confidence that the distribution includes all of the "actual" values (i.e., the distribution is made to encompass a wider set of values), which is often considered the "conservative" approach. The commenter believes in some cases this could result in more optimistic (i.e., lower) dose estimates. The commenter refers to the conclusions of the IAEA-NEA International Peer Review of the TSPA-SR (pp. 55-56) in asserting that the effects should be more serious if the median is used as the statistical measure. We do not believe this would necessarily be the case, for the same reason that the arithmetic mean is more affected by extreme values than is the median. In any event, we believe it is NRC's responsibility to examine DOE's data and assumptions to ensure that its performance assessments are appropriate and do not rely on overly conservative or overly optimistic parameter values. We believe proper implementation of the principles of "reasonable expectation" will limit the potential for "risk dilution" of this type, particularly the emphasis on the "full range of defensible and reasonable parameter values."

The same commenter (0263) disputes our statements that the probability threshold for FEPs in our proposal is the same for the entire 1 million-year period. The commenter believes the use of the median would actually result in a threshold that effectively excludes the effects of some low-probability, high-consequence FEPs from consideration in the post-10,000-year performance assessment results. The commenter seems to conclude that such a FEP must be in at least 50% of the realizations to "influence the median." However, we must point out again that a FEP with annual probability of 1 in 100 million (10^{-8}) would not be likely to appear in 50% of realizations, regardless of the compliance measure selected. This annual probability translates to a 1% chance of occurrence within 1 million years, well below 50%. Using probabilistic sampling methods and assuming a series of 300 realizations (based on previous DOE efforts), such a low-probability FEP would be likely to be present in only a few realizations at most (and possibly in none of them).

Comment 0202-1 suggested an alternative measure for comparison to the dose standard. This commenter believes neither the arithmetic mean nor the median provides a sufficiently stable or accurate measure of disposal system performance. The commenter suggests using the "mean of the peaks," which involves averaging the peaks (maximum doses) of the individual realizations, rather than the "peak of the mean," which averages the individual realizations at each time step and identifies the maximum of that curve. The commenter believes the peak of the mean is less stable because it is more affected by uncertainty in parameter values, which tends to make the individual peaks less coincident and has the overall effect of lowering the mean (if there is high confidence that the peak will occur at a specific time, the "mean of the peaks" and "peak of the mean" would be the same; however, if the peaks are widely separated in time, each peak may be averaged with many "non-peak" values, giving a lower overall estimate compared to the average for all individual peaks). For similar reasons, this commenter also believes the peak of the mean is more susceptible to "risk dilution," as discussed above. The mean of the peaks is less affected in this situation because it does not depend on the timing of the individual peaks. The mean of the peaks may be seen as preferable in situations where a considerable number of individual realizations exceed the regulatory standard at some time (or in an extreme case, where they all do), but the mean dose curve remains below the standard. However, we would be concerned that such a conclusion would credit each realization with a level of precision that is difficult to defend, given the many factors contributing to uncertainty in long-term projections (see Section 6 of this document for more discussion). We believe it is more defensible to consider the projections in an aggregated fashion. In addition, we believe NAS intended the peak of the mean be used, as indicated by its recommendation to assess compliance with the standard "at the time of peak risk." (NAS Report p. 2) There is no "time of peak risk" if the mean of the peaks is the measure of compliance.

Regarding the accuracy of the relative measures, reference to the cited PhD dissertation (Docket No. EPA-HQ-OAR-2005-0083-0098) indicates that "accuracy" is determined by comparison to a "nominal" case in which a single deterministic realization of the hypothetical system is conducted using average parameter values. It is not clear that this "nominal" case should be considered the "expected" performance, nor does it capture the range of system performance that is the objective of probabilistic assessments. To say that the peak of the mean "consistently underestimates" risk implies that the nominal deterministic case provides the best representation of overall system risk, which may not be the case.

Further, while it may provide useful information, we have concerns as to whether the mean of the peaks can be considered to correctly represent risks to an exposed individual. While the nature of the calculation makes it likely to be higher than the peak of the means (unless the two are identical), we note the referenced dissertation statement that "the mean-of-the-peaks metric does not necessarily correctly portray risk in terms of factoring in both the probability and consequences of the exposure to specific individuals living in the future. This metric averages the peak doses, even though those peak doses may be widely spaced over time and beyond the expected life-span of a single individual." (EPA-HQ-OAR-2005-0083-0098, p. 6) By contrast, "the peak-of-the-mean metric factors into the estimate of risk both the probability that a particular individual will be exposed and the extent the individual is exposed." The peak of the mean approach has the advantage of being a more realistic description of the range of potential receptor dose rates at all points during the compliance period, whereas the mean of the peaks approach cannot be considered to reflect the dose potential for the RMEI at any particular time since it averages peak dose rates that are separated in time. From a regulatory perspective, because it represents the evolution of the entirety of the disposal system over time, the peak of the mean may provide a more meaningful basis for decision-making. At each point in time, the progression of the individual realizations and the mean dose curve can be more easily viewed in relation to one another as indicative of "expected performance." The mean of the peaks, on the other hand, relies on the combination of specific points of distinct realizations that may make it more difficult to relate to the overall safety of the system, and the remainder of each realization is of no consequence in the evaluation of that system. Except perhaps in the extreme situation where all (or substantially all) of the realizations exceed the regulatory standard, it is not clear exactly what information the mean of the peaks conveys about the disposal system as a whole. See also Section 2, Issue M of this document for some discussion of this topic.

Comment 0264-6 encourages us to go even further in addressing uncertainties and conservatisms, believing this will counteract NRC tendencies to take a very conservative position in licensing. The commenter appears to be suggesting that a median dose of "two or three times the standard dose criteria" (which we interpret to be 15 mrem/yr) would be sufficient if the probability threshold for FEPs were changed to only consider FEPs with a 25% chance of occurrence (1 chance in 4). It is unclear whether this would be an annual probability or a cumulative probability over the 1 million-year period. However, we believe important FEPs would be excluded from the analyses by such a screening level, which would be inconsistent with the purpose of a probabilistic analysis. We believe it is important to consider FEPs shown to have occurred at the site in the relatively recent geologic past (past few million years) in order to have a sense of the natural processes and events that might affect disposal system evolution.

We further disagree that the probability threshold for FEPs should be connected with the statistical measure of compliance, and that the selected statistical measure gives inappropriate emphasis to low-probability/high consequence FEPs. Connecting these two concepts could easily introduce bias in setting up the performance scenarios if the analyst was attempting to predetermine the results of probabilistic assessments to show compliance. We have taken care to define the probability threshold independent of any consideration of the final performance measure to expressly avoid the possibility of introducing such a bias. We believe performance scenarios should be developed, considering only the FEPs relevant to the site, and constructed accordingly, not with an eye on the eventual compliance measure that will be applied to the results of the assessments.

The direction from NAS concerning low-probability/high consequence events advised that the standard should be designed such that it "does not rule out an adequately sited and well-designed repository because of highly improbable events." (NAS Report p. 28) We interpret this as clearly indicating that low-probability/high consequence FEPs could reasonably be expected to exist for the repository setting over time, but that they should be kept in perspective within the set of identified FEPs and not overly emphasized in performance assessments or compliance decision-making. In our proposal, we explained how lowering the probability threshold for FEPs to include events now considered "very unlikely" would create unreasonable and unworkable consequences for the performance assessments over the period of geologic stability. (70 FR 49049) Low-probability FEPs, but those still above the threshold, are included in probabilistic assessments, but their consequences are weighted according to their probability and therefore placed in perspective relative to the higher-probability FEPs that constitute the bulk of the expected performance scenarios.

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Section 8 Climate Change

1. Who knows what future climate change may happen to affect these things. The uncertainty is all too great to accept. (Comment 0105-5)

2. EPA allows the use of stylized scenarios for climate variability, that are simplified to a level that is consistent with the equally stylized assumptions that must be made for human behavior over extremely long time periods. This approach would be required for the analysis of most other very-long term hazards. (Comment 0174-6)

3. Because predicting future climate over both in the short and long run is an inexact science at best, EPA has written a rule to permit DOE to make, for compliance purposes, the one future compliant assumption we know not only to be wrong but absurd.

Future climate at Yucca Mountain is important because it strongly influences the rate at which waste containers and other metal barriers corrode. EPA and its new proposal permits the assumption that, after 10,000 years and out to one million years, the climate at Yucca Mountain can be assumed to remain unchanged for the purpose of those compliance determination.

Enough is already known about past variation in climate to see not only the absurdity of the assumption, but also to put some limits on the magnitude of changes they expect in the future.

Obviously, EPA can do better than they allow the assumption the climate will remain unchanged after the next 10,000 years. The fact the Agency has not done so is additional evidence of assisting DOE and of EPA's clear intent to pave the way for Yucca Mountain licensing rather than establish legitimate and truly protected health and safety regulations. (Comment 0209.7-8)

4. EPA does know that wetter periods will occur at some future time, and we can analyze how the repository will perform when those periods do occur. EPA suggests that because the site geology will have a dampening effect on climate changes, masking the effects of changes several hundred years or less in duration, changes of longer-lasting duration also need not be analyzed. This also is inapposite. As indicated by the NAS language that EPA cited, this dampening effect should transfer the focus to longer-term climate changes (for example, glacial states that might last for thousands rather than hundreds of years). NAS Report at 93. The short-term dampening effect provides no reason for ignoring long-term changes. (Comment 0226-87)

5. As the NAS report and EPA's own past statements indicate, significantly wetter climates will occur and will adversely impact repository performance. In mandating that those conditions be assumed out of existence, EPA's proposed rule would ignore the NAS's clear recommendation. Dr. Thorne indicates (Appendix E), EPA’s specification that only constant climate conditions may be considered ignores the possibility that other factors influenced by global warming will have a substantial effect on deep percolation of water into the repository. (Comment 0226-88)

6. EPA makes three very broad assumptions about climatic and hydrologic behavior at Yucca. These are that (1) future climatic conditions at Yucca can be bounded by the observed range of conditions over past glacial-interglacial cycles; (2) consideration of climate changes after 10,000 years will introduce uncertainties that do not exist in the period before 10,000 years; and (3) only long-term average responses of the system to changes in infiltration are of relevance. However, as is explained in detail in the report attached in Appendix E, prepared by Dr. M. C. Thorne with input from eminent climatologists Dr. Jonathan Overpeck, Dr. Thomas Wigley, and hydrologist Dr. Howard Wheater, these conclusions are not adequately substantiated by EPA. The full Appendix E must be considered. The effects of different climates after 10,000 years can be better investigated using current and developing techniques that would command substantial support in the scientific community. Therefore, EPA's climatic bounding and infiltration conclusions are at best premature, and at worst unsound. Certainly, these effects are not appropriately the subject of advance specification by rule. *See Climatic Considerations Relevant to the Draft EPA Rule*, by Dr. Michael C. Thorne. Moreover, as Dr. Thorne points out, EPA has unreasonably failed to consider the impact of anthropogenic releases of carbon dioxide on climate and infiltration.

As a result, EPA's assumptions about climate and infiltration over the long term at Yucca are arbitrary and capricious. (Comment 0226-115)

7. The writing supporting the proposed rule seems to equate the situation in some European countries with what's expected at Yucca Mountain and uses the approach some of these countries are proposing for very long timeframe performance calculations as models for how similar calculations should be done for the US repository. In countries like Finland and Switzerland, these countries will be buried in alpine and continental glaciers, whereas Yucca Mountain will simply be wetter than presently. The Yucca mountain site would be little different than today - only with increased precipitation. The approaches from other countries don’t offer themselves as models for the US repository, and I believe that you are misusing the approaches as models. (Comment 0258-1)

8. We commend EPA for proposing a stylized approach to addressing climatological FEPs beyond 10,000 years. Such an approach is necessary to bound speculation about potential future climate states. However, we recommend that EPA take this approach one step further by specifying that climate should be assumed constant over the beyond-10,000-year period instead of stipulating that NRC define values to represent future climate change. Human behavior and climate are inexorably linked. To vary one and not the other will create inconsistencies in the analysis that will lead to artificial results not representative of any conceivable future population. For example, why would the future RMEI continue to maintain his crops almost entirely with groundwater (as does today’s present day rural–residential desert dweller) when those crops might already be receiving significant amounts of rain due to climate change to a wetter environment? Our argument that climate should be held constant at the present-day state is supported by the knowledge that today’s relatively dry climate is a conservative approximation of future climates, because it is so dry, forcing relatively high dependence on groundwater. Groundwater is by far the most significant contributor to potential future radiation exposures. The assumed present-day RMEI is virtually 100% dependent on groundwater. The extreme unlikelihood that an individual in

any future climate state could be more dependent on groundwater would make a regulatory specification of present-day climate highly conservative. (Comment 0298-20)

9. Furthermore, recent EPRI global climate modeling work suggests that anthropogenic greenhouse gases may delay the onset of the next glaciation cycle by 130,000 to more than 500,000 years. Hence there is even more uncertainty about whether specifying higher infiltration rates as representative of long-term average climate. Given both this new information and the reasons stated above, we do not agree with EPA's recommendation to NRC that "a doubling of today's average annual precipitation beginning at 10,000 years and continuing through the period of geologic stability would provide a reasonable scenario." Fixing the long-term climate to that of the present day would be more appropriate. (Comment 0298-21)

10. A range of possible climate states, rather than constant climate conditions assumed for the next 1 million years should be required to be incorporated in the performance assessment. (Comment 0302-18)

11. EPA claims that exposures to contaminated groundwater would be less likely if the area were to become wetter in the future, because surface water would become more available and reduce use of the groundwater (even if the groundwater is more contaminated as a result of increased precipitation and water infiltration into the repository). Yet, EPA concedes that a wetter climate means that more people are likely to live closer to the site and, thereby, use groundwater closer to the site. This alone increases the risk posed, and must be taken into account. (Comment 0302-19)

12. The greater the effective moisture, the higher the risk of infiltration or recharge. Hence, if climate change increases groundwater infiltration into the repository, this may cause an increase in radionuclide dissolution and higher release rates from the waste. Moreover, because pollution includes any man-made or man-induced alterations of the radiological integrity of water, such releases could cause direct violations of the Clean Water Act and Safe Drinking Water Act. The four effective climate states each have a varying level of effective moisture. With the exception of the monsoon climate state, the interglacial period – modern-day Yucca Mountain - has a lower annual precipitation and higher annual temperature than the stations selected to represent the other climate states. Hence, glacial and intermediate climate states are predicted to be cooler and wetter than modern and, therefore, would have more effective moisture and lower evaporation rates. Glacial and intermediate climate states are the most important in terms of impending infiltration because they have more effective moisture compared to the other climate states. Thus, precipitation would be stored more easily under these conditions than under current climate conditions.

This notion is supported by the National Academy of Sciences, and referenced by the EPA in paragraph 8 of Section II.D.2.d.: "Change to a cooler, wetter climate at Yucca Mountain would likely result in greater fluxes of water through the unsaturated zone." These increased levels of infiltration threaten rates of radionuclide release from the repository and subsequent transport to the water table. (Comment 0312.2)

13. In Section II.D.2.d. paragraph 3, the proposal references NAS statements concerning climate speculation: "Although the typical nature of past climate changes is well known, it is obviously impossible to predict in detail either the nature or the timing of future climate change. This fact adds to the uncertainty of the model predictions." However, the present docket underestimates uncertainties linked to the science of climate change. It is possible, for example, that past climate cannot serve as an analog for future climates. Other notions include aspects of the paleoecologic record such as reconstructing past climate and resolution and timing of specific events in the past. In additions, human behavior might greatly enhance chaotic behavior within the climate system. Indirect effects of human activity on climate can simply be only speculated upon. There is also uncertainty in future climate itself, perhaps past climate may not repeat in the future. Moreover, according to Saxon Sharpe, the author of *Future Climate Analysis – 10,000 years to 1,000,000 years after Present* and others, many linkages to climate change are not fully understood. For example, connections with the El Nino Southern Oscillation (ENSO) cycles, solar variability, increased atmospheric carbon dioxide, and ocean-atmosphere interactions are unclear. Likewise, factors influencing the timing of climate cycles, the role and mechanisms of global oceanic circulation, global effects of land use and land surface alterations, and the role of biological processes are yet to be clearly defined in association with climate change.

While EPA's evaluation of FEPs seems logical at first glance, many related externalities are wholly ignored. While uncertainties such as astronomical activities are screened out by probability, it is impossible to ignore FEPs that are not understood – such as the indirect activity of human and other linkages to climate change, and future temperature and precipitation values affecting repository behavior. (Comment 0312.3)

14. EPA acknowledges that "it is possible to assume any number of scenarios of climate over [1 million years]," yet the proposal recommends standards based off a "climate scenario that assumes reasonable temperature and precipitation values," essentially ignoring the myriad number of ambiguities presented. Future temperature and precipitation values that may be considered "unreasonable" are disregarded. These "reasonable expectations" may in fact be taken too lightly. As a result, model predictions used by the EPA do not entirely characterize future climate conditions, and therefore misrepresent a main, looming threat: radionuclide contamination into the surrounding water resource that is used for domestic and agricultural purposes.

Future climate conditions can only be speculated upon and hence, future temperature and precipitation values are unknown. Therefore, it is possible that conditions beyond 10,000 years (or less) may very well be *unreasonable*. Disregarding this view results in an oversimplified assumption that undercuts the objective of EPA to protect public health and the environment. Subsequently, the Clean Water Act and Safe Drinking Water Act are undermined.

Section 301 of the Clean Water Act states that it is "unlawful to discharge any radiological… agent, any high-level radioactive waste… into the navigable waters." Further, the Safe Drinking Water Act maintains a 4 mrem/year Maximum Contaminant Level standard for beta particles and photon emitters in drinking water. Although the Yucca Mountain facility certainly does not intend to pollute the underlying waters with radionuclides, and while the National Academy of Sciences concluded that "scientifically justifiable analyses of repository behavior over many thousands of years in the future can be made," uncertainties unaccounted for – yet still associated with climate change - should persuade the EPA to follow a precautionary principle in setting standards.

The EPA's failure to recognize the true ambiguity of climate change has the potential to seriously undermine their model predictions. EPA should establish a precautionary standard based not only upon "reasonable" climate scenarios, but upon conditions *reasonably unlikely* as well. (Comment 0312.4)

15. The impacts of future changes in climate should be taken into account explicitly in the DOE's performance assessments including the consideration of periodic cycling through different climate states on the performance of the isolation system. (Comment 0314.1-8)

16. This treatment of climate change in the EPA's proposed rule is scientifically incorrect, will tend to underestimate the impacts from the disposal of spent fuel in the repository, and does not appear to be consistent with the recommendations of the 1995 National Research Council review as required by federal law. In the executive summary to its *Technical Bases for Yucca Mountain Standard*, the NRC committee stated that "We further conclude that the probabilities and consequences of modifications by climate change, seismic activity, and volcanic eruptions at Yucca Mountain are sufficiently boundable that these factors can be included in performance assessments that extend over this time frame [one million years]." Later in the report, the NRC committee elaborated on the treatment of climate change that it felt should be included in the performance assessments and noted that recent research has indicated that the past 10,000 years are probably the only sustained period of stable climate in the past 80,000 years. Based on this record, it seems plausible that the climate will fluctuate between glacial and interglacial states during the period suggested for the performance assessment calculations. Thus, the specified upper boundary, or the physical top boundary of the modeled system, should be able to reflect these variations (especially in terms of
ground water recharge). Thus, the use of a constant value as proposed by the EPA would not be consistent with the NRC committee recommendations that the "probabilities and consequences" of future climates changes are sufficiently well understood to allow the "variations" in water infiltration to be taken into account. In fact, the DOE performance assessments as presented in the *Final 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* published in 2002 already explicitly took into account the variation in future climate changes in its prediction of doses out to one million years. (Comment 0314.1-14)

17. Beyond the issue of whether the proposed rule is consistent with the recommendations of the National Research Council as required, the use of a constant or average infiltration rate for the period from 10,000 to one million years is not scientifically valid and would not accurately represent the impacts of climate change on the performance of the repository. The response of the geologic system to increases in available water is not a simple linear one in which increased infiltration rates lead to a proportional increase in water flux through the repository. As summarized by Jane Long of the University of Nevada, Reno and Rod Ewing of the University of Michigan in 2004 At present, there is no accepted

conceptual model that explains the travel times and can consequently be used to infer the flux. If climate change were to produce a larger influx of water, saturation in the mountain could increase. Permeability under any proposed model increases nonlinearly with saturation. **Small increases in percolation flux could significantly increase fluid flow through the repository horizon. This nonlinear response is one of the greatest challenges in predicting the behavior of hydrologic systems over long periods.** (Comment 0314.1-15)

18. The issue of climate changes is of significant importance to the predicted long-term performance of the repository. The Total System Performance Assessment presented by the Department of Energy in its 2002 Final EIS for Yucca Mountain included a consideration of the transitions between future climate states, and found that the resulting dose predictions were also cyclical and that "[t]he multiple peaks occurring 200,000 years or more after repository closure are driven by transitions between climate states." For a sense of the scale of these cyclical changes, the difference between the highest peak dose and the lowest value before the next peak in the DOE predictions was roughly a factor of ten Not unexpectedly, the DOE found that "[t]he peak annual individual dose usually coincided with the occurrence of a wetter climate period." The use of a constant climate state over the period beyond 10,000 years as proposed by the EPA would washout the important impacts brought about by the changes between climate states and would tend to underestimate the actual peak dose that would be expected from the repository. This underestimation would, along with the use of the median dose, lead to even larger risks for distant generations being possible under the proposed rule. This would further aggravate the issues of intergeneration equity discussed in section one. The final rule issued by the EPA should require the DOE to explicitly consider the long-term fluctuations in climate and to use conservative assumptions about the timing and duration of wetter climate states given the non-linear response of the transport models and the large influence of climate on the long-term performance of the Yucca Mountain repository. (Comment 0314.1-16)

19. Recent experimental studies on the growth rates of calcite and opal in the Exploratory Studies Facility suggest that the deep environment is buffered from dramatic changes in infiltration rates, even over time scales during which major pluvial events have occurred. This supports EPA' s proposal that the nature and extent of climate change should be reasonably represented by constant conditions taking effect after 10,000 years to the time of geologic stability. The Department also agrees that assuming water flow will increase as a result of climate change is reasonable and appropriate. (Comment 0352-15 (supplemented from Comment 0396))

Response to Section 8:

As can be seen from the comments, there remains considerable debate about how projected climate change over the next 1 million years will affect the Yucca Mountain disposal system. We recognized and accepted this notion in the preamble to our proposal (70 FR 49058), and argued that in light of the uncertainty involved in making a determination of wetter and drier climate scenarios, a more effective and reasonable way of considering how climate will affect the disposal system was through the use of a stylized scenario for the climatological FEP. We followed the direction of the NAS in proposing this scenario. NAS stated the following with regard to climate change at Yucca Mountain:

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

(NAS Report pp. 77–78)

NAS also stated that it is impossible to know with any certainty when transitions to glacial climate would occur, but noted that it surely will occur over the next 1 million years. (NAS Report p. 91) The committee suggested that a doubling of the effective wetness may be sufficient for a scenario that encompasses climate change over the compliance period of 1 million years (discussed in greater detail below). We agree with that premise, and also believe that uncertainties about predicting the precise timing and magnitude of future climatic fluctuations cannot be significantly reduced by additional research into past climatic cycles or modeling of current climate. Therefore, we believe that the stylized scenario NAS proposed is a reasonable indicator of repository performance out to 1 million years.

In an effort to avoid confusion, we will first define some of the terms as we use them in this section, and in the preamble to the final rule. These terms are used in the broad context of the discussion on climate change and how it may affect the disposal system, but it should be remembered that our rule language specifically states that the climate change analysis is limited to the effects of *increased water flow* through the repository (incidental of its path to the repository, which is left to the discretion of the NRC to determine) as a result of climate change. Using the definitions below, we have attempted to trace liquid movement from the atmosphere to the repository.

- Precipitation means any form of water particles, such as frozen water in snow or ice crystals, or liquid water in raindrops or drizzle, that fall from clouds in the atmosphere and reaches the earth's surface.

- Infiltration means the process of water entering the soil at the ground surface and the ensuing movement downward when the water input at the soil surface is adequate. Infiltration becomes *percolation* when water has moved below the depth at which it can be removed (to return to the atmosphere) by evaporation or evapotranspiration. Percolation is also referred to by the NRC as *deep percolation*

(70 FR 53315), and is defined by NRC as the amount of water that is available to reach the repository horizon. We use percolation in the same context as NAS used the term *effective wetness* which they defined as the ratio of precipitation to evapotranspiration. (NAS Report p. 91) NAS was concerned about quantifying the flux of water through the unsaturated zone, which could affect rates of radionuclide release from waste forms, and transport to the water table.

- Seepage means the inflow of ground water moving in fractures or pore spaces of permeable rock to an open space in the rock, such as a drift. Specifically, the amount of percolation flux that enters the drift in a given time period. In this case, seepage refers to the water that flows into the repository, and contributes to the release and transport of radionuclides out of the repository.

Commenters 0105 and 0226 remarked that we had failed to recognize the true ambiguity of climate change. We disagree. We indeed recognized the ambiguous and unpredictable nature of climate change, which is why we proposed to eliminate as much ambiguity as possible by using the NAS suggested stylized scenario focusing upon increased seepage into the repository. We were also concerned about the possibility of over-speculation of climate change (as evidenced by the comments we received) over such extremely long time periods, possibly out to the next 1 million years. The NAS also recognized this fact in its report, stating "Although the typical nature of past climate changes is well known, it is obviously impossible to predict in detail either the nature or the timing of future climate change. This fact adds to the uncertainty of the model predictions." (NAS Report p. 77)

As we stated in the preamble to the proposal (70 FR 49058), we agree with the NAS direction to us and stated that it is not useful to have unconstrained speculation on future climate during the period of geologic stability, because (as we saw in the comments) it is possible to assume any number of scenarios of climate over this large amount of time, and there is very little evidence available to accept or refute most of them. Because it is not possible to predict every situation that could occur over such a long time, we felt that the best course was to construct a climate scenario that results in reasonable rates of water flow into the repository , and allow this scenario to run throughout the period of geologic stability.

To reiterate, we are more concerned about the overall net increases in water flow (seepage) through the repository, and how that may contribute to increased release and transport at the repository. As we stated, we do not believe that it is important to know or predict, with certainty, precisely when climate states with peak precipitation occur during the performance period, because there are too many permutations and uncertainties in trying to project a future set of climate conditions.

For example, Commenter 0298 provided information that the change from the current interglacial period to a cooler, wetter glacial climate may be delayed up to 500,000 years because of anthropogenic insertion of carbon dioxide into the atmosphere. Commenters 0312 and 0314 argued that connections of climate with the El Niño Southern Oscillation (ENSO) cycles, solar variability, increased atmospheric carbon dioxide, and ocean-atmosphere interactions are unclear. Factors influencing the timing of climate cycles, the role and mechanisms of global oceanic circulation, global effects of land use and land surface alterations, and the role of biological processes are yet to be clearly defined in association with climate change. Also, nonlinear responses to small increases in precipitation present great challenges in predicting the behavior of hydrologic systems over long time periods. We agree with the commenters that the uncertainties are too great to make specific, precise predictions about future climate states.

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

We proposed to explicitly require that DOE assume water flow into the repository will increase as a result of climate change. We left it to NRC as the licensing authority to specify the values to be used to represent climate change in estimating water flow. However, we expect that a doubling of today's average seepage beginning at 10,000 years and continuing through the period of geologic stability would provide a reasonable scenario, given NAS's statements regarding potential effects on recharge. (NAS Report pp. 91-92) NRC could also use the range of projected precipitation values for different climate states and specify a reasonable long-term average precipitation based on the duration of each climate state over the period of geologic stability. We believe that either approach will allow for a reasonable estimate of how water will impact the site without subjecting the assessments to speculative assumptions that may well be irresolvable, while providing a reasonable indicator of disposal system compliance. NRC might choose to express the ground-water flow effects directly as infiltration, percolation or seepage rates or other representative parameters, avoiding the necessity of translating precipitation and other climate-related parameters

There are too many uncertainties in trying to project a future set of climate conditions, and it is difficult to place specific times on when discrete pulses of precipitation should be injected into the modeling. (NAS Report p. 77) Instead, we believe that it is reasonable to assume an average increase in seepage into the repository over the entire time from 10,000 years through the period of geologic stability to 1 million years, and to model those consequences. An increase in average seepage throughout the period of geologic stability is a more reasonable approach because it assumes a constant source of water eventually reaching the repository. This scenario need not be dominated by highs or lows in precipitation over the time period and does not require speculation about the exact timing or transient effects of shifts in climate. Rather, setting a constant value somewhat higher than today's average annual rainfall (large enough to account for the increase in seepage into the repository) and extending it out through the period of geologic stability would account for the greater potential for available fluids at the time of the failure of the waste packages. We believe that this approach provides a reasonable test of the repository conditions throughout the period of geologic stability, and will give a more conservative estimate of potential fluid flow, as well as potential for migration of radionuclides out of the repository.

Our line of argument in the preamble was to have DOE determine how the disposal system responds to the effects of a permanent *increase* in water flow through the repository as a result of climate change. We believe that the idea of increased water flow was lost on many commenters, who stated that they were opposed to our use of an *unchanged* seepage rate, the connotation being that the climate parameters would remain the same as we see today. We did not propose to use the current climate state at Yucca Mountain, nor did we propose modeling with *less* water flow into the repository. We attempted to follow the direction that NAS gave us. This could affect the rates of radionuclide release from the waste and transport to the water table, although the location of the repository in the subsurface would provide a time lag for climate change effects. For this reason we require a permanent increase of water flow through the repository, in contrast to using unpredictable cycles of precipitation/infiltration that, at low points, would be similar to the infiltration found in the area today, in order to maximize the potential for effects to be seen.

Commenter 0209 stated that future climate at Yucca Mountain is important because it strongly influences the rate at which waste containers and other metal barriers corrode. We agree in principle with the comment. The availability of water to contact the waste packages is an important initiator for corrosion processes. However, we also recognize that corrosion is also correlated with respect to temperature in the repository. We have considered the effects of climate by requiring an increase in the amount of water flow into the repository. This will allow a constant, steady migration of water into the repository. This in turn will allow water to constantly be available, and should produce a conservative, yet reasonable rate of degradation for the engineered barriers in the repository.

Commenter 0258 suggested that we should not equate climate situations in Europe with the Yucca Mountain area, because the two situations will be different. Certain European facilities may be covered with glaciers, while Yucca Mountain will only see increased precipitation. We agree, and our proposed future climate requirements were in agreement with the commenter; namely an increase in water flow into the repository. We are more concerned with how the repository system responds to a larger influx of moisture, and we have resolved this by recommending that the effective moisture be increased. We believe that this represents a cautious, yet reasonable approach in attempting to project disposal system response to climate change.

Commenters 0174 and 0302 asked why we did not modify the behavior and characteristics of future populations, even though we acknowledged that some circumstances may be different with increased infiltration (e.g., higher release rate of radionuclides from the repository into the ground water). We followed the advice of NAS regarding the possible changes in characteristics of society in the future. NAS described several changes that climate change could impart on the disposal system. One of the changes might be a shift in the distribution and activities of human populations. (NAS Report p. 92) A cooler, wetter climate may provide a more hospitable environment, increasing the population, and (some have argued) possibly changing the parameters we have outlined for future societies. NAS also noted, “there is no simple relation between future climatic conditions and future population.” (NAS Report p. 92) We acknowledged this situation in the preamble to the proposal (70 FR 49059), and chose not to modify any conditions for future populations, because we continue to believe that the proposed lifestyle we chose is conservative, but similar to that of most people living in Amargosa Valley today.

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Section 9 Intergenerational Equity

Issue A: General comments regarding intergenerational equity

1. The proposal assumes it is ethically permissible to expose future generations to radiation levels far higher than would be tolerated today. (Comment 0103-4)

2. The standard will burden future generations of Nevadans with significantly higher radiation exposure than ourselves. (Comments 0126-1 and 0127-1)

3. The EPA is dismissing the need for generational equity and is instead claiming that future generations should face some of the highest radiations doses in the world. (Comments 0130-1 and 0195-5)

4. The attempt to bifurcate this radiation standard throws out all attempts at generational equity and puts future generations at tremendous risk. (Comment 0132-1)

5. The increased dose limit after 10,000 years is a complete violation of principles of inter-generational equity, as well as public health and environmental protection. (Comment 0133-2, 0135-2, 0137-2, 0141-2, 0146-2, 0147-2, 0148-2, 0159-2, and 0163-2)

6. You're proposing to allow very high levels of radiation after 10,000 years. I don't think deciding that after 10,000 years we don't need to worry about radiation on future generations is a good idea. I don't want them exposed to high levels of radiation any more than I do my grandchildren. (Comment 0136-1)

7. It is irresponsible fiscally, environmentally, and inter-generationally. The land and its surroundings would be rendered unfit for habitation for a period in excess of the number of years homo sapiens have walked the earth. (Comment 0142-2)

8. It is unethical to expose future generations to higher levels of radiation than current generations. Yet, EPA throws this fundamental principle out by applying a standard that is 70 times weaker for future generations. EPA is proposing to allow an action that will kill and harm people for hundreds of thousands of years, people who had no say in the decision nor received any benefit from it. (Comments 0145-4, 0293-7, and 0302-9)

9. People are our prime natural resource. I find transference of exposure to our toxic garbage to future generations to be ethically repulsive! Do you remember the courageous citizens of West Valley? They decided prior to the partial clean-up that they wanted to have now the maximum allowable exposures, rather than pass these exposures on to future generations. You are out of touch with the spirit of the American people. (Comments 0151-1 and 0169-1)

10. EPA has correctly noted that the reasonable goal is to assure that current activities would not be expected to create catastrophic or irreversible harm. This is a reasonable and appropriate goal that we should aspire to for all human activities, but do not. Certainly, the 350 mrem per year limit EPA will apply to Yucca Mountain, which is in fact a stricter limit than we now permit for indoor radon, falls well below this threshold. (Comment 0174-4)

11. This is a complete violation of principles of intergenerational equity, as well as public health and environmental protection. (Comment 0175 -2, 0177-2)

12. What will we tell future generations when they ask why a huge portion of the southwestern United States is nearly uninhabitable? (Comment 0199–2)

13. Unfortunately, contrary to the unequivocal directions provided by the D.C. Circuit Court of Appeals, the current proposed radiation standard fails to adequately protect health and safety. Although proponents of the new standard argue that this rule actually provides health and safety guarantees for an unprecedented one million years, the standard, in reality, in fact, permits future generations of Nevadans to be intentionally subjected to radiation levels prohibited everywhere, both nationally and internationally. (Comment 0209.6-2)

14. Rather than promulgating a revised radiation protection standard more stringent than the previous standard in the interest of public health and safety, EPA actually relaxes the standard. Even though EPA previously determined that citizens should be exposed to no more than 15 millirems per year, the new proposed standard would permit exposures of between 350 and 1,050 millirems per year, depending on whether median or mean exposures are considered. This relaxation of protection for citizens living close to the proposed repository amounts to the least stringent radiation protection standard in the world. (Comment 0209.6-3)

15. On behalf of the Nevada Department of Justice, I respectfully urge EPA to rescind its proposed rule. In the interest of protecting public health and safety, it is imperative that EPA design a standard truly capable of protecting present and future generations of Nevadans from unacceptable radiation levels when the radiation risks are at their peak. (Comment 0209.6-8)

16. If adopted, the proposed Yucca Mountain standard will permit countless generations of Nevadans to be intentionally exposed to levels of radiation that would never be tolerated anywhere else, either in the United States or internationally. (Comment 0209.7-3)

17. DOE tells the nation not to worry, these levels of radiation won't be experienced for 200,000, 300,000 years. But the proposed standard will be set today to accommodate that level of radiation. Even if it were moral to argue that it's okay to delay the risk to unborn generations of the future, the legal allowance will be in place to accept and institutionalize that level of risk today. And it is certainly not moral to delay the risk.

Under the proposed rule, these doses would be permitted to occur generation after generation for hundreds of generations. It's hard to conceive of a proposed environmental regulation or action that raises such serious questions of generational immorality.

EPA is proposing to commit an action that will kill people for hundreds of thousands of years, people who have no say in the decision nor received any support or benefit from it. They bear only the cost, a huge human cost. (Comment 0209.12-4)

18. But all of the people you quote say things like target, qualitative, benchmark -- remember all of those kinds of -- vision. There's all of those words you used to say that when we go out beyond, we've got to take a somewhat different logic. Okay, do it. But just because you do that means that you can say any standard is the most morally -- the most biologically recommended, but we don't know how to ascertain it. In other words, you can recommend beyond, why recommend 350 when you can recommend 15? (Comment 0209.16-2)

19. So when you guys look at these things, you need to really think about what you're doing because I have to look after generations that come behind me. I don't look at things for myself. I'm here. I'll be gone in a few years, but there's generations that are coming behind me that I have to look for. I have to protect. And you people need to do the same thing. The government needs to think about what they're doing. And they really need to protect the future generations because I hate to see my people be obliterated from this Earth. And if that happens that is not something that we made. It's something that non-Indians have done to us. (Comment 0209.17-3)

20. Given the exceedingly poor record of radioactive contamination management at other sites since World War II, the message is clear that the federal government and the U.S. Congress considers the Southwestern U.S. and Northwestern Mexico to be expendable. The irreversible effects of the contamination from 177,000 tons of high-level toxicity or lethal radioactive material won't be felt for a few generations, so current politicians feel safe from being held accountable during their own lifetime. As long as their present crop of local voters aren't freezing in the dark or at immediate risk of deadly radioactive contamination themselves, what do they care for the future residents of Nevada, Arizona, California and Mexico, or for the Pacific Ocean? The radioactive contamination from Yucca Mountain cannot be permanently contained, and we all know it. There is no manmade structure that has ever stood as long as the half-life of Plutonium-239. Yucca Mountain will eventually render an enormous area of this country permanently unfit for habitation. So the message is simple: Millions of Southwesterners and our future generations are expendable. (Comment 0211.3-3)

21. I'm here today to show you who you will be hurting. It is not your problem, and it is not his problem, but it is our problem. It is my children and my children's children who will be affected by this inhumane radiation standard. (Comment 0211.4-1)

22. Your disregard for future generations is inexcusable and irresponsible. You must go back and set the standards to truly protect us. (Comment 0213–1)

23. Mountain is in the cost of a system that is more expensive than necessary to provide adequate protection. In the case of the Yucca Mountain repository, the value to society is so high that the cost of the design is not a substantial issue. Another impact .. is the imposition of an extraordinarily difficult burden of proof on the licensee and an associated delay in opening the repository. Delay has two effects. First, it increases the hazard from radioactive waste that could be more safely stored in a geologic repository. Second, the unavailability of a licensed repository is the principal barrier to the expansion of nuclear power. A major expansion of nuclear power may represent the only feasible approach to transition from a fossil-fuel based economy to a sustainable energy economy that would not lead to a substantial reduction in our standard of living. The longer that transition is delayed, the greater the financial impact on world economies and the global environmental impact from the emission of greenhouse gases. (Comment 0215-2)

24. Despite the new amendments, I do not believe there are sufficient safeguards in place to protect future generations. (Comment 0218-1)

25. The plan inexcusably calls for the relaxing of the radiation standards over time, putting future generations and the fragile web of life at risk. I believe that a weak or minimal principle of justice is not an acceptable principle to apply to any generation, now or in the future. To discount the value of future generations and knowingly allow increased exposure to radiation and potentially increased cancer rates is wrong, plain and simple. (Comment 0221–1)

26. EPA's failure of explanation stands in sharp contrast to its prior Yucca rule, in which EPA clearly articulated the "fundamental principle of intergenerational equity" that "we should not knowingly impose burdens on future generations we ourselves are not willing to assume." 66 FR 32107. EPA does not explain whether it is abandoning this "fundamental principle" now, or how its proposed rule, which quite clearly does impose additional burdens on future generations, could possibly be reconciled with this "fundamental principle." (Comment 0226-61)

27. EPA's intergenerational equity rationale, to the extent that it exists, fails for an important additional reason: EPA has never explained how a lax second-tier standard benefits anyone. While EPA's entire theory appears to be that providing future generations with the same protection we provide ourselves today would impose burdens upon present generations, EPA has not stated what those burdens are. Indeed, it has identified *no* possible trade-off that will result in any present harm if current levels of acceptable risk are sustained after 10,000 years. If EPA is implicitly suggesting that the benefit to this generation from the lax future standard is the present success of Yucca Mountain, it strays into impermissible territory, for EPA has no authority to pre-determine that the Yucca Mountain repository should be built regardless of health and safety threats. With the NWPA and EnPA, Congress gave EPA one duty—to set the health-based radiation standard for Yucca. It did not call upon EPA to evaluate whether the success of the nation's repository program at Yucca today can justify a weaker standard of care for future generations. EnPA section 801(a) (1) requires EPA to promulgate a "public health and safety standard for protection of the public from releases [from Yucca]." Section 801(a) (2)

refers to this standard as "health-based." A "public health and safety" or "health based" standard must be based on a consideration of what is an acceptable level of risk; it may not be based on economic costs or a balancing of costs and benefits. *National Cottonseed Products Ass'n v. Brock*, 825 F.2d 482 (D.C. Cir. 1987) (citing *American Textile Manufacturers Ins't v. Donovan*, 452 U.S. 490 (1981)); *NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987); *Union of Concerned Scientists v. NRC*, 824 F.2d 108 (D.C. Cir. 1987). Moreover, Nevada disputes whether Yucca Mountain would actually provide any benefit to present generations. As Nevada has pointed out in detailed past comments, both the site itself and, potentially more importantly, the massive project of transporting 70,000 tons of nuclear waste across the country to the site pose enormous risks to present generations. *See* Nevada, *Comments on Department of Energy's Draft EIS*. Similarly, a lax second-tier standard provides significantly reduced protection to generations living within the 10,000-year period. If the repository is licensed on the *assumption* that peak dose will occur after 10,000 years, and that assumption proves wrong, the first-tier standard will provide no protection to the people who bear the brunt of the repository's impacts. Instead, those generations, whom EPA has never suggested should receive the same minimal protection it would accord to generations in the post- 10,000-year period, would be put at greater risk by EPA's decision to rationalize a lax second-tier standard on the theory that later harms are somehow more permissible. (Comment 0226-67)

28. Permanent disposal of nuclear waste at Yucca Mountain is not a matter of balancing risks to near-term generations against risks to far-future generations. Designing disposal systems that would minimize harm to far future generations will also minimize the risks to ourselves and our descendents over the next 10,000 years. The double standard proposed for Yucca Mountain constitutes an admission that we do not yet know how to do this. (Comment 0267-8)

29. The proposed 40 CFR 197 provides a level of protection for the first 10,000 years after the repository is closed, and less for those people after 10,000 years. In fact, the all pathway standard is weakened by a factor of approximately 24, and the groundwater standard is eliminated. Why should people living after 10,000 years be afforded less protection? This is a blatant disregard to future generations and an irresponsible policy. The 15 mrem/yr dose limit should be imposed through the period of peak risk, which is more like 300,000 years (according to DOE’s calculations), and the Safe Drinking Water Standard should also extend through this period. (Comments 0268-1, 0289-2, and 0328-1)

30. There is no justification for EPA using a 350 millirem standard at Yucca Mountain for the time period after 10,000 years. We strongly beleive that we must plan now to protect all our future descendants as well as we want to be protected today. (Comment 0274-1)

31. EPA's proposed regualtions should NOT be adopted and are contrary to both law and policy. The proposed standards fail to protect future generations and instead DUMP the legacy of todays idiocy onto the citizens of tomorrow. EPA proposes to provide the DUMP the benefit of the doubt that it is safe unless others prove it harmful EPA does this by biasing the analysis based oin uncertainty in favor of releases rather than in toward protection of individuals and the environment. This is both unconsionable and illegal. EPA

should instead adopt a standard that is unifrom through time as propsed by Nevada, that includes groundwater protection, that presumes loss of institutiional control, that presumes unrestricted use of all land save the repository itself. (Comment 0275-2)

32. It should be pointed out that these huge doses proposed would not be for a single point in time but would likely extends for hundreds of generations. People would be getting doses that would result in something on the order of 1 out of every 36 of them, or worse, getting cancer, from wastes produced millennia before them, based on decisions about which they had no say. This would be a form of intergenerational immorality on a scale not seen before in human history. (Comment 0296-5)

33. Furthermore, [350 mrem/yr] is not a dose that occurs for a moment and then recedes to far lower levels. Under the EPA proposed rule, these doses would be permitted to occur generation after generation, for hundreds and thousands of generations. For EPA to recommend such high levels of radiation exposure to generations in the distant future is a complete reversal of progress in preventing human exposure to ionizing radiation. (Comment 0301-7)

34. EPA's proposal for a two-tiered radiation protection standard and two different methods for assessing regulatory compliance is not only scientifically questionable, it is also unethical and a gross violation of current EPA regulations (and internationally accepted public health norms) that guarantee all individuals an equal protection against all radiation exposure above the legal limit. Rather than providing better protection for future generations, the new EPA rule sanctions a 2,300 percent higher exposure limit for individuals living in the period beyond 10,000 years than what is permitted for individuals in the first 10,000 years. Future generations, who had no part in creating the deadly nuclear waste, are permitted to be poisoned without their consent under the proposed EPA rules. (Comment 0301-8)

35. Intergenerational equity has been the foundation of U.S. and international public health and safety laws. Yet, in its draft rule, EPA throws this fundamental principle out by applying a standard that is more than 23 times weaker for hundreds of future generations. (Comment 0302-7)

36. According to science ethicist Dr. Kristin Shrader-Frechette in her recent article in *Science and Engineering Ethics*, "E.P.A.'s double radiation standards for different generations…suggest that we merit more protection than our descendants. Yet we, not they, profit from nuclear power plants that produce the radioactive waste." (Comment 0302-10)

37. Do not assume that future generations will develop coping mechanisms to deal with liabilities we have yet to find a solution for, such as the disposal of nuclear power reactor waste. The EPA and other agencies are now, routinely, employing long-term "Institutional Control" regulatory provisions to pass on massive liabilities to future generations. In the case of DOE's nuclear explosives testing grounds, at the Nevada Test Site (NTS), one remediation option was estimated to cost $7.29 trillion.* Due to economic and other

impracticalities the Institutional Control option was chosen instead of actual cleanup. (Comment 0309-5)

38. On page 49027, column 3, EPA points to “site characterization studies, laboratory testing, and expert judgment” as the analytical basis for the range of expected parameter values. But EPA must keep in mind that the falsification of data, the use of uncalibrated instruments, as well as documented corruption amongst the so-called “experts” on the Yucca Mountain Project has thrown Yucca's scientific and technical bases into extreme doubt. (Comment 0324-25)

39. We who are alive today have a species responsibility toward those who follow us, to provide protection from the residues of our radioactive waste-generating practices. EPA must advise NRC to require DOE to do far better at designing and carrying out high level waste isolation, and of assuring long-term isolation of the high-level wastes which NRC and the DOE have heedlessly allowed the U.S. military and commercial nuclear industries to produce. (Comment 0331-4)

40. EPA's proposed radiation standard is the least protective radiation standard in the world and is based on an assumption that it is permissible to expose future generations to radiation levels far higher than what we would tolerate today. (Comment 0341-10)

41. The EPA is endangering future generations. I pray that you will make better decisions. (Comment 0343-3)

42. I object to your recent issuing of standards for radiation protection for the Yucca Mountain Project in Nevada. Please consider the well-being of our future generations. (Comment 0346-1)

43. [T]he 350 mrem/yr proposed by EPA represents an annual individual risk within the range of annual individual risks associated with other EPA and NRC regulations that were identified in the Committee report (Table 2.4 on page 50) as starting points for discussions of risks. These risks range from greater than 10-4 to less than 10-6 and represent approximate dose levels ranging from a few millirem to nearly a rem. It should be noted that none of these other regulations apply for such a long period of time, so there is no directly comparable precedent for how to apply any concept of intergenerational equity at the time of peak dose. (Comment 0352-23)

44. The attempt to bifurcate the radiation standard throws out all attempts at generational equity and puts future generations at tremendous risk. (Comment 0354-2)

45. The proposal would protect people for the first 10,000 years to currently applied standards of protection, but would then doom future generations after that time to a 1 in 36 cancer rate (or even worse, up to a 100% cancer rate, due to EPA mathematical manipulation), and a 1 in 72 fatal cancer rate (or even worse). Such proposed cancer rates and fatal cancer rates are horrifying, and EPA must withdraw such an unacceptable

proposal. This is a complete violation of principles of inter-generational equity, as well as public health and environmental protection. (Comment 0355-1)

46. The point regarding future generations is here we are saying that we have standards for us for 25 millirem today from a single nuclear facility. And we're saying we're going to get the benefits and we're going to protect ourselves more than we're going to protect future generations who are going to get none of the benefits. (Comment 0368.3-5)

Response to Issue A:

We received extensive comment on our proposal from the perspective of its potential impact on far-future generations as compared to the current or next few generations. Commenters on this point questioned our reasoning behind proposing a higher dose standard for the far future, and disagreed with our interpretation of literature on the subject. Ultimately, most commenters expressed the view that there is no justification for the level of protection to be different from today's level, whether it is 10,000 or 1 million years (or even longer into the future).

We first note that the NAS did not make a specific finding or recommendation with regard to the concept of intergenerational equity. As discussed below, the NAS spoke in general terms to this concept, but it did not make a recommendation that the Agency is obligated to be consistent with. EPA remains committed to the principle of intergenerational equity, which holds (in part) that the risks from a current action should not be greater to future generations than would be acceptable today. A strict reading of this principle initially would lead to the conclusion that the same level of protection must apply at all times, or for as long as the action presents risks. However, we believe that peak dose limits over extremely long times should be viewed as qualitatively different from limits applied at earlier times; in other words, the basis for judgment at different times is not the same. We believe the peak dose standard we are establishing in our final rule appropriately considers this differing basis for judgment and provides the necessary protections for future generations. We are not establishing the proposed 350 mrem/yr level as our final peak dose standard; instead, we are establishing 1 mSv/yr (100 mrem/yr) as the public health and safety standard to apply for the period beyond 10,000 years and up to 1 million years. As discussed in the preamble to the final amendments, the dose level of 100 mrem/yr is well-established as protective of public health, and as such represents a robust standard for public health protection in the extreme far future. International organizations such as ICRP, IAEA, and NEA recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Domestically, both NRC and DOE incorporate the 100 mrem/yr level into their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," Docket No. EPA-HQ-OAR-2005-0083-0407).

In particular, we have tried to understand how the concept of intergenerational equity is viewed when applied to periods up to 1 million years, because only in the context of radioactive waste disposal has there been serious consideration of such time frames. For example, does the idea of "risks no greater than would be acceptable today" take on a different meaning over periods during which human evolutionary change may occur, and the state of society and technology develop in ways not reasonably foreseeable today? Many commenters expressed the view that it does not. However, as we discussed in our proposal, a number of regulatory and scientific bodies suggest that it may be appropriate to relate longer-term standards to background radiation levels, which strictly speaking would be "greater than would be acceptable today" from a waste management practice, but are not routinely considered as a major risk factor in collective and individual decision-making.

The concept of intergenerational equity is of sufficient importance to underlie two of the nine fundamental radioactive waste management safety principles endorsed by IAEA ("The Principles of Radioactive Waste Management," Safety Series 111-F, 1995, in particular Principles 4 and 5, respectively, Docket No. EPA-HQ-OAR-2005-0083-0053, which relate to protection of future generations and burdens on future generations, respectively) and has been incorporated into the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (an international agreement ratified by more than 30 countries, including the U.S., Docket No. EPA-HQ-OAR-2005-0083-0393). We also considered in our proposal documents prepared by the National Academy of Public Administration (NAPA) and Swedish National Council for Nuclear Waste (KASAM) (Docket Nos. EPA-HQ-OAR-2005-0083-0077 and EPA-HQ-OAR-2005-0083-0197, respectively). NAPA is a Congressionally-chartered organization whose purpose is to provide assistance to government in assessing and effectively addressing issues of governance, including future implications of contemplated actions. KASAM was created by the Swedish government in 1985 to provide an independent review of issues related to nuclear waste. The IAEA principles are discussed in Issue B of this section, and the NAPA and KASAM documents are discussed in Issue C.

Commenter 0209.16 accuses us of being "disingenuous" by claiming there is no consensus regarding obligations to future generations. The commenter has misunderstood our statements. We do not question whether there is an obligation to future generations, but we believe there is no consensus regarding the nature of that obligation, for how long it applies, whether it changes over time, or how it can be discharged.[10] Regarding radioactive waste management and geologic disposal, there is general agreement that assurances can be provided that the protections offered will be similar to those acceptable today for periods approximating 10,000 years, which in itself is a very long time (exceeding as it does the entire span of recorded human history). We reached such a judgment in establishing the 15 mrem/yr standard in 40 CFR part 191 (and again in our 2001 rulemaking), based on our conclusions that the capabilities of disposal and modeling technology were sufficient to allow implementation with reasonable expectation for 10,000

[10] NEA reaches similar conclusions: "The design and implementation of a repository involves balancing of risks and responsibilities between generations. The obligations of the present generation toward the future are complex, involving not only issues of safety and protection but also of freedom of choice and of the accompanying burden of responsibility, and of the need to transfer knowledge and resources. Our capacity to deliver these obligations diminishes with distance in time, which complicates the setting of criteria to be used today in order to demonstrate that obligations to the future will be met." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, 2007, p. 25)

years (58 FR 66401, December 20, 1993; 66 FR 32097-32098, June 13, 2001). However, as one considers times in the hundreds of thousands of years and beyond, can similar assurances be offered when, as we believe, the underlying bases for those assurances have fundamentally changed? What form can those assurances take (i.e., can we reasonably make assurances regarding our ability to distinguish among and control incremental radiation exposures over such long times)? Can they provide the same level of confidence? We have selected a standard that is consistent with the public dose limit accepted internationally and nationally, and therefore has a strong basis for protectiveness today. We believe this is a reasonable level of commitment that will protect public health and safety over such long times, given the complexities of the situation and what we see as our responsibility to establish a level of compliance, not a soft target or reference level that could be exceeded for unspecified reasons and by unspecified amounts.

A number of commenters cite the statements of the NAS committee regarding intergenerational equity to support their position that a higher dose level for longer times is contrary both to that principle and the NAS recommendation. We disagree, and have discussed the second point in some detail in other sections of this document (see Section 2, Issue C, for example). Regarding the question of intergenerational equity, we cited the NAS discussion in our proposal (70 FR 49036). In citing NRC and IAEA sources, the NAS wrote (NAS Report pp. 56-57, emphasis added):

> A health-based risk standard could be specified to apply uniformly over time and generations. Such an approach would be consistent with the principle of intergenerational equity that requires that the risks to future generations be no greater than the risks that would be accepted today. Whether to adopt this *or some other expression of the principle of intergenerational equity* is a matter for social judgment.

We generally agree with the NAS statement. A single dose standard applicable at all times would typically be consistent with a close reading of the principle of intergenerational equity. However, NAS clearly acknowledges that "some other" approach could also be consistent with that principle. We believe it is reasonable to conclude that "some other" approach must include situations where it may not be reasonable to apply the same dose standard at all times because of the extremely long compliance period. We believe establishing a peak dose standard for the Yucca Mountain disposal system is a situation in which "some other expression of intergenerational equity" is more appropriate than is applying a single dose standard of 15 mrem/yr throughout the compliance period. The rulemaking process we are following is the accepted way for "social judgment" to be incorporated into regulations.

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

Further, as discussed in more detail in Section 2, Issue C of this document, Robert Fri, who chaired the NAS committee, testified on March 1, 2006 before the Senate Environment and Public Works Committee (Docket No. EPA-HQ-OAR-2005-0083-0380). Mr. Fri provided his personal views on our proposal as it related to the NAS recommendation regarding compliance at the time of peak dose. He expressed the opinion that extending the 15 mrem/yr standard to the time of peak dose, if it were to be judged against the RMEI, "runs the risk of excessive conservatism," although this combination of dose limit and receptor was acceptable at 10,000 years. He noted that one committee member had recommended such an approach combining long time frames with a "deterministic" receptor, which was rejected by the committee (see pp. 100-103 and Appendix D of the NAS Report for this alternative view). The committee had recommended use of a probabilistic critical group, which we believe would have led to lower projected doses than would the RMEI we defined (see Section 2 of this document). Mr. Fri did not offer an opinion on the consistency of our 350 mrem/yr proposal with the NAS recommendation; however, he viewed it as intended to reduce "the risk of excessive conservatism." We believe his testimony can reasonably be interpreted as suggesting that there are circumstances in which applying 15 mrem/yr throughout the 1 million-year compliance period could result in a standard directly contrary to the committee's overall goals, which emphasized the use of "cautious, but reasonable" assumptions and care in the use of "pessimistic scenarios and parameter values." (NAS Report pp. 100 and 79, respectively) In such a case, it must be considered whether such a conclusion would have implications for the appropriate expression of intergenerational equity.

In light of the NAS statements, we have also considered how to identify the appropriate "expression of the principle of intergenerational equity." First, we have considered the nature of the compliance demonstration that DOE is to provide. Over the extended time frames established in our rulemaking, we believe there are significant uncertainties affecting the ability to project doses and make meaningful distinctions among those projections. We also recognize that the capability of the technology used to assess compliance is a factor that has been considered in the setting of public health protection standards (e.g., remediation technologies or contaminant detection limits). As a result, we believe it is appropriate to consider potential exposures in the very far future in a broader context of protectiveness. From these perspectives, the 100 mrem/yr level is comparable to the range of risks represented by domestic and international regulations identified by NAS for EPA to consider, "all of which are consistent with recommendations from authoritative radiation protection bodies". (NAS Report p. 49 and Tables 2-3 and 2-4) The nominal annual risk of fatal cancer associated with 100 mrem/yr, 5.75×10^{-5}, is reasonable when the significantly extended time frames under consideration, with the attendant uncertainties, are taken into account. [11] We have determined that the final peak dose limit is protective of public health and safety and provides a reasonable test of the disposal system for the time frames in question. See also Section 6 of this document for discussion of uncertainties.

[11] The Agency concludes that it is not reasonable to apply its traditional risk-management policies, in which the goal is to constrain lifetime excess cancer risk to between 10^{-4} and 10^{-6}, when establishing a compliance standard applicable for periods longer than 10,000 years and up to 1 million years. The Agency does not believe it is reasonable to view projected doses of 100 mrem/yr in the extreme far future as comparable to doses of 100 mrem/yr incurred today, or even projected to occur within 10,000 years.

Commenter 0352 similarly notes that none of the regulatory precedents considered by NAS in developing its "starting point" for the peak dose (risk) standard applied for periods approaching 1 million years, so there is no basis for drawing comparisons or making conclusions regarding fulfillment of principles of intergenerational equity. Nevertheless, we find that our final standards represent a valid and appropriate expression of intergenerational equity.

Commenter 0226 cites legal precedents in charging that our proposal violated the EnPA direction to establish "public health and safety standards" by not including specific analysis of public health impacts, and argues as well that erroneous assumptions regarding the timing of the peak dose would put people at greater risk within the first 10,000 years. Our final peak dose standard of 100 mrem/yr is consistent with the internationally and nationally accepted public dose limit, and we conclude that the nominal annual risk of fatal cancer from this dose is reasonable and comparable to the range of risks NAS suggested EPA consider, particularly when applied for up to 1 million years. We have determined that this standard will protect public health and safety for up to 1 million years, and have reason to believe that the peak dose standard will also have the effect of constraining projected doses below 15 mrem/yr for the first 10,000 years (see Section 6 of this document). It is NRC's responsibility to evaluate DOE's technical case for compliance with our standards. The legal aspects of the comment are addressed in Section 24, Issue F, of this document.

Section 9 Intergenerational Equity

Issue B: EPA's standards violate IAEA principles of intergenerational equity

1. EPA's proposed rule is similarly suspect in light of the NWPA, which requires protection for future generations. In the NWPA, Congress stated that "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 or future generations." NWPA § 111(a)(7). This Congressional statement supports EPA's erstwhile "fundamental principle" that "we should not knowingly impose burdens on future generations that we ourselves are not willing to assume." 66 FR 32107. But it is irreconcilable with EPA's current proposal to subject future generations to burdens that current generations have never deemed acceptable. Congress's statement is similarly inconsistent with any implication that future generations need not be accorded protection and ethical standing. EPA's proposed rule also violated the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, to which the United States has agreed. That convention provides that contracting parties shall take appropriate steps to "strive to avoid actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation." Section 101 of the National Environmental Policy Act has similar language in its declaration of a national environmental policy. The EPA rule reflects no such effort. It instead is predicated on an unlawful repudiation of this principle, for it would *purposefully* "impose reasonably predictable impacts on future generations greater than those permitted for the current generation." (Comment 0226-62)

2. The EPA rule is also contrary to one of the key IAEA "Principles of Radioactive Waste Management" (IAEA 1995), agreed to by the United States, that "radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today." EPA offers no reason why the United States should change its policy now with respect to Yucca and Nevadans. Nor does it have the authority to set or change U.S. policy in this regard; its sole duty here was to set a health-based standard that would protect this *and* future generations. (Comment 0226-63)

3. Relaxation of radiation protection standards for future generations who will not benefit from nuclear power plants that produced the waste is contrary to basic ethics, cost-benefit analysis principles, and internationally accepted radiation protection guidelines, including for radioactive waste. These widely accepted guidelines include those by the International Atomic Energy Agency and the International Commission on Radiological Protection and radiation protection authorities in other countries. This has been recognized by scientific bodies, including the National Academy and in the past by the EPA. (Comment 0314.1-1)

4. EPA does not explain how this two-tiered standard is consistent with this widely accepted "intergenerational equity" principle, particularly since the 350-millirems-per-year standard greatly exceeds the acceptable radiation dose limit (10 to 30 millirems per year) described in the NAS report which is based upon a general consensus in the scientific community for the exposure limit allocated to high-level waste disposal. The NAS 1995 report referred to the principle of "intergenerational equity", which states that the risks to future generations should be no greater than the risks that would be accepted today. We recommend that EPA adopt this principle of "intergenerational equity" by establishing a radiation protection standard that applies uniformly over time and subsequent generations, i.e., would not increase from 15 to 350 millirems per year after 10,000 years, as EPA proposes in their revised standards. EPA in its prior 2001 standard explained the "fundamental principle of intergenerational equity" by stating that "we should not knowingly impose burdens on future generations we ourselves are not willing to assume.' 66 Fed. Reg. at 32107. EPA does not explain how the proposed rule, which imposes higher risks on future generations by raising the limit from 15 millirem per year to 350 miilirems per year, is consistent with this principle. (Comment 0326-1)

5. The level of protection of 350 mrem/yr is consistent with the general principle of intergenerational equity…[which] has two aspects. These aspects are that the current generation should (1) strive to avoid actions that impose reasonably predictable impacts on future generations greater than those acceptable today and (2) act in a manner that avoids the imposition of undue burdens on future generations. The current generation must devise and implement a safe and workable means of disposition of radioactive waste that does not simply defer the problem to future descendants, or impose unacceptable risks on them. Selecting a level that is toward the upper end of the risks that are considered acceptable today is an appropriate way to ensure intergenerational equity by reducing the risk that the inherent and almost unavoidable conservatisms in a repository performance assessment might lead to rejection of a repository that would provide adequate protection to the public today, or in the far distant future. At the extreme, it would be possible to select a level of

protection so low that it would undercut the national policy of geologic disposal and thus prevent the current generation from fulfilling its responsibilities to take care of the waste it has generated. (Comment 0352-25)

6. Finally, but most importantly, this proposed standard is immoral. It has long been resolved both in the United States and internationally that it is unethical to expose future generations to much higher levels of radiation than current generations. EPA stated as much in its final rule for its first radiation standard for Yucca Mountain. Yet EPA's proposed rule blatantly tramples on the principle of intergenerational equity. Equal protection under the law is a cherished American principle. EPA's proposal violates this protecting certain generations to one standard but other generations to a much weaker standard. (Comments 0368.13-5 and 0368.6-7)

Response to Issue B:

Several comments referred to principles of intergenerational equity as set forth by the International Atomic Energy Agency (IAEA), cited by NAS in its discussion of intergenerational equity. (NAS Report pp. 56-57) Many of the more general comments in Issue A of this section expressed similar positions, but did not refer to the IAEA principles.

In 1994, the IAEA defined intergenerational equity in two of its principles of radioactive waste management:[12]

Principle 4: Radioactive waste shall be managed in such a way as to assure that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today.

Principle 5: Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

In considering how to establish public health protection standards for periods up to 1 million years, these principles form the basis for judgments as to how well those standards conform to the overall objectives of intergenerational equity.[13] We will focus on Principle 4 (impacts on future generations), as the emphasis in Principle 5 (undue burdens) is to encourage the current generation to take steps to manage the waste, rather than leave decisions to succeeding generations, although there is recognition that succeeding generations should have some degree of flexibility in carrying out the plans of the current generation (to the extent that burdens may relate to environmental impacts, such as the need to remediate ground-water contamination, they would essentially be addressed under

[12] "The Principles of Radioactive Waste Management," Safety Series 111-F, 1995 (Docket No. EPA-HQ-OAR-2005-0083-0053)
[13] The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (an international agreement ratified by more than 30 countries, including the U.S.) includes similar statements in its General Safety Requirements: "(vi) strive to avoid actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation"; and "(vii) aim to avoid imposing undue burdens on future generations." (Chapter 3, Article 11) (Docket No. EPA-HQ-OAR-2005-0083-0393)

Principle 4).[14] The current policy to pursue disposal would thus be consistent with the intent of Principle 5. However, such considerations are outside the scope of our statutory responsibility for this rulemaking. Our role is limited to the development of health and safety standards for a specific course of action, geologic disposal at Yucca Mountain. We are not making judgments regarding the appropriateness of geologic disposal as a waste management policy in general, or the suitability of the Yucca Mountain site in particular.[15]

A strict reading of Principle 4 initially would lead to the conclusion that the same level of protection must apply at all times, or for as long as the action presents risks. Many commenters encouraged this interpretation. However, we have noted the typical practice internationally, which is to establish a firm compliance standard for an initial period, then to view dose projections as more qualitative indicators at longer times, without a firm compliance requirement (see the preamble to the final amendments).[16] Perhaps, though, this is an accepted interpretation of Principle 4, because the initial compliance level is often used as a reference or goal for the longer-term projections, suggesting that the intent is to continue to use the initial compliance level as a guideline for decision-making.[17] If so, we must consider 1) whether an approach specifying a different level of protection as a compliance standard for the far future can also be consistent with Principle 4 and 2) if so, what role considerations of intergenerational equity play in determining that longer-term level of protection.

Because IAEA has defined the basic obligation to future generations from radioactive waste management, we are using it as the primary reference point for judging consistency with those obligations. A key question is the meaning of the term "predicted impacts" in Principle 4. We have cited IAEA documents to the effect that projected doses for periods

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[14] "This principle is based on the ethical consideration that the generations that receive the benefit of a practice should bear the responsibility to manage the waste. Limited actions, however, may be passed to succeeding generations, for example, the continuation of institutional control, if needed, over a disposal facility." (Paragraph 317); "The management of radioactive waste should, to the extent possible, not rely on long term institutional arrangements or actions as a necessary safety feature, although future generations may decide to utilize such arrangements, for example to monitor radioactive waste repositories or retrieve radioactive waste after closure has been effected." (Paragraph 320)

[15] Similarly, we have no basis to conclude that the near-term consequences of not licensing the Yucca Mountain repository are so dire that the safety of future generations can be compromised, or that nuclear power should or should not be pursued. The question of waste retrievability, which may require balancing the need for complete containment and isolation of the waste with the need to allow future generations to implement alternative policy decisions, also does not affect our disposal standards. The overall framework supporting geologic disposal as the national policy was established by Congress, and it is the responsibility of Congress to weigh the factors affecting the urgency or workability of that policy, and to identify alternative methods for managing wastes, if necessary. Congress thus has the responsibility to ensure that future generations are not overly burdened by current policies and actions, but are, in fact, provided the necessary resources to conclude or improve on those actions (and then are able, in turn, to meet their obligations to the future).

[16] The UK is an exception to this practice, as it has established a risk "target" that applies throughout the life of the facility. ("Disposal Facilities on Land for Low and Intermediate Level Wastes: Guidance on Requirements for Authorisation")

[17] In the French standard III.2.f, "Guidelines for Geologic Disposal," for the initial period, a level of 25 mrem/yr "determines the acceptability of the dose." At later times, when dose projections are supplemented by more qualitative arguments for safety, it is considered a "reference level."

longer than 10,000 years should increasingly be considered "illustrative" or "indicative" and that the "aim of the assessment is not to predict the actual performance of the disposal system."[18] However, it may be argued that the cited documents are lower-level technical guidance documents, and not reflective of the views of the IAEA as a whole. The most recent IAEA publication of interest, however, is the 2006 Safety Requirements document on "Geological Disposal of Radioactive Waste" (WS-R-4, Docket No. EPA-HQ-OAR-2005-0383). Safety Requirements documents are the highest-level IAEA publications on specific topics, and are consensus documents of Member States. As such, they can be legitimately viewed as representing the positions of the IAEA and wholly consistent with its principles of radioactive waste management, including Principle 4.

On the predictive capability of dose assessments, WS-R-4 states: "It is recognized that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Nevertheless, estimates of doses and risks for long time periods can be made and used as indicators for comparison with the safety criteria."[19] (Section A.3) This indicates that, while they may not be viewed as "predictions," dose projections can provide useful information in relation to the safety criteria for "long time periods."

However, "an indication that calculated doses could, in some unlikely circumstances, exceed the dose constraint need not necessarily result in rejection of a safety case. In very long timeframes, radioactive decay will reduce the hazard associated with the geological disposal facility; however, uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases…Care has to be exercised in applying the criteria for periods beyond the time where the uncertainties become so large that the criteria may no longer serve as a basis for decision making." (Section A.7) This indicates that at some point comparison with the safety criteria does not, and perhaps should not, establish a basis for judgments about facility safety.

WS-R-4 does not specify "the time where uncertainties become so large." However, other references in the document provide a reasonable basis for characterizing such terms as "very long timeframes" and "long time periods." WS-R-4 makes the following specific references to time periods associated with disposal (emphases added):

> 3.30 The containment of the radionuclides in the waste form and packaging over an *initial period of hundreds to thousands of years* ensures that the majority of

[18] "Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," TECDOC-767, 1994, Docket No. EPA-HQ-OAR-2005-0083-0044; and "Regulatory Decision Making in the Presence of Uncertainty in the Context of Long Lived Radioactive Wastes," TECDOC-975, 1997, Docket No. EPA-HQ-OAR-2005-0083-0045, respectively. We also note the NAS statement that "The results of compliance analysis should not, however, be considered as accurate predictions of the expected behavior of a geologic repository." (NAS Report p. 71)

[19] The "safety criteria" include an overall dose limit of 1 mSv/yr (100 mrem/yr) and a source-specific constraint (i.e., for a single disposal facility) of no more than 0.3 mSv/yr (30 mrem/yr). (Section 2.12)

shorter lived radionuclides decay in situ (Requirements concerning containment);

3.32 The geological disposal facility shall be sited in a geological formation and at a depth that provide isolation of the waste from the biosphere and from humans over the long term, *for at least several thousand years*, with account taken of both the natural evolution of the geological disposal system and events that could disturb the facility (Requirements for isolation of waste);

3.35 Over time periods of *several thousand years or more*, the migration of a fraction of the longer lived and more mobile radionuclides from the waste in a geological disposal facility may be inevitable (Requirements for isolation of waste).

We believe it is reasonable to summarize the IAEA's position as follows:

- For "at least" several thousand years ("the long term," which may perhaps extend to 10,000 years), the waste should be isolated from the biosphere and humans;
- Releases of radionuclides are inevitable, perhaps beginning late in the initial "long-term" period;
- During this initial "long-term" period, the dose constraint should not be exceeded except in "unlikely circumstances" (i.e., low-probability scenarios);
- In "very long timeframes" (tens to hundreds of thousands of years), the dose constraint may be exceeded in other than low-probability situations without causing rejection of the safety case;
- At these times, the safety criteria applicable during the initial "long-term" period may no longer be an appropriate basis for decision making;
- Projected doses that exceed the dose constraint may be of a magnitude similar to doses from natural sources of radiation;
- At some point beyond about 10,000 years, possibly as long as 1 million years, comparison of projected doses with the safety criteria cannot provide useful information.

Logically, if at times longer than about 10,000 years, projected doses that exceed the initial dose constraint are not indicative of unacceptable performance and can still be consistent with principles of intergenerational equity, it follows that a longer-term dose constraint (representing a level not to be exceeded) can be higher than the initial constraint without violating those same principles.

We find a similar position expressed by the ICRP: "The dose/risk constraints should increasingly be considered as reference values for the time periods farther into the future…transgressions of constraints do not necessarily oblige rejection of a proposed safety case, merely because their value is estimated to be exceeded…*This must not be misinterpreted as a reduction in the protection of future generations and, hence, a contradiction with the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results*." (Publication 81, Paragraph 77, Docket No. EPA-HQ-OAR-2005-0083-0417, emphasis added)

In conclusion, EPA remains committed to the principles of intergenerational equity. However, we do not interpret these principles as requiring that the same compliance standard must apply at all times (and, in particular, not at times in the extreme far future, such as we are addressing in the amendments to 40 CFR part 197), and believe the preceding discussion demonstrates that such a strict interpretation does not necessarily comport with guidance from the very organizations that have largely defined these principles as they apply to geologic disposal. We therefore conclude from this discussion that having multiple dose standards applicable over different time periods is not *a priori* inconsistent with the principles of intergenerational equity as set forth by IAEA. In addition, the reasons stressed by IAEA and ICRP for viewing projections in the far future as qualitatively different from relatively short-term projections are consistent with the concerns we emphasized in limiting the compliance period to 10,000 years in our 2001 rule. We believe the approach we are adopting today, incorporating an initial dose standard for the initial 10,000 years, with a separate standard applicable beyond that time and up to 1 million years, is valid and comports with the principle of intergenerational equity.

Section 9 Intergenerational Equity

Issue C: NAPA and KASAM reports

1. I want to focus on intergenerational equity. One of you made the statement that you -- that the document, which we've been studying closely, founds itself, bases itself on the best experts in the world. That's not true. That's not true at all.

It is true that in the field of environmental ethics, you will find controversy about what kinds of obligations do we have toward future generations. And there are few who say we couldn't have any because we don't even know who they could be. They may even be so like ourselves, these folks argue, that we wouldn't know how to obligate ourselves or not to where they may be very unlike ourselves. And then on what ground could you have an obligation to even know what they're talking about? That's one school of thought. It's a very small school of thought.

If you'd like to corroborate the statement that I just made, you cite the National Academy of Public Administrators, Reference 1, Reference 2, Reference 3. Go look at Reference 3, which is the -- oh, no, Reference 1 in that book is the entertainer bibliography. If you go to the first section, it's called Intergenerational Equity or Environmental Ethics -- one or the other. Anyway, that's where all that stuff is.

And you'll see there a paragraph or so of summary of about 125 articles and books in the field regarding this topic we're discussing right this minute. If you go through that and simply check off which of those even addresses what we're talking about and then put them in a column -- yes, meaning that they hold to a certain view; and then no, if they don't hold to that view -- here's what you find: About 52 of them discuss the question of whether we have moral obligations to future generations. About a half of eight, in other words teeter-totter -- maybe yes, maybe no. There's reasons here, those reasons there, so half and half.

There are eight articles that go half and half, so some weight toward the no. There are 44 that say we do have moral obligations to future generations. So when you write, as you did, that there is no consensus on the question in the literature, that is literally correct, of course. However, it's disingenuous because, although there's no consensus, there is a strong preponderance of conviction amongst all those you cite, or your citation cites that scholars all over the world hold to the view. And Chapman and McCombie,who you cite with the authority over and over and over, summarize this chapter and say the same thing, mainly that the moral obligation that we have to those in the future is substantially the same as the one we consider ourselves to have to each other here and now.

And if you look around this room at the ones who are still here, look at the irony of this. Not one man or woman in this -- today since 4:30, 5:00 o'clock has spoken on behalf of him or herself for the present generation. So here you have an interesting falsification.

In other words, these people, who by your account probably diminish their sense of moral responsibility the farther away the generation goes from here, from today, all of these men and women have argued on the behalf of the Nevadans of 12,006. That's 10,001 years from now, 2005 plus 10,001 years. We've argued for them, not ourselves. How on Earth could we do that if we feel nothing or if we feel that it's diminishing?

It's true your mathematics diminishes, granted. But what you've done is premise your entire document on the claim that, as the mathematical predictability of quantitative dosage standards diminishes with increasing uncertainties and a cross-plain of uncertainties going out, therefore, the moral responsibility does the same thing. We don't hold that view, we don't hold that view. We hold the view, for example, that murder is wrong. We don't say that murder is wrong today, but a hundred years from now it will 93 percent wrong. And then 20,000 years from today, it will be 41 percent wrong, and then 500,000 years from today, it will be 11 percent wrong. We don't do that. Some things in morality are wrong and some are right.

And the brotherhood and sisterhood of men and women has been held by every religion and all of the philosophers as long as we have a history. And I'm talking the whole world, and I'd be happy to give you citations and backup.

So it is simply not true that this diminishing moral responsibility standard that you've used has the credential of being well-rooted in the history of religions and of morality and debate amongst ethicists around the world. We don't hold those views.

It's true, yes, there are huge complexities about resources and degrees of responsibility and how could you acquit yourself of your responsibility. And there's huge questions about the sustainability of the institutions. How can you ascertain any standard if the institutions themselves go to pot? You don't even address that. You have no discussion in the document about process, about democracy, about how to give these things moral legitimacy. And like those who follow us, you should have. (Comment 0209.16-1)

2. EPA's proposed rule also reflects a basic philosophical misunderstanding of intergenerational equity. Principles of intergenerational equity traditionally have been designed to *protect* future generations from unfairly bearing the burdens of current generations' activities. For example, EPA stated that "we should not knowingly impose burdens on future generations that we ourselves are not willing to assume." 66 FR 32107; *see also* Appendix D. Yet EPA apparently would turn that notion on its head, implying that intergenerational equity is a *justification for*, rather than a bar to, subjecting future

generations to burdens that our generation has never been willing to impose upon itself. In the name of intergenerational equity, EPA suggests that it may appropriately impose contamination levels beyond anything our generation accepts for itself, and to do so for a period that is orders of magnitude longer than the entire history of human civilization. *See* Figure 1, *supra* (graph showing the duration of the period of *median* doses close to 350 millirem/year); *compare* EPA, Response to Comments at 3-8 (2001) ("no regulatory body we are aware of considers doses of 150 mrem to be acceptable") (emphasis added). This is as rational as invoking the Christian Golden Rule to justify theft. As discussed in detail by Professor Fleming, the traditional premise of nuclear waste regulation has been that current generations do owe duties to future generations, and that those future generations should not suffer harms greater than those risked by the generations that actually derive the benefits from nuclear activities. Intergenerational equity is a constraint, not a license for current regulators to do whatever they please. Even the obscure sources EPA selectively cites cannot sustain its implied contrary theory. *See* Appendix D (characterizing EPA's choice of sources as "cherry- picking"). First, the National Academy of Public Administration ("NAPA") report does not support EPA. That report recommends a "sustainability principle" that "no generation should deprive future generations of the opportunity for a quality of life comparable to its own." While the report also recommends that "each generation's primary obligation is to provide for the needs of the living and next succeed ding generations" and that "near-term hazards have priority over long term hypothetical hazards," these recommendations are premised on the need to avoid trade-offs where present generations suffer an injustice, and on the concept of a "rolling present" which requires each generation to provide the next with the opportunity to reevaluate decisions and make changes. EPA never explains how its proposed two-tiered standard can be reconciled with those principles, and indeed it could not. EPA has identified no injustice the present generation would suffer were EPA's standard consistent, and thus NAPA's former premise for favoring current generations does not exist. Nor can EPA provide any opportunity for future generations to revisit the burdens EPA now proposes to impose, and thus the ability to create a "rolling present" does not exist. (Comment 0226-64)

3. EPA's other key source—a 1998 document by the Swedish National Council for Nuclear Waste ("KASAM")—contains none of the propositions for which it is cited. In response to questions from Nevada regarding where in KASAM's report any of these statements existed, EPA conceded that they did not exist, and advised that the relevant comments instead came from another Swedish paper published in 2004 that is not yet publicly available in English. EPA then provided Nevada with an English language translation of only one chapter of that document (chapter 9), which EPA claims supports its position. Read in context, neither Chapter 9 nor the full 2004 Swedish document even remotely supports EPA's proposal. Chapter 9 does describe a "minimal principle of justice"—as Appendix D points out, it is apparently the only discussion of that purported minimal principle—but the principle, as stated, does not support EPA's theory at all. Instead, the authors state that if we accept the minimal principle of justice as a reasonable principle for environmental ethics, it will have clear consequences for the nuclear waste issue. Thus, we are obliged to use nuclear power today in a manner that does not harm future generations—even if those generations are very distant. We cannot escape from our obligations just because they have to do with the very long-term consequences of our actions. OAR-2005-

0083-0197, at 429. The Principle of Minimal Justice applies for an unforeseeable period of time in the future and, quite simply, means that as long as living creatures exist on this planet, we have an obligation to not do anything that today that could jeopardize their life and health in the future. *Id.* at 445. …Therefore, on the basis of this principle, the specification for the repository should be completely clear: We must build a repository that can protection [sic] human beings and other living organisms for hundreds of thousands of years into the future – or for as long as we can anticipate that the waste is hazardous. *Id.* at 446. Paradoxically, uncertainty concerning the future state of society, technology and knowledge clearly provides us with clear guidance for how we, today, must design a repository in a morally responsible manner. *It must be designed so that, without controls and corrective measures, it can protect the human beings who will live in its vicinity from about the year 2050 and a couple of hundred of thousand years in the future*. *Id.* at 447 (italics in original.) (Comment 0226-65)

4. The Principle of Minimal Justice requires that, with our technology, we do not jeopardize future generations' possibilities for life. *First and foremost: Do no harm. This means that we should only construct a repository if we know that it is safe enough to protect future generations. Id*. at 449. This discussion is impossible to reconcile with the principle EPA purports to extract from this document. The authors quite clearly do not believe that current regulators have license to do whatever they please so long as they do not compromise future generations' prospect for survival. Instead, they state that any repository must "do no harm" "for as long as we can anticipate that the waste is hazardous." *Id.* The remaining sources EPA cites also provide no support for its implied but unarticulated intergenerational equity position. For example, EPA cites several sources for the principle that long-term numeric projections are of less value, and implies that these somehow bolster its suggested theories of intergenerational equity. Those general statements, however, do not rebut the clear findings of the NAS that long-term numeric projections for Yucca Mountain will have value and should be the proper basis for a compliance assessment. Several of the sources EPA cites suggest that numeric assessment is inappropriate only in post-*million*-year time periods—a proposition irrelevant to EPA's current decisions about assessing compliance in the post-10,000-year period. And even the 2004 KASAM report Chapter 9, from which EPA purports to extract a highly permissive principle of intergenerational ethics, is clear: "To refrain from long-term assessments on account of the difficulty of making them can never be considered to be a reasonable level of ambition." *Id.* at 446 (quoting KASAM, Nuclear Waste – Research and Technique Development 32 (2002). (Comment 0226-66)

5. What EPA does not state in is that the first requirement and assumption in the KASAM report is that a candidate repository site will be shown to provide permanent isolation of the waste. Terms such as minimal and weak principles of justice relate to how intergenerational issues are considered, not to justify taking a huge toll on the health of our future generations. (Comment 0257-3)

6. Is there also an implicit hope that future generations will forgive us for failing them? Yes, it seems the hope is that, although a "weak principle of justice" is all we can muster,

future generations will not care too much, and we will be safely removed from their blame. (Comment 0267-4)

7. How can we make decisions that will serve humanity and the Earth for a million years or more? The proposed rule in the August 22, 2005 Federal Register does contain the answer to that question, but it is not the proposed double standard. Instead, it is summed up on page 49035, a citation of the principles set forth by the National Academy of Public Administration (NAPA) in its 1997 report "Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly across Generations." (Comment 0267-6)

8. The argument that follows this citation in the rule proposal is puzzling as a justification for the double standard: "Application of the NAPA principles would lead each generation to an approach that would best address the problem without unduly limiting the options available to succeeding generations to modify that approach or to take other actions to address their needs." In other words, if we take care of ourselves, it is up to successive generations to take care of themselves. But the very premise of permanent waste disposal is its irrevocability. "Each generation" that succeeds this one will have no "option to modify" whatever approach we take. Instead of shifting the responsibility to future generations, the NAPA principles tell us that *if we take irrevocable action we must get it right.* This is especially true when we know very well that the long-term hazards are anything but hypothetical—they are real and inevitable. (Comment 0267-7)

9. Specifying a million-year compliance period shifts priorities in favor of hypothetical hazards in the far distant future and it does so at the expense of today's near-term, concrete used fuel disposal needs. Hence, the proposal fails to satisfy the "chain of obligation" principle. (Comment 0298-3)

10. The dilemma presented by a million-year standard is therefore this – it requires analysts to venture into an unprecedented world of hypothetical speculation in the name of protecting individuals 25,000 generations in the future from an underground hazard that is no more significant than what already exists in nature. The placement of a requirement for such esoteric long-term speculation in front of a program of near-term national importance represents an extreme skewing of priorities in the wrong direction – directly opposite what is intended by the "Chain of Obligation" principle. Consistent with this principle, EPA should be placing a greater emphasis on the health and safety of current and near-term generations than on that of far future generations about which little can be known. But this proposal gives deference to the latter by placing a speculative million-year analysis at the front end of a rigorous licensing process that must be completed as a prerequisite to the implementation of the nation's vital used fuel disposal program – making it an issue that will have a significant impact on the nation's used fuel management system. (Comment 0298-7)

11. EPA's existing 10,000-year standard satisfies all four of the principles articulated by The National Academy of Public Administration (NAPA), as cited by EPA, for balancing risks, costs, and benefits fairly across future generations. (Comment 0298-10)

12. The plan inexcusably calls for a relaxing of the radiation standards over time, putting future generations – and the fragile web of life – at risk. I am disturbed by the concept of a "sliding scale" of moral responsibility over time that is discussed in the proposal. And I believe that a "weak" or "minimal" principle of justice is not an acceptable principle to apply to any generation, now or in the future. To discount the value of future generations and knowingly allow increased exposure to radiation and potentially increased cancer rates is wrong, plain and simple. Every generation deserves a strong principle of justice, and I urge you to set radiation standards that protect the health of communities, wildlife, groundwater, and the land – now and in the future. (Comments 0305-1 and 0348-1)

13. One of the arguments used by the EPA is a conclusion from The Swedish National Council for Nuclear Waste (KASAM) which "...concludes that increasing uncertainties 'means that our capacity to assume responsibilities changes with time. In other words, our moral responsibility diminishes on a sliding scale over the course of time' (page 49036, Federal Register, 8-22-05). However, KASAM and the EPA do not supply any evidence or justification to back up the notion that our responsibility for future generations should diminish with time. In fact, the radiation standard should become more stringent in the future because of the inevitable corrosion which will effect the nuclear waste casks over time. This disregard for future generations is not acceptable to the values of the Big Pine Paiute Tribe. Human actions today must take into account serious and life-threatening effects on future generations, no matter how far into the future. (Comments 0360-3 and 0363-3)

14. The million year standard, we believe, does not meet the chain of obligation requirement. This is defined as each generation's primary obligation is to provide for the needs of the living and succeeding generations. Near-term concrete hazards have a priority over long-term hypothetical hazards. Specifying a million year compliance period shifts priorities in favor of hypothetical hazards in the far distant future and it does so at the expense of near-term concrete waste disposal needs today of a significant national importance. (Comment 0368.8-3)

15. Underpinning this overall approach is a faulty assumption that we can apply different principles of justice to different generations. The EPA instead introduces a sheer cliff at 10,000 years that moves from a strong principle to a minimal principle. In effect, the EPA is arguing that uncertainties suddenly arises at 10,000 years but then disappears from 10,000 years to a million years. As a result, the people living 10,000 years from now will be protected by a strong standard while those living 10,001 years from now will not. (Comment 0368.10-3)

Response to Issue C:

Issue B of this section discussed the concept of intergenerational equity as it is expressed in the fundamental radioactive waste management safety principles endorsed by IAEA ("The Principles of Radioactive Waste Management," Safety Series 111-F, 1995, in particular Principles 4 and 5, respectively, Docket No. EPA-HQ-OAR-2005-0083-0053, which relate to protection of future generations and burdens on future generations, respectively). We also briefly discussed in our proposal documents prepared by the National Academy of Public Administration (NAPA) and Swedish National Council for Nuclear Waste (KASAM) (Docket Nos. EPA-HQ-OAR-2005-0083-0077 and 0197, respectively). NAPA is a Congressionally-chartered organization whose purpose is to provide assistance to government in assessing and effectively addressing issues of governance, including future implications of contemplated actions. KASAM was created by the Swedish government in 1985 to provide an independent review of issues related to nuclear waste. The documents are summarized in the following paragraphs.

The NAPA and KASAM documents[20] provide examples of ethical and decision-making constructs that take a middle ground between the bounding positions that either our obligations to future generations are unwavering regardless of when they might live, or that there are no obligations to future generations, save perhaps for those immediately following our own. Both documents also focus on issues related to radioactive waste management, which has typically considered intergenerational equity over time frames far in excess of those addressed in other public policy contexts. However, NAPA examines these issues in the specific context of remediation of radiologically-contaminated DOE sites, while KASAM's examination is directly concerned with intergenerational equity as it relates to geologic disposal. Still, we believe the views expressed by the NAPA committee are relevant to the process of establishing regulatory standards applicable for times on the order of 1 million years. As the NAPA committee stated, "these principles are not limited in their value to the specific task set for the Academy by DOE. They can serve as a prototype for many public programs which have intergenerational consequences, and provide an ethical and philosophical starting point for many such public concerns."

Both documents firmly establish that there are obligations to future generations, but offer somewhat different frameworks for defining the level and strength of those obligations. NAPA's approach is based on an articulation of obligations to future generations, but provides for the use of balancing considerations to inform decision-making. NAPA defines four basic principles:

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

[20] "Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly Across Generations," 1997; and "Nuclear Waste, Ethics, and Responsibility for Future Generations," Chapter 9 of "Nuclear Waste State of the Art 2004," respectively

These principles outline a hierarchy of responsibilities, which can be influenced by factors such as the action we propose to take, the justification for that action, and its potential effects on future generations. The more significant the effects of an action on future generations, the stronger its justification must be. If a contemplated action may result in a hazard to future generations, but failure to take that action will definitely have negative effects on the current and succeeding generations, the action may be justified. An action that will present a hazard to future generations may also be justified if the known near-term hazard is judged to be equivalent or greater. However, if that action is likely at some point in the future to (for example) cause widespread damage or death, create a high incidence of acute or chronic illness, or render significant areas uninhabitable for long periods of time, the action should only be taken if it is necessary to avoid problems of a similar nature, if not magnitude, in the near term.

An important aspect of the NAPA approach is its reliance on the "rolling present," as incorporated into the Chain of Obligation. This requires recognition that current generations either may not have the information or ability to make a decision, or that future generations may have cause to revisit decisions that are made. Similar to IAEA's Principle 5 in this regard, current generations must not simply pass their problems along to the next generation (no generation could then be expected to take action if passing the problem along was a viable option), but must provide resources and knowledge to help that generation continue implementing policies or reach its own decisions.

KASAM takes a different view, and in fact finds a logical disconnect in reconciling NAPA's principles. For example, KASAM questions how the "opportunity for a quality of life comparable to its own" for future generations can be preserved if the "primary obligation is to provide for the needs of the living and succeeding generations." Further, while NAPA presents balancing factors to guide decision-making, KASAM focuses more on the strength of obligations to future generations. KASAM identifies three "principles of justice" that convey our responsibilities in the context of geologic disposal:

- Strong Principle of Justice: We have an obligation to exploit or consume natural resources in such a way that subsequent generations can be expected to achieve an equivalent quality of life to ours. This principle can be discharged for 5 or 6 generations, or about 150 years.
- Weak Principle of Justice: We have a moral obligation to exploit natural resources in such a manner that not only the present generation but also future generations can satisfy their basic needs. This principle can be discharged for an additional 5 or 6 generations, or out to about year 300.
- Minimal Principle of Justice: We have a moral obligation to exploit or consume natural resources in such a way that we do not jeopardize future generations' possibilities for life. This principle applies at all times.

In this construction, these obligations become more limited over time, primarily because our ability to identify the needs of future generations becomes more limited. As a result, "our capacity to assume responsibilities changes with time. In other words, our moral responsibility diminishes on a sliding scale over the course of time."[21] Therefore, in the KASAM view, it is not so much a matter of the justification for the actions we are contemplating, and the potential effects of those actions on future generations, as our ability to relate to those generations in the first place that defines our obligations.[22] As a result, KASAM sees that our obligations quickly become "minimal." This leaves open the question of whether our obligations would remain "strong" if only we were able to understand the needs of future generations, or whether other considerations would then become relevant. KASAM suggests that our ability to positively influence the future is much more limited than our ability to negatively influence it, and that this might also be a factor in defining the strength of obligations. NAPA agrees that "it is impossible for members of the current generation to know the lifestyles, concerns, and preferences of future generations." However, this is not seen by NAPA as a reason to make choices that limit the options of future generations, or to assume a lesser obligation based on the passage of time.

It should be understood that both NAPA and KASAM approach their principles from a much broader perspective than we are able to exercise in establishing health and safety standards. Both documents incorporate wider considerations of safety in determining an overall course of action. NAPA is explicit, for example, in suggesting that "near-term concrete hazards" may outweigh "long-term hypothetical hazards." Similarly, KASAM suggests that our obligation to provide safe disposal through isolation of the waste may outweigh our obligation to allow future generations the option to take a different action by retrieving the waste. KASAM also considers that intergenerational equity begins with the decision to use nuclear power, and it is incumbent on the generation making that decision that it be applied in a way that does not result in "harm" to future generations. There is, of course, also the argument that the uncertainties involved in evaluating the safety of geologic disposal are best addressed by a program of interim or retrievable storage until those uncertainties can be resolved. We have already noted that such considerations are outside the scope of our action and authority.

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[21] This view was first expressed in KASAM's 1998 State of the Art Report to describe "the dilemma with which we are confronted, based on the realisation of the long-term effects of our actions. On one hand, we cannot renounce our responsibility for these actions. On the other hand, we cannot, at the same time, refrain from a responsibility to fulfil our basic obligations to the current generation...A prerequisite for this is a basis for decision-making that enables us to make a reasonable assessment of the consequences. Inevitably in this situation, we are confronted by a *time limit*. This limit is set by the human capacity to imagine – anything exceeding the bounds of human measurement cannot be comprehended by humans. The limit is also imposed by the fact that the uncertainties of our base of knowledge, which include the capacity to determine the durability of the system's technical design, increase as a function of the increasing timespan-perspective. The degree of credibility in the material used as a basis for decision-making diminishes also over the course of time. Science too, has its limits of credibility. This means that our capacity to assume responsibility changes with time. *In other words, our moral responsibility diminishes on a sliding scale over the course of time*." (pp. 26-27, emphases in original) The point here is that, as consequences become farther removed in time from our actions, it becomes increasingly difficult to say anything meaningful about how we might have altered those consequences (other than perhaps not taking action at all). That is, it becomes more difficult to relate the outcomes to decisions we made. This may be true as well if succeeding generations continue on the same course of action, presumably modifying decisions we made.

[22] For example, the KASAM document takes the position that people living in the 19th century would have had a better basis to project the needs of our generation than would people in the 16th century, therefore the "moral responsibility" to protect our needs would also have been greater.

Similarly, the impact of our standards on future generations must also be viewed in a limited way. Incorporated into both the NAPA and KASAM approaches is a distinction between the significance of those potential effects on future generations. These effects are characterized by terms such as "quality of life," "basic needs," "interests," and "possibility for life," all of which are open to interpretation, not to mention more stark terms such as "irreversible" or "catastrophic."[23] KASAM provides some perspective by defining "basic needs" to include such things as "food, water, energy, housing, health care and education." Thus, we can envision a continuum of obligations to future generations. At one end of the spectrum is the idea that our actions should not prevent future generations from achieving a quality of life comparable to our own. We can perhaps equate "quality of life" with "interests" as representing something beyond or in addition to basic needs, such as better food or housing, wealth, jobs that do not demand hard physical labor, leisure time, or access to entertainment. Toward the center of the continuum is the requirement that we take no action that would limit those generations' ability to obtain their basic needs or necessities, and at the other end is the more limited goal of not affecting their potential for life itself.

We are establishing 1 mSv/yr (100 mrem/yr) as the public health and safety standard to apply for the period beyond 10,000 years and up to 1 million years. We have determined 100 mrem/yr to be protective of public health and safety as a peak dose standard for the Yucca Mountain repository. As discussed in the preamble to the final amendments, international organizations such as ICRP, IAEA, and NEA recommend 100 mrem/yr as an appropriate standard as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Domestically, both NRC and DOE incorporate the 100 mrem/yr level into their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," Docket No. EPA-HQ-OAR-2005-0083-0407). This standard will protect public health and safety for up to 1 million years, and will also protect the needs and aspirations of future generations.

Many commenters disputed our interpretation of the NAPA and KASAM documents (70 FR 49035-49036), or took issue with the documents themselves. Commenter 0226 argues that our discussion of the Chain of Obligation principle as formulated by NAPA ("Each Generation's Primary Obligation is to Provide for the Needs of the Living and Next Succeeding Generations. Near-term Concrete Hazards Have Priority Over Long-Term Hypothetical Hazards.") is misleading, as we have not explained the "near-term hazards" that must be balanced by a higher long-term standard ("EPA has identified no injustice the present generation would suffer"). The commenter argues that we should not, and in fact are not allowed to, consider the potential failure of Yucca Mountain to be licensed as a "near-term hazard." The commenter further argues, in an attached appendix (discussed in more detail in Issue D of this section), that once we deem 350 mrem/yr "acceptable," we can no longer frame this as a "hypothetical hazard" for periods beyond 10,000 years.

[23] The Joint Convention on the Safety of Spent Fuel and on the Safety of Radioactive Waste Management (discussed in Issue B of this section) introduces another term as an overall objective that "the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations." (Chapter 1, Article 1, Docket No. EPA-HQ-OAR-2005-0083-0393)

However, we did not propose to determine our standard by enumerating "concrete" and "hypothetical" hazards. Our statutory role under the EnPA is to establish public health protection standards for the proposed repository at Yucca Mountain. Congress established the national policy of geologic disposal, and Congress is the appropriate venue for considering the hazards, costs, and benefits in deciding on such a policy. Our rulemaking does not consider factors outside the scope of the Yucca Mountain disposal system. Therefore, we did not point to specific imminent hazards to public health or the environment that require immediate movement of the waste, which we assume is meant by the commenter. Nor did we, as suggested by Commenter 0215, consider the potential for increased use of nuclear power to offset the effects of climate change, which the commenter suggests could ultimately increase the quality of life for future generations. Such considerations are not relevant to our rulemaking. Our single firm citation of the Chain of Obligation Principle perhaps could have been better framed, as the appendix submitted by Commenter 0226 puts it, as a question of our capacity to ensure that an equivalent level of protection can be provided to the current and all future generations (echoing the questions posed above, "what form can assurances of protection take, and can they provide the same level of confidence?"). (See Issue D of this section for discussion of the commenter's appendix.) We expressed the view that establishing a 15 mrem/yr standard throughout the period of geologic stability would put far-future generations' interests above those of current and succeeding generations (70 FR 49040). We believe this to be true because of the uncertainties influencing dose projections. We believe the NAS committee, with numerous references to "bounding" approaches, also recognized that the assessments would effectively become more stylized as the compliance period increased, and that a compliance standard applicable at times approaching 1 million years might be different in some significant respects from its recommendations. We emphasized that it was not a question of whether that level of performance could actually be achieved, although as noted in Section 2, Issue B of this document, geologic disposal has always had the recognized potential for doses exceeding 15 mrem/yr in the far future. Rather, we believe a 15 mrem/yr standard over the period of geologic stability would not adequately recognize the changing basis for regulatory decision-making. Ultimately, we believe we have developed standards that are protective of public health and the environment, meaningful, implementable, and provide a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation. In our view, an unchanging 15 mrem/yr standard would not present a reasonable test when applied for up to 1 million years.

Commenter 0226 also takes issue with our discussion of the KASAM Minimal Principle of Justice, highlighting the statement that "we should only construct a repository if we know that it is safe enough to protect future generations." The commenter states that our conclusions "are impossible to reconcile" with this principle. Commenter 0257 similarly points out that the underlying assumption in the KASAM report "is that a candidate repository site will be shown to provide permanent isolation of the waste." An important question that is not addressed by either commenter is, how is "safety" determined at various times in the repository's evolution? We have discussed in detail in Section 4, Issue A, of this document the approaches taken internationally to making such a determination. It should be clear that in Sweden, "safety" becomes more subjective as time passes, e.g., it may be acceptable at longer times to exceed the compliance level established for the first 1,000 years ("[i]f the calculated risk exceeds the criterion…the underlying causes of this should be reported on," but this is not necessarily cause for rejection). (Docket Nos. EPA-HQ-OAR-2005-0083-0047 and 0388) Beyond 100,000 years, "a strict quantitative comparison of calculated risk in relation to the criterion for individual risk in the regulations is not meaningful." Why that level is exceeded, by how much, and how much emphasis can be placed on quantitative dose projections changes over time, as it must. Consistent with direction in the EnPA and the NAS recommendations, we have not taken such an approach.

Commenter 0226 goes on to criticize our statements regarding the utility of dose projections at long times. These statements "do not rebut the clear findings of the NAS that long-term numeric projections for Yucca Mountain will have value and should be the proper basis for a compliance assessment." The commenter then points out that some references refer only to projections after 1 million years ("irrelevant to EPA's current decisions") and cites the KASAM report: "To refrain from long-term assessments on account of the difficulty of making them can never be considered to be a reasonable level of ambition." We agree, which is why we required such assessments in our 2001 rulemaking. We also repeat a statement from our proposal (70 FR 49035), which the commenter also cites: "In view of the way in which uncertainties generally increase with time, or simply for practical reasons, some cut-off time is inevitably applied to calculations of dose or risk. There is, however, generally no cut-off time for the period to be addressed *in some way* in safety assessment, which is seen as a wider activity involving the development of a range of arguments for safety." (NEA 2004, Docket No. EPA-HQ-OAR-2005-0083-0046, p. 39, emphasis in original)

However, we disagree with the thrust of the comment and believe the commenter is confusing the concepts of dose assessments and dose standards. We believe we accurately represented international sources on both points. These sources do generally take the position that numerical assessments eventually lose their utility (e.g., "calculations of dose and risk should not be extended to times beyond those for which the assumptions underlying the models and data can be justified," NEA, cited at 70 FR 49027). This sentiment is in complete agreement with NAS statements regarding geologic stability: "After the geologic environment has changed, of course, the scientific basis for performance assessments is substantially eroded and little useful information can be developed." (NAS Report p. 72, see also Section 10 of this document) However, even for shorter periods when assessments can provide insights into disposal system performance, the typical approach internationally is not to hold the results of those assessments to strict numerical limits, but to view them more as qualitative indicators of performance (see, for example, 70 FR 49026-49027).[24] This approach acknowledges that the nature of dose

[24] NEA notes: "There is agreement that calculations of dose and risk in the future are illustrations of possible system behaviour rather than predictions of outcomes, and there is consensus that, in the long term, numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than as absolute limits in a legal context." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, Docket No. EPA-HQ-OAR-2005-0083-0408, p. 24)

projections changes over time, so that comparison of those projections to strict numerical limits may not be the most meaningful indicator of equity over long time frames. We recognize that NAS recommended an assessment of compliance against a numeric standard at the time of peak dose (risk). However, as noted above, we believe NAS also recognized that dose projections would effectively become increasingly stylized, and emphasized "bounding" approaches and "quantifying" uncertainties for that reason, while making no recommendation on the level of the peak dose standard, or even putting forward a range for that final standard based upon scientific considerations, leaving the final decision as the policy matter the committee believed it to be. (NAS Report pp. 5 and 20) We have already discussed the NAS recommendation, placing it in its original context of judgment against a probabilistic critical group, a less conservative receptor than the RMEI.[25] Even in that context, the committee indicated that a compliance standard that changed over time could be a valid expression of intergenerational equity. (NAS Report pp. 56-57) As described in the preamble to the final amended standards, the chair of the NAS panel expressed his personal concern that our proposal would be too conservative had we adopted the 15 mrem/yr standard for the entire period of geologic stability. (Docket No. EPA-HQ-OAR-2005-0083-0380) We have worked to develop a standard in which projections could be reasonably used to assess compliance as the NAS intended, taking into account the factors affecting both the compliance standard and the usefulness of projections at very long times.

From these perspectives, the 100 mrem/yr level is comparable to the range of risks represented by domestic and international regulations suggested by NAS for EPA to consider, "all of which are consistent with recommendations from authoritative radiation protection bodies," and among which was the ICRP-recommended 100 mrem/yr public dose limit. (NAS Report p. 49 and Tables 2-3 and 2-4) The nominal annual risk of fatal cancer associated with 100 mrem/yr, 5.75×10^{-5}, is a reasonable level of risk when the significantly extended time frames considered in this rulemaking, with the attendant uncertainties, are taken into account. We conclude that our final standards will protect public health and safety, as required by the EnPA, and represent a valid and appropriate expression of intergenerational equity.

Commenter 0298 argues that a standard applicable for 1 million years, regardless of its level, will violate the principle of intergenerational equity. "The placement of a requirement for such esoteric long-term speculation in from of a program of near-term national importance represents an extreme skewing of priorities in the wrong direction…this proposal gives deference to [far future generations] by placing a speculative million-year analysis at the front end of a rigorous licensing process that must be completed as a prerequisite to the implementation of the nation's used fuel disposal program." The commenter goes on to state that our 2001 standards satisfied all four NAPA principles and provide intergenerational equity.

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

Section 9 Intergenerational Equity

Issue D: State of Nevada Appendix D

1. Having incorrectly determined that "uncertainty" renders impossible a traditional, apportioned standard, EPA proposes that it needs an alternative, and that 350 millirem/year is acceptable as a putative "policy" choice. But EPA offers no real explanation of why 350 millirem/year, which EPA does not consider acceptable today or 10,000 years from now, should be considered acceptable after 10,000 years. EPA hints that principles of intergenerational equity somehow support its proposed rule, but for a series of reasons, that implication is illogical, unjustified, and ethically wrong. These flaws are explained in detail in Appendix D, a white paper prepared by Professor Patricia Ann Fleming, Ph.D. Dr. Fleming's full report must be considered. She considers the ethical implications of EPA's proposed action and the ethical rationales EPA has stated, or implied, in support of that rule, and concludes that EPA misconstrues accepted principles of intergenerational ethics, mischaracterizes the sources upon which it relies, and has offered an incomplete and internally inconsistent ethical rationale. (Comment 0226-59)

2. Initially, EPA's discussion of intergenerational equity is fatally vague. EPA never actually states what equitable principle it is adopting. Instead, EPA's proposed rule provides a cursory, selective, and inaccurate survey discussion of a few intergenerational equity theories, none of which EPA itself has ever adopted in the past. *See* Appendix D (discussing EPA's selective use of sources and its mischaracterization of the limited set of sources it does cite). EPA then hints at the notion that an action is equitable so long as it does not impose catastrophic burdens upon future generations. EPA never clearly articulates the principle it is endorsing, or explains why EPA considers that particular principle to be just, equitable, or appropriate. That failure of explanation leaves intergenerational equity as an improper basis for EPA's rule, for EPA cannot merely hint that a policy justification for its proposed action *might* exist; it must actually articulate and support its purported policy rationale. (Comment 0226-60)

Response to Issue D:

Commenter 0226 provided an appendix with extensive discussion of intergenerational equity issues, many of which have been touched upon in Issues A-C of this section (the appendix is in the docket at Docket No. EPA-HQ-OAR-2005-0083-0230). Professor Fleming, the author of the appendix, generally finds our discussion lacking in clarity and depth, when compared to the body of work on this topic. She also views our consideration of the NAPA and KASAM document as questionable, finding that neither of these documents is widely referenced in peer-reviewed literature. She also finds the viewpoint of Chapman and McCombie in “Principles and Standards for the Disposal of Long-Lived Radioactive Wastes” (Docket No. EPA-HQ-OAR-2005-0083-0061) to be “logically problematic” in its “appeal to nature” as a guide for determining long-term acceptable doses (a “fallacy” the author seems to find common in “the nuclear waste community”). We will address several specific aspects of this appendix here.

First, Professor Fleming addresses the concept of the "rolling present" put forward by NAPA, relating it to the concept of "institutional constancy" in an earlier KASAM report (Nuclear Waste State-of-the-Art Report 1998, Docket No. EPA-HQ-OAR-2005-0083-0056). It is argued that there is no opportunity for a "rolling present" in this case because we have made no provision to review and update our standards as the state of knowledge increases, "nor can EPA provide any opportunity for future generations to revisit the burdens EPA now proposes to impose" (Comment 0226-64). We disagree. As pointed out earlier, our standards are part of an entire framework established by Congress to implement its chosen national policy, geologic disposal. Promulgation of our standards is not the final opportunity for future generations to review this policy. We reserve the right to amend our standards in the future if warranted. Similarly, NRC licensing would allow construction and operation of the repository, but the waste must remain retrievable for a significant period of time, likely to be at least several generations. Closure of the repository and termination of the license also requires a demonstration to NRC of compliance with regulatory requirements. Here we also think it appropriate to consider the other element of intergenerational equity, which is the burden to be placed on future generations in addressing past practices. The fundamental difficulty in addressing radioactive waste is that regardless of the management method selected, succeeding generations will necessarily assume some burden, by virtue of the long-lived nature of the hazard. Geologic disposal has been seen as a way to make that burden minimal beyond the time necessary for implementation, in that a goal of geologic disposal is to provide the necessary containment and isolation without the continued commitment of resources for active maintenance or even reliance upon future generations' knowledge of the facility. The requirement for retrievability has been seen as a way not to foreclose the opportunity for newer technology or better approaches to be identified by succeeding generations. By contrast, reliance on continued storage, without an identified method of ultimate disposal, may reflect the current generation's ability to address the problem, but has also been seen as an abdication of responsibility in leaving it to future generations to find a permanent solution.

Any number of factors could influence national policy and the way Yucca Mountain would be operated. For example, it has been proposed that a Global Nuclear Energy Partnership (GNEP) be pursued that would emphasize advanced technologies for reprocessing spent fuel and reactor designs that would result in less waste. Such an effort could significantly affect the volume and characteristics of the waste needing disposal. (See the testimony of Paul Golan, DOE Acting Director of the Office of Civilian Radioactive Waste Management, before the Senate Environment and Public Works Committee, Docket No. EPA-HQ-OAR-2005-0083-0380) Similarly, successful development of technology for transmutation of long-lived isotopes could significantly reduce the time necessary for isolation of waste. It is also possible for Congress to take specific action, as it did when it directed us to develop site-specific standards for Yucca Mountain. Professor Fleming does not believe this is sufficient, and suggests that an explicit requirement for review of the Nuclear Waste Policy Act and all subsequent actions on a regular basis be implemented (e.g., every 20 years).

As a second point of interest, Professor Fleming recognizes valid ethical bases for concluding that there is no obligation to future generations, and also discusses situations in which current and succeeding generations would take precedence over future generations, even if obligations are acknowledged to exist. Further, she concludes that we have not followed the NAS direction to "as a matter of policy address whether future generations should have less, greater, or equivalent protection." (NAS Report p. 56) Our proposal is criticized for not "muster[ing] arguments in support of the [greater or equivalent protection] positions and then explain[ing] why the 'lesser duty position' is morally preferable." As noted above, we do not question that there are obligations to future generations in the management of radioactive waste, as stated in the IAEA Principles of Radioactive Waste Management, both in terms of impacts to future generations and in the burdens placed on those generations for waste management. Professor Fleming makes the distinction between "basic needs" and "welfare interests" (or "wants"). When the needs of current and future generations are in conflict with respect to a specific action, the most difficult ethical decisions must be made. Where needs are in conflict with wants, however, needs must always be given precedence. She characterizes the current situation as the "wants" of current generations to pursue geologic disposal resulting in denial of "needs" of future generations through a higher peak dose standard. She concludes that "[t]he multiple dose protection standard proposed by the EPA jeopardizes future humans' possibilities for life." We do not believe this is a reasonable conclusion. We are not, however, establishing the proposed level as the final peak dose standard. We are instead establishing a level of 1 mSv/yr (100 mrem/yr) as the public health and safety standard to apply for the period beyond 10,000 years and up to 1 million years. As discussed in the preamble to the final amendments, the dose level of 100 mrem/yr is well-established as protective of public health, and as such represents a robust standard for public health protection in the extreme far future. International organizations such as ICRP, IAEA, and NEA recommend its use as an overall public dose limit in planning for situations where exposures may be reasonably expected to occur. Domestically, both NRC and DOE incorporate the 100 mrem/yr level into their systems of regulation (10 CFR 20.1301 and DOE Order 5400.5, respectively), and NCRP also endorses the ICRP system of protection (NCRP Report 116, "Limitation of Exposure to Ionizing Radiation," Docket No. EPA-HQ-OAR-2005-0083-0407). We believe it provides, as Professor Fleming cites, "the same opportunity that we have had to live healthy, happy, and satisfactory lives."

We have, of course, concluded that a higher standard is appropriate to address the uncertainties inherent in projecting doses for periods approaching 1 million years. Professor Fleming points out that time is generally not considered an ethically acceptable reason for diminished protection for future generations. That is, we should look at any future generation, even one presumed to live 1 million years from now, as we would look at our own children: "The chain of obligation does not weaken our duties to future generations; it does just the opposite: it establishes those duties as equally strong across generations." Thus, time "does not change the strength of the moral duty we have to provide equal protection from harm (no matter how 'negligible') to their basic need for health." We do not believe, however, that the time frames under consideration in geologic disposal are as easily accommodated by this concept.

Finally, Professor Fleming makes a distinction between our obligation to future generations and our capacity to discharge those obligations. In other words, we may not be able to assure the same level of protection for all generations, but if we were able to do so, would we consider it a moral obligation? By its very nature, geologic disposal extends this question to time frames not considered in other contexts. If a fundamental principle is that it cannot rely on continued maintenance, geologic disposal cannot be implemented without projecting the performance of the disposal system, developed using current knowledge and technology, over times far in excess of those considered in other applications. As the time covered by the assessment increases, the confidence that the current knowledge base is representative of "real" conditions at such times necessarily diminishes, and assessments effectively become more stylized. If as a result, the basis for decision-making also changes, it must be considered whether equivalent protection can be demonstrated at times as far removed as 10,000 and 500,000 years, and whether that demonstration is as simple as a comparison of dose or risk constraints, especially if at later times they are considered as "indicators" or "reference levels".[26]

Professor Fleming suggests that the "rolling present" is the way to acknowledge that future generations may have a greater capacity to address the issue than we do, and that we do not "reduce [duties] or weaken them because of uncertainty associated with time." The author also states that NAS "rejected" uncertainty in compliance assessments as a reason for "not providing guidance beyond 10,000 years." However, the question is not one of providing guidance. We addressed earlier the distinction between conduct of dose assessments and establishment of dose standards. The French and Swedish approaches discussed in Section 4, Issue A of this document provide significant guidance on long-term projections. We provided guidance for post-10,000-year projections in our 2001 rule, and could have provided additional guidance regarding long-term features, events and processes (FEPs), similar to that in our current rulemaking. The distinction is that NAS recommended assessing compliance against a standard at the time of peak dose (risk). As we have stated elsewhere, this approach is atypical in the international community. We believe it has always been implicit in the concept of geologic disposal that it may not be possible to offer assurances of equivalent protection to all future generations, and that the potential exists for doses to at some point exceed those considered acceptable today, in spite of our best efforts (see Section 4, Issue A of this document, as well as Section 2, Issue B). We note that the recently approved IAEA Safety Requirements for Geological Disposal of Radioactive Waste (WS-R-4), which represents a consensus document of member states, includes the following statement: "In very long timeframes…uncertainties could become much larger and calculated doses may exceed the dose constraint. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases." (Docket EPA-HQ-OAR-2005-0083-0383, paragraph A.7, p. 37) This

[26] NEA observes these difficulties: "The design and implementation of a repository involves balancing of risks and responsibilities between generations. The obligations of the present generation toward the future are complex, involving not only issues of safety and protection but also of freedom of choice and of the accompanying burden of responsibility, and of the need to transfer knowledge and resources. Our capacity to deliver these obligations diminishes with distance in time, which complicates the setting of criteria to be used today in order to demonstrate that obligations to the future will be met." ("Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and Bases of Safety Criteria," NEA-6182, 2007, p. 25)

statement clearly indicates that projected doses that would be unacceptable in the near term may be acceptable at later times, which would be difficult to reconcile with the IAEA's own principle that "predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today" (Docket No. EPA-HQ-OAR-2005-0083-0390, p. 6) unless it is accepted that either "future generations" does not mean "all future generations" or that the uncertainties involved in dose projections make such direct comparisons less meaningful at longer times. See Issue B of this section for discussion of the IAEA principle.

We have taken the latter position, which we believe to be consistent with the consensus international views, and have developed standards that are protective of public health and the environment for all generations during the period of geologic stability, while addressing the issue of long-term uncertainties in projecting performance. NAS itself "recognize[d] that there are significant uncertainties in the supporting calculations and that the uncertainties increase as the time at which peak risk occurs." (NAS Report p. 56) We believe NAS anticipated that assessments would effectively become more stylized at longer times, leading to its many references to "bounding" approaches and "quantifying" uncertainties. NAS concluded that uncertainties could be sufficiently bounded to make compliance assessments feasible, but implicitly considered in its discussion of intergenerational equity the possibility that a standard applicable at the time of peak dose might differ from its recommendations in some important ways. (NAS Report pp. 55 and 56-57) We noted in our proposal that ICRP took a similar view in its Publication 81, "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste," stating that "as the time frame increases, some allowance should be made for assessed dose or risk exceeding the dose or risk constraint. This must not be misinterpreted as a reduction in the protection of future generations and, hence, a contradiction with the principle of equity of protection, but rather as an adequate consideration of the uncertainties associated with the calculated results" (Docket No. EPA-HQ-OAR-2005-0083-0087). Determining whether a dose limit is adequately protective of both current and future generations must also consider the ability of performance assessments, and those who interpret them, to distinguish between differing repository designs, as well as different conceptualizations of total system performance over very long time frames. In our view, it makes little sense to assert that a 15 mrem/yr dose limit for the period within 10,000 years is more "protective" than a higher limit much later in time if, in the time frame of hundreds of thousands of years, the uncertainties in projecting disposal system performance cannot easily make distinctions at such incremental levels. Where fundamental uncertainties have significant effects, decisions about overall safety based on incremental doses may be less supportable.

As noted earlier, NAS indicated that a dose standard changing over time could be a valid expression of intergenerational equity. However, as pointed out by Professor Fleming, NAS also stated that "EPA should as a matter of policy address whether future generations should have less, greater, or equivalent protections." (NAS Report p. 56) This is a particularly challenging request, given that our task is to identify a specific numerical standard of safety against which the performance of the disposal system will be judged for up to 1 million years. However, the fact that one approach may be justified and consistent with the objectives of intergenerational equity does not automatically mean that it should be preferred over other approaches that may be equally justified and consistent with those objectives. Consistent with the strictest interpretations of IAEA Principle 4 (see Issue B of this section), we have essentially accepted the obligation to provide current levels of protection at Yucca Mountain for 10,000 years, as we did with our original 40 CFR part 191 standards. To say that people beyond that time "should" have lesser protection involves either a judgment that the pursuit of geologic disposal takes precedence over future generations, which we have already concluded is outside our purview, or a judgment that our obligation is somehow changed. On the other hand, it may not be possible to provide the same level of protection, even if we believe it "should" be provided. Whether that "should" then automatically cause a rejection of the safety case is another question. As we interpret the IAEA statements, it should not.

Further, it is not clear that the relative equity of different standards can be judged by a simple comparison of the allowable doses. We discuss in the preamble to the final amended standards, and in Sections 2 and 4 of this document, the personal Senate testimony of NAS committee chair Robert Fri. As we noted in those discussions, he stressed the importance of the receptor in constructing the standards, and indicated that the connection between the receptor and the compliance period may affect the level of conservatism in the dose projections (i.e., in his view, the RMEI effectively becomes a more conservative receptor as the compliance period is extended from 10,000 to 1 million years). As a result, he suggested that a 15 mrem/yr peak dose limit in our rule could be viewed as "overly conservative" from the NAS perspective and not consistent with the intent of the committee. In such a case, it must be considered whether such a conclusion would have implications for the appropriate expression of the principle of intergenerational equity. The importance of these remarks is in the recognition that judgments of "conservatism" or "equity" must be based on the overall character of the assessment, which is not determined by the dose standard alone.

We have provided generations up to 10,000 years with the same level of protection applicable to current activities. However, as the time period covered by the assessment increases, the level of uncertainty in dose projections increases, so that they can no longer be viewed in the same way. Without a comparable basis for judgment, the "protection" offered by the standard at widely varying times cannot be directly equated, even if the dose standard is the same. Our ability to provide assurance of protection in that sense is similarly diminished. It is not clear how comparison of "protection" can be made under such circumstances, although we conclude that, far from offering "equivalent protection," a 15 mrem/yr peak dose standard would be unreasonably restrictive and demand more than can be reasonably expected from performance assessment models when large uncertainties are present. In such a case, the protectiveness of the long-term standard on its own merits assumes primary importance. We can say with confidence that the 100 mrem/yr peak dose standard being established today will protect public health and safety for the period between 10,000 and 1 million years, and protection comparable to that provided by the 15 mrem/yr standard for the first 10,000 years, even if it is not possible to state that the protection is equivalent in all respects (or, indeed, whether it is greater or less) to the 15 mrem/yr standard applicable for the first 10,000 years.

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Section 10 Compliance Period

1. I protest the folly of this EPA proposed public health standards for the planned high-level radioactive waste disposal facility at Yucca Mountain, Nevada to attempt to protect public health for 1 millions years. It is not within the foreseeable future scientific capabilities to identify all possible adverse geologic and societal events that may occur in the next million years; much less to take actions that will protect public health. I do not know the source of the desire to protect the population of southern Nevada a million years from now. The idea of 1 million year public safety protection is pure folly and a waste of public funds. This EPA concept for public health should be dismissed as unreasonable and arbitrary and without foundation. (Comment 0090-1)

2. Whichever standard is applied it should be applied for all time. At no time now or in the predicted future should the release of radioactive materials be allowed to exceed these levels. (Comment 0091-3)

3. This proposed 1,000,000 year criterion is ridiculous and should not be promulgated. This will unnecessarily increase the cost of nuclear waste disposal. If other technologies were to be held to this standard, technological progress would cease. No doubt this is the desire of the uninformed eco-zealots who try to pawn this on us in the name of protection. Common household waste disposal does not even meet this standard. EPA must establish reasonable standards. Known civilization has only existed a small fraction of this proposed time. It is unreasonable to doubt that if we allow it to progress, that technologically advanced society could not solve any unlikely problems that result from this waste storage a thousand years from now. (Comment 0093-1)

4. I find the extension of the time from for the Yucca Mountain rules to one million years to be absolutely preposeterous. The rules should apply no longer than the current life of the nation, about 200 years. By then, the people of the US, if such still exists, will probably not even be able to read, much less interpret, the rules. This is silliness in the extreme. (Comment 0094-1)

5. "NAS recommended standards that would apply to the time of maximum risk and stated that there is "no scientific basis for limiting the time period of the individual-risk standard to 10,000 years or any other value." The above statement is irrelevant with respect to the health and safety of the public. 10,000 years is a convenient threshold regardless of what the NAS or Nevada has to say. NAS and Nevada are entitled to an opinion. The opinion of both NAS and Nevada should be noted for the record, but rational decisions should made by the EPA, even if they are not directly in line with the hypothetical arguments. If this repository meets a 10,000-year criterion, then any rational adult would agree that is adequate. The age of the nation for practical purposes is 229 years (2005 - 1776). One million years translates to 4,367 times the age of the nation. To try to regulate anything to this magnitude of time is fairy tale. To try to predict anything to this magnitude of time is fairy tale. No nation has ever or will ever remain intact for this magnitude of time. To try to regulate in this arena is simply foolish. I recommend that no time periods past 10,000 years be used. Common sense should prevail. (Comment 0095-1)

1. The proposed compliance period is too severe as no human being can predict, nor should they attempt to regulate, outcomes past a few thousand years. The EPA should "Require that the design of the repository have a reasonable chance of success in resulting in a maximum dose of 15 mrem/year to the maximally exposed individual through 3000 years following disposal, based on the assumption that engineered containment of radionuclides will be successful in totally sequestering them for at least 1, 000 year**."** If you think about it, 3,000 years is the time human beings have been recording their activities in writing. In the past 10,000 to 15,000 years ice ages have occurred. It is arrogant for us to think we can subject a project to such long term requirements as the EPA is proposing. (Comment 0110-1)

2. This weaker standard sets radiation exposure at 15 millirems for the first 10,000 years, then increases to 350 millirems one day later. It is unprecedented for the to set expiration dates for public health standards; however, this is exactly what the new EPA proposed standard would do. (Comment 0111-2)

3. As a scientist/engineer who has worked with government agencies over the years, the thought that they can either assess and/or control and ensure the encapsulation safety of emissive material for even 1,000 years, much less 10,000 or (choking back laughter) 1-million years….No, I can't agree with these changes since I believe that the continued lack of competence already demonstrated gives one no confidence that the DoD/DoE/EPA are capable of doing anything in this area properly. (Comment 0114-1)

4. In addition, while a de facto time period of 10,000 years has been established internationally for protection from radiation, no such standard exists for any other toxic material or other risk. (Comment 0209.9-3)

5. Ten thousand years is an unimaginably long period of time for regulatory compliance. While NARUC does not agree that an extension beyond 10,000 years is warranted, we recognize the EPA has to comply with the D.C. Circuit's instructions on remand. (Comment 0217-3)

6. EPA's proposed rule presumes that the period of geologic stability is 1,000,000 years. While this may prove to be a reasonable limit to the performance assessment, what NAS actually said was that the period of geologic stability was "on the order of 10^6 years." NAS Report at 69. The rule should not absolutely preclude consideration of time scales in excess of 1,000,000 years if justified by considerations of geologic stability and the need to assess long-term performance of the natural barriers. (Comment 0226-118)

7. EPA is apparently aware that in the proposed rule, the true compliance period effectively ends at 10,000 years. In its discussion of deteriorating repository performance, the proposed rule notes that "[i]f 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)." 70 Fed. Reg. at 49028

(emphasis added). The reference to the "regulatory time period" in this sentence, contrasted with a point of time hundreds of thousands of years in the future, would be incomprehensible if EPA believed that the real compliance period extended through the period of peak dose. (Comment 0226-121)

8. Inclusion of any numerical 10,000 year dose standard is unnecessary, inappropriate and detrimental to the environment. The NAS report allowed the EPA to make decisions on the standard on policy matters and I believe that the 15rem/yr 10,000 year standard is sufficiently protective and all that is needed. EPA should, as a matter of policy, not technical bases, conclude that there is no need for a post 10,000 year standard. No other toxic materials are regulated beyond the 10,000 year period. Radiation has been on the earth since the earth began and Neanderthals roamed the earth just 30,000 years ago. Compliance projections beyond 10,000 years are not meaningful because of the uncertainties involved. They have little societal usefulness, except possibly to reject any repository site due to excessively expensive unendingly complicated regulatory proceedings. Society's resources would be much better utilized in addressing other more urgent environmental issues than arguing about multi hundred thousand year dose projections. (Comment 0264-2)

9. While in general I agree with the proposal put forward, I have some serious concerns about the usefullness of protection standards for periods far into the future. The reliability of projections even to 10000 years are hardly more than guesses as to the performance of the repository system. (Comment 0277-1)

10. All of these regulations should have the caveat of "as long as reasonably possible" added to them, in the event that current systems of government and regulation alter or cease to exist at some future time. (Comment 0277-3)

11. EPA has proposed standards that, from a conceptual standpoint, are protective of public health and safety. Yet, while promulgation of these standards represents progress toward the important national goal of safe and effective disposal of used nuclear fuel and other high-level radioactive byproducts, it does not constitute the most effective implementation of the court's mandate. Industry strongly believes that extending the repository regulation beyond 10,000 years does not represent sound public policy or effective regulation. Therefore, the nuclear energy industry opposes this proposal. (Comment 0298-1)

12. NEI reminds EPA that the court specifically offered the agency two possible approaches to address its finding. The first is the option that EPA has chosen, which is to revisit the standards. The second is to clarify the basis for the compliance period of 10,000 years either by seeking legislation from Congress, as the court specifically suggested, or alternately by following the roadmap for addressing the policy aspects of this issue also provided by the court. Although EPA has chosen to extend the compliance period, this is not the best way to address the court mandate. Since EPA has chosen to revisit the standard, NEI recommends that the agency follow the roadmap the court provided in its decision to overcome the deficiencies in the original rulemaking process and finalize the proposed standards so a 10,000-year period is retained. The legislative histories of the 1992

Energy Policy Act and 2002 Yucca Mountain Development Act clarify the intent of Congress to apply a 10,000-year compliance period for the Yucca Mountain repository. (Comment 0298-2)

13. Congress foresaw this potential problem in 1992. This is why Congress, through the EnPA, instructed the NAS to develop recommendations on "reasonable standards" including answering the question of whether or not the probability of human intrusion breaching the repository could be predicted "over a period of 10,000 years." In equating "reasonable" with 10,000 years in this instance, Congress was on very solid footing. The necessity of limiting regulatory compliance periods to reasonable lengths of time is widely recognized in the international regulation of hazardous material disposal. (Comment 0298-6)

14. Conversely, a 10,000-year standard provides ample protection for future generations for at least as far as we can reasonably foresee without placing an unreasonable burden on current and near-term generations. Furthermore, EPA's existing requirement for an analysis of longer-term performance in the Yucca Mountain Environmental Impact Statement provides for a meaningful look into the far future, without imposing an unreasonable quantitative compliance standard. EPA should heed its "great concern" about the implementability of such a million-year standard and pursue the path that remains open to clarify and reinforce its original policy decision to limit the period of regulatory compliance to 10,000 years. (Comment 0298-8)

15. EPA included a separate groundwater provision in 40 CFR 197 for policy reasons and the court agreed with EPA's rationale for doing so. Seen in that light, a properly grounded 10,000 year compliance period would be acceptable. In fact, the court in *NEI* outlined a roadmap for doing exactly that in suggesting that, by pegging the compliance period initially to that time when radiation dose reaches its peak, EPA may then proceed to methodically and logically develop a compliance period of 10,000-years…Properly grounded on the Academy's findings and recommendations and explained, a 10,000-year compliance period strikes an appropriate and proper balance between long-term coverage and implementability. (Comment 0298-9)

16. Such an approach, founded on the NAS's findings and recommendations, is not only consistent with the decision in *NEI*, it reflects just what Congress had in mind when in enacted the EnPA...In considering the Yucca Mountain Development Act, Pub. L. 107-200, Congress was well aware of the 10,000-year period for evaluating compliance. No concern was expressed with respect to this aspect of the Yucca Mountain program, nor was there any indication that such a period was at odds with what was envisioned in the EnPA or the subsequent NAS report. The NAS report itself, recognized that it was addressing only scientific matters and that EPA's rulemaking -- even as it accepted the NAS's scientific views -- could well be driven by policy considerations as well as pure science. (Comment 0298-11)

17. One important caution regarding any effort to set a dose limit a million years into the future is that just because the level chosen takes into account the inevitable variability of analytical results in the face of long-term uncertainties (while still being safe) does not

mean that the analysis, or any regulatory decision based upon it, will be meaningful. The reason for this is that there is a difference between precision and accuracy. While our analytical tools may be precise enough to evaluate radiation exposures to within hundreds of millirems a million years in the future, that still does not mean that the result will be accurate in any meaningful way. No matter how carefully we seek to be reasonable in defining assumptions, there is simply too much about the next million years that is not knowable, including the evolutionary status of the human race. Therefore, not only do we take no position on EPA's proposal of 350 millirems per year, but we would be unable to support any number EPA might choose. Again, we do not believe that the establishment of any quantitative regulation looking one million years into the future represents sound public policy. (Comment 0298-15)

18. We recommend that the new EPA radiation protection standard should remain in effect in perpetuity with no time limit. (Comment 0326-3)

19. Duke considers the key element of EPA's proposed standards, the million year dose limit for Yucca Mountain, to be inappropriate. The time frame involved is simply too long for effective regulatory implementation. One million years is orders of magnitude longer than the span of human civilization, and the changes that the world will see over that time span are impossible to reliably predict. A limit on projected doses for one million years would be a regulatory paperwork exercise, not a measure that protects public health and safety. Duke believes that EPA's previous regulatory framework, *i.e.*, a 10,000 year standard with a requirement to assess longer time periods in an environmental impact statement, was a reasonable and protective approach. Rather than promulgating a million year standard, Duke advises EPA to address judicial concerns by providing policy justification for the 10,000 year standard. If EPA should choose to promulgate a million year standard, the approach outlined in the proposed revision to 40 CFR Part 197 is generally reasonable. However, as noted above, the concept of the million year standard is inherently flawed, so there can be no good way of implementing it. (Comments 0330-1 and 340-1)

20. We further assert that it is futile and also foolish to try to plan complete protection for even the most exposed individual so far in to the future. Such an effort is completely inconsistent with the amount of effort expended on avoiding present and near term risks. For example, toxic substances, such as other heavy metals, are not even regulated for 10,000 yeas. If with present knowledge of climate and geology we are not setting up future populations for undue risk, that should be sufficient. (Comment 0350-2)

21. I believe that the 15 mrem/yr 10,000 year standard is sufficiently protective and all that is needed….there is no need for a post 10,000 year standard. (Comment 0351-2)

22. The proposed EPA rule presents an appropriate blend of technical and policy considerations to address the Committee recommendation that compliance with an individual radiation protection standard extend through the time of geologic stability, which, for Yucca Mountain, the Committee found to be on the order of one million years…Extending the regulatory period to address doses at the time of peak risk has the

potential to introduce arbitrary and unbounded speculation into the assessment of repository performance…In developing a regulation that deals with this unprecedented time period, EPA has quite properly considered not only the time period but also the related elements of the regulation, including: the level of protection, the requirements for the performance demonstration, and the appropriate statistical measure of performance. There is no scientific or policy basis for a presumption that a standard that is appropriate for 10,000 years would necessarily be appropriate for a time scale up to 100 times longer, with proportionately greater uncertainties. (Comment 0352-2)

23. I think that trying to set standards for a 10,000 year period is pretty iffy under the best of circumstances with the best of scientists with the best intentions. I think it's admirable to have some standards to try and (unintelligible) to try and set standards for a million years, I think passes ridiculous and I would hope that any standard that the EPA does set is (unintelligible) because things will change so much (unintelligible). (Comment 0364.1-1)

24. …the industry strongly believes that extending the repository regulation beyond 10,000 years is not sound public policy nor effective regulation. We, therefore, oppose the standard. (Comment 0368.8-1)

25. NEI recommends that EPA follow the road map that the court provided in its decision to overcome the deficiencies in the original rule making and finalize the currently proposed standards so that the 10,000 year period is retained. The legislative history supporting both the 1982 "Energy Policy Act," which set this regulation in motion, and the 2002 "Yucca Mountain Development Act" approving the site for further development and licensing makes clear that Congress meant for the compliance period to be limited to 10,000 years. The agency should act immediately to either seek clarification from Congress or reassert the original policy of 10,000 years as I have described. (Comment 0368.8-2)

Response to Section 10:

Many commenters consider the idea of regulatory standards applicable for 1 million years to be unrealistic. Various commenters characterized our proposal to regulate to such times as "folly," "unreasonable and arbitrary and without foundation," "ridiculous," "absolutely preposterous," "silliness in the extreme," "a fairy tale," "simply foolish," "arrogant," "unnecessary, inappropriate, and detrimental to the environment," "a regulatory paperwork exercise," "inherently flawed," "futile and also foolish," and "passes ridiculous." Some view 10,000 years with similar skepticism, and recommend a much shorter compliance period. Others recognized our reasons for making such a proposal, but disagreed that it was necessary to address the Court decision. A few commenters stated that the standards should apply beyond 1 million years.
Regarding periods beyond 1 million years, Comment 0326-3 states that the standard (at a level of 10-30 mrem/yr) "should remain in effect in perpetuity with no time limit." Similarly, Comment 0091-3 states, "Whichever standard is applied it should be applied for all time," although the commenter believes that the 15 mrem/yr standard is not protective, and should be reduced to 2.5 mrem/yr or even lower.

Comment 0226-118 notes that "what NAS actually said was that the period of geologic stability was 'on the order of 10^6 years.' The rule should not absolutely preclude consideration of time scales in excess of 1 million years if justified by considerations of geologic stability and the need to assess long-term performance of the natural barriers." Our final standards incorporate a compliance period of 1 million years, and no compliance standard applies to projected doses beyond that time. As with our 2001 rule, NRC will have to make judgments regarding the overall safety of the disposal system over very long times. We have not specified standards to apply beyond 1 million years, which we believe reasonably implements the NAS recommendation by equating 1 million years with the period of geologic stability, for the purposes of regulatory decision-making. We took NAS's phrasing of "on the order of" in the more colloquial sense of "approximately" (NAS Report p. 72) or "about" (NAS Report p. 85), rather than as a statement regarding "order of magnitude," as some have suggested. We note also the phrasing on page 91 of the NAS Report, where the committee again addresses the "boundability" of factors "in performance assessments that extend over periods on the order of *about* 10^6 years." (emphasis added) We believe our decision to define the period of geologic stability as ending at 1 million years is appropriate from a regulatory policy perspective and justified by site-specific scientific information. More discussion of geologic stability and our reasons for setting a regulatory time limit at 1 million years may be found at the end of this section and in of the preamble to the final rule.

The same commenter (in Comment 0226-121) suggests the "true compliance period" is still 10,000 years, citing references to the "regulatory time period" in our proposal. The commenter finds this "incomprehensible if EPA believed that the real compliance period extended through the time of peak dose." The commenter neglects the context in which these statements appear (70 FR 49028, Docket No. EPA-HQ-OAR-2005-0083-0042). The discussion addresses NRC's judgments using "reasonable expectation" as a guide to reaching its decisions. The paragraph preceding that cited by the commenter frames the context as "40 CFR part 197 as originally promulgated" and notes elements of regulatory compliance determinations left to NRC specification. The statement highlighted by the commenter refers to the difficulty presented in the licensing decision if "dramatic deterioration" is seen at a particular time in the future, which is generally true regardless of the length of the compliance period. That difficulty would certainly be enhanced if such deterioration appeared shortly after the end of the compliance period, rather than in the very far future. The following sentence reinforces the context: "With the initial issuance of 40 CFR part 197…" The next paragraph states "We propose to *continue* this general approach of not specifying the bases or mechanisms for a compliance decision, *except* that the post-10,000-year analyses are *now proposed* to be part of the 40 CFR part 197 standards with a quantitative limit imposed" (emphases added). We recognize that similar NRC judgments may be involved in evaluating projected doses shortly after 10,000 years under our final amendments, when the long-term peak dose standard of 1 mSv/yr (100 mrem/yr) is in effect. Theoretically, "dramatic deterioration" after 1 million years would also be of concern. However, we do not believe similar conclusions can be drawn or supported regarding the nature of disposal system evolution at such different times, nor do we believe it is appropriate to attempt such evaluations beyond 1 million years. We recognized in our 2001 rule that significant loss of containment within the initial 10,000-

year period, or shortly thereafter, would be potentially more significant, and required that longer-term projections be placed in the EIS to provide more complete information. By contrast, maintaining substantially complete containment until late in the 1 million-year compliance period or beyond would be indicative of a repository operating at a much higher level of performance.

Some commenters proposed alternatives for the period of compliance. Comment 0094-1 points out that the United States has only existed as a nation for about 200 years, and suggests this as an appropriate regulatory timeframe, since "the people of the U.S., if such still exists, will probably not even be able to read, much less interpret, the rules." Comment 0095-1 accepts the 10,000-year period, but similarly notes that "[t]he age of the nation for all practical purposes is 229 years. One million years translates to 4,367 times the age of the nation…No nation has ever or will ever remain intact for this magnitude of time." Comment 0110-1 recommends a compliance period of 3,000 years, "the time human beings have been recording their activities in writing," "based on the assumption that engineered containment of radionuclides will be successful in totally sequestering them for at least 1,000 years." Several other commenters expressed skepticism about the 10,000-year timeframe, but did not offer a specific alternative. For example, Comment 0114-1 questions the premise that even 1,000 years is achievable because "the continued lack of competence already demonstrated gives one no confidence that the DoD/DoE/EPA are capable of doing anything in this area properly." Comment 0277-1 characterizes projections to 10,000 years as "hardly more than guesses." Comment 0364.1-1 likewise states that "trying to set standards for a 10,000-year period is pretty iffy under the best of circumstances with the best of scientists with the best intentions." We recognize that the complexities involved in projecting performance for 10,000 years may not be fully appreciated when consideration of such times has become routine in radioactive waste disposal applications, and when the focus is shifted to times out to 1 million years. However, we have always applied the "reasonable expectation" approach to emphasize that "proof" of performance cannot be provided in the usual sense. Nevertheless, we believe that, in general, 10,000 years remains a reasonable period of regulation during which mathematical modeling of the disposal system can provide significant insights into its behavior (for example, its response when thermal stresses are most significant) and can serve as a basis for regulatory decision-making. We believe international experience, including that at WIPP, supports this approach.

Many comments expressed opinions that the idea of predicting conditions around the repository, or society in general, as well as disposal system performance and dose projections, over a period of 1 million years is untenable (Comments 0090-1, 0093-1, 0094-1, 0095-1, 0110-1, 0113-15, 0277-1, 0298-15, 340-1, 350-2, and 0364.1-1). The time frame for societal planning and forecasting is typically in the range of hundreds of years. Some comments point out that few nations have remained intact beyond a few hundred years without suffering periods of significant lapse in stable government, and that the history of organized societies only extends for thousands of years. These observations lead many commenters to conclude that attempting to "regulate" for 10,000 or 1 million years is simply a meaningless concept. We acknowledge the difficulties and uncertainties in making such predictions far into the future and we have attempted to factor these considerations into our standard. But we do not think the effort is meaningless. NAS clearly voiced the opinion that uncertainties are boundable and manageable and that performance assessments projections to the time of peak dose could be meaningful and useful for compliance decisions. We concur with this general finding and have included provisions in our final rule that we believe effectively respond to uncertainties and will make the compliance determination more meaningful.

Some comments expressed a concern that a compliance period of one-million years, from a societal perspective, was untenable because there is no certainty that an institutional presence can be assumed to exist and to actively "regulate" the disposal system so far in the future (Comments 0090-1, 0095-1, 0110-1, 0217-3, and 0227-3). These comments assert that the time horizon for predicting societal change and institutional stability/controls is only on the order of hundreds of years at most, and that the time frame for recorded history is only in the thousands of years. We understand the perspective in these comments and agree that an institutional presence far into the future cannot be assumed to be effective for actively "regulating" the disposal system. This same sentiment can be voiced for a 10,000-year compliance period as well. However, the intent of deep geologic disposal is to develop a waste disposal system that will perform acceptably in the absence of human monitoring and intervention. For the limited time frame of societal actions and stability, requiring a demonstration of acceptable very long-term performance in a regulatory process executed today is in essence an exercise of good engineering practice in a regulatory context. The tool for assessing performance of a deep geologic repository are the performance assessment calculations specified in the standard, i.e., the engineered repository is designed, in combination with the natural barrier, to perform acceptably over a period far in excess of what could reasonably, or even optimistically, deemed to be the period of institutional control, and therefore the time that government institutions can be expected to persist and to enforce regulations.

The fact that the demonstration relies upon modeling of the components of the disposal system that cannot be confirmed through measurement or observation introduces uncertainty into the judgment, but also ensures that each component will be subjected to detailed scrutiny. The NAS pointed out that the assessments should focus on the period of maximum risk whenever it occurs (within the geologic stability period), and our peak dose standard addresses this recommendation by requiring a demonstration of acceptable performance (disposal system performance assessments) over the period of geologic stability. We recognize the significant uncertainties involved in this demonstration and we believe we have constructed a reasonable test for repository performance at peak dose, as described in the preamble to the final rule and other discussions in this document. We believe that the peak dose requirement is sufficiently strict that the best science and engineering, within restraints of resource limitations, will be applied to the disposal system. NAS expressed a similar view in concluding that our standards need not address ALARA principles: "it is nothing other than sound engineering practice to consider whether reductions in radiation dose or risk can be achieved through engineering measures." (NAS Report p. 125)

We also received comments pointing out the disparity in regulation between radioactive waste and other types of toxic materials. Comment 0093-1 states that "[i]f other technologies were held to this standard, technological progress would cease…technologically advanced society [will] solve any unlikely problems that result from this waste storage a thousand years from now." This commenter and Comments 0209.9-3, 0264-2, and 0350-2 all made similar points that no other substances are regulated for periods beyond 10,000 years, even when such substances, such as heavy metals, do not decay over time. We used a similar justification in issuing our 2001 rule, citing this as the specific example offered by the NAS committee regarding circumstances in which policy considerations might justify a compliance period that did not extend to the time of peak dose. However, the Court of Appeals did not accept this reasoning as providing consistency with the NAS technical recommendation, rather than the committee's views on policy; therefore, we have established a compliance period that extends up to 1 million years.

Other commenters argued that we should try again to justify the 2001 standards as consistent with the NAS recommendation regarding compliance at the time of peak dose. Comment 0095-1 believes that the NAS statement regarding "no scientific basis for limiting the time period of the individual-risk standard" is "irrelevant with respect to the health and safety of the public." Further, "10,000 years is a convenient threshold regardless of what the NAS or Nevada has to say" and that EPA should make "rational decisions…If this repository meets a 10,000-year criterion, then any rational adult would agree that is adequate." Comments 0298-1, 0298-2, 0298-15, and 0368.8-1 assert that our proposal "is not the best way to address the court mandate" and "does not represent sound public policy or effective regulation." The commenter refers to the legislative history of the EnPA to support the contention that Congress intended a 10,000-year compliance period and "was well aware of the 10,000-year period for evaluating compliance" when it approved the site recommendation in 2002. The commenter recommends that we "clarify and reinforce [our] original policy decision to limit the period of regulatory compliance to 10,000 years." To do this, we would follow the "roadmap" outlined by the court that would begin with the NAS recommendation, "then proceed to methodically and logically develop a compliance period of 10,000 years," which "strikes an appropriate and proper balance between long-term coverage and implementability."

Our difficulty here, as we expressed in our proposal (70 FR 49032), is that we do not see that the D.C. Circuit ruling presented us with a clear "roadmap" to justifying the 10,000-year compliance period. We agree that the Court said it might have been a different case had we started with the NAS technical recommendation, and addressed our policy concerns from that starting point. Conceivably, that might have left us with a 10,000-year compliance period, but that is not the only conceivable outcome. However, the Court was not receptive to our policy arguments and reacted strongly to specific wording in our rulemaking, which led it to conclude that we had disregarded the NAS recommendation. We do not see a way of crafting the arguments that will dispel that impression, as the commenter suggests. Ultimately, as we stated in the proposal, "it is not clear how EPA's earlier explanation of its policy concerns might be reconciled with NAS's technical recommendation." The commenter further points out that "EPA included a separate groundwater provision in 40 CFR Part 197 for policy reasons and the court agreed with EPA's rationale for doing so. Seen in that light, a properly grounded 10,000-year compliance period would be acceptable." We disagree that these situations are comparable. The Court gave us deference to implement our ground-water protection policies in 40 CFR part 197 precisely because the NAS made no recommendation regarding such a standard, and our interpretation of the EnPA as providing us with the authority to establish such a standard was reasonable. By contrast, the individual-protection standard is at the core of the EnPA direction to us and the time over which compliance with such a standard should be assessed is a focal point of the NAS recommendations. Thus, the issue of consistency with NAS, which was the basis for the Court ruling, is fundamental to one aspect and irrelevant to the other. Our policy arguments have already failed to sway the Court. Therefore, we see extending the compliance period as the most appropriate approach in view of the language in the Court's decision and the weight accorded by the Court's decision to the committee's technical recommendations concerning the period of geologic stability. We believe we have appropriately "accommodated" our policy concerns in the provisions related to the peak dose standard, statistical measure of compliance, and FEPs.

Comment 0277-3 suggests that we should recognize the potential for future changes (or disappearance of) government and regulation. We are aware of the limitations of dose projection methodologies and the inherent uncertainties in projecting behavior of a disposal system over very long time frames, and we believe this understanding of uncertainty lies behind the commenter's phrase, "as long as reasonably possible." However, we believe the concept of geologic disposal already recognizes these potential changes. Licensing decisions are predicated on the acceptability of projected doses into the far future, not on what may be physically "possible" to measure or assess at various points in time. It is well-recognized that human behavior cannot be projected with confidence for more than a few decades to perhaps a hundred years into the future. A fundamental goal of geologic disposal is to provide a level of containment and isolation that will protect future human societies without imposing a burden on those societies to invest resources in maintaining the repository, or rely on their continued knowledge of its existence. To that end, the length of time for which institutional controls can be expected to prevent deliberate intrusions into the repository is limited.

A few comments agreed that our approach is a reasonable way to address the Court decision, even though they believe our 2001 standard included all that was necessary to protect public health. Comments 0217-3, 0340-1, and 0352-2 expressed this opinion, although, as Commenter 0340 put it, "the concept of the million year standard is inherently flawed, so there can be no good way of implementing it." Comment 0298-1, while disagreeing with the approach as discussed above, also stated that "from a conceptual standpoint, [the proposed standards] are protective of public health and safety," although "we [are] unable to support any number EPA might choose" to apply for 1 million years. This commenter and Commenter 0352 also stressed the difficulties in assigning meaning to very long-term projections. Comment 0298-15 notes the difference between precision and accuracy: "While our analytical tools may be precise enough to evaluate radiation exposures to within hundreds of millirem a million years in the future, that still does not mean that the result will be accurate in any meaningful way." Similarly, Commenter 0352 cautions that "[e]xtending the regulatory period to address doses at the time of peak risk has the potential to introduce arbitrary and unbounded speculation into the assessment of repository performance…There is no scientific or policy basis for a presumption that a standard that is appropriate for 10,000 years would necessarily be appropriate for a time scale up to 100 times longer." We discussed at length in our 2001 rulemaking and 2005 proposal our concerns regarding the usefulness of very long-term projections in making regulatory decisions, which was a principal factor in limiting the compliance period to 10,000 years in our 2001 rule. We believe the overall approach we have taken in this final rule to extending the compliance period appropriately considers these inherent difficulties and results in standards that are protective of public health, meaningful, implementable, and provide for a reasonable test of the disposal system that is consistent with the NAS Report, D.C. Circuit decision, and the principles of reasonable expectation.

Regarding our decision to equate the period of geologic stability with 1 million years, and to establish that time frame as the compliance period, we believe this is an appropriate decision for both regulatory policy and scientific reasons. We believe our policy decision is supported by NAS: "It is important, therefore, that the 'rules' for the compliance assessment be established in advance of the licensing process." (NAS Report p.73). We believe, therefore, as a matter of regulatory philosophy and policy, that a relatively loosely defined stability period "on the order of" one million years is not sufficiently specific for regulatory purposes, i.e., implementing our standards and reaching a compliance decision. Indeed, NAS clearly considered that the compliance period could be one of the "rules" that should be established for compliance assessments. (NAS Report p. 56) Comment 0226-118 suggested that the period of geologic stability could be longer (or interpreted "on the order of one million years" as possibly as long as ten million years), and said our rule should allow consideration of longer timescales if justified by considerations of geologic stability. The actual period of geologic stability at Yucca Mountain is unknowable, and we disagree that an open-ended compliance standard is justified over such time frames. We believe that the applicant (DOE) and the compliance decision-maker (NRC) must have definitive markers to judge when compliance is demonstrated, and that a loosely defined time frame does not provide such a marker for implementation of our standards in a licensing process. We believe that the geologic stability period of 1 million years that we have defined provides the necessary marker, and is within our discretion to set as a matter of policy. (See generally NAS Report p. 3) To do otherwise we believe would leave the licensing process in a potentially untenable situation of dealing with possibly endless debate over exactly when a peak dose occurs in relation to a compliance period time limit. Such debate can arise because of the inherent uncertainty that exists in characterizing the complex processes and variables involved in projecting performance of the disposal system over very long periods of time. As the NAS explained, "although the selection of a time period of applicability has scientific elements, it also has policy aspects we have not addressed." (NAS Report p. 56)

On this point, we are in general agreement with the international community, in which there is widespread acceptance of the proposition that quantitative performance projections at very long time frames have limited utility for regulatory decision-making, and that 1 million years may be a reasonable reference point beyond which such projections either should not be required or should be considered only in their broadest sense.[27] However, we believe it is also necessary to address NAS's scientific judgments regarding geologic stability at Yucca Mountain.

While NAS did not define with precision the period of time that the geologic environment likely would remain stable, for purposes of our regulation we believe scientific information can be relied upon to support a firm definition of that period as ending at 1 million years after disposal. Further, we believe that equating a specific time period with the "period of geologic stability" is a site-specific decision, as NAS's statements regarding geologic stability were wholly in the context of Yucca Mountain. (See, for example, NAS Report p. 69: "The time scales of long term geologic processes at Yucca Mountain are on the order of 10^6 years"; and NAS Report p. 85: "The geologic record suggests this time frame is on the order of about 10^6 years."). Therefore, we have considered how the natural processes and characteristics at the Yucca Mountain site would support defining the period of geologic stability, for regulatory purposes, as ending at a specified time after disposal. In considering the natural setting, many comments expressed the view that the site's natural characteristics are so conducive to rapid release and transport of radionuclides, only the waste packages and other engineered barriers would make it possible for significant doses to be delayed much beyond 10,000 years. We believe it is therefore also appropriate to consider the geologic stability period from the perspective of a reasonable length of time to allow significant events acting on the waste packages and engineered barriers, and ultimately leading to release of radionuclides, have a reasonable probability of occurring within the designated time period. Natural processes and events would contribute to both the package failures and to the subsequent transport of radionuclides, even if such failures occur relatively late in the period under consideration. It should be clear that we are not attempting to predict when geologic conditions at and around the site will have altered so dramatically that today's understanding of the site would be irrelevant to the conditions at such a time in the future. Rather, we view the period of geologic stability in this regulatory context to be a period long enough for natural FEPs projected to occur during that period, as defined by examination of the site's geologic record and the specifics defined in our

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[27] For example, in general guidance documents, the IAEA has stated that "little credibility can be attached to assessments beyond 10^6 years." ("Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories," IAEA-TECDOC-767, p. 19, 1994, Docket No. EPA-HQ-OAR-2005-0083-0044) In its final 2006 Safety Requirements for Geological Disposal of Radioactive Waste, IAEA also states "Care needs to be exercised in using the criteria beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making." (Docket No. EPA-HQ-OAR-2005-0083-0383, page 11, paragraph 2.12) As a country-specific example, final guidelines from the Swedish Radiation Protection Authority state that "the risk analysis should be extended in time as long as it provides important information about the possibility of improving the protective capability of the repository, although at the longest for a time period of one million years." (Docket No. EPA-HQ-OAR-2005-0083-0388) Also, in an example where the official guidelines specify a risk target that is of undefined duration, the United Kingdom's National Radiological Protection Board has stated that "[o]ne million years is…the timescale over which stable geological formations can be expected to remain relatively unchanged," while concluding that the scientific basis for risk calculations past one million years is "highly questionable." ("Board Statement on Radiological Protection Objectives for the Land-based Disposal of Solid Radioactive Wastes," 1992 Documents of the NRPB, Volume 3, No. 3, p. 15, Docket No. EPA-HQ-OAR-2005-0083-0416)

rulemaking, to contribute to a reasonable test of the disposal system by having their effects, if any, manifest themselves in the results of performance assessments during that period. Engineered barrier performance is the factor leading to consideration of periods as long as 1 million years.

A consideration of the geologic history of the site, in the areas of igneous and seismic activity, also supports a 1 million year stability period. Information compiled by the NRC (Docket No. EPA-HQ-OAR-2005-0083-0373) concerning basaltic igneous activity around the site shows that this type of activity has been the only activity around the site through the Pliocene (beginning roughly 5.4 million years ago), and that the volume of eruptive activity (both tuff and basaltic material) has decreased continually over the last 10 million years (Coleman et al., 2004, Docket No. EPA-HQ-OAR-2005-0083-0378). From the identification of surface features as well as indicators of buried remnants of past volcanic activity, the episodes of basaltic activity around the site can be shown to have occurred in clusters of events around 1 million and 4 million years ago (Hill, 2004, Docket No. EPA-HQ-OAR-2005-0083-0373). The occurrence of these clusters indicates that the nature and extent of past volcanic activity can be reasonably well characterized and that annual probabilities for such events can be reasonably estimated from the geologic record around the site. Annual probabilities of volcanic disruptions to the repository have been estimated by various investigators, and range from as high as 10^{-6} to as low as 5.4×10^{-10} (Coleman et al, 2004, Docket No. EPA-HQ-OAR-2005-0083-0378).

Further, while geologic stability may be viewed as being affected primarily by large-scale events, accumulations of small-scale changes over very long time periods also have the potential to alter the geologic setting and affect the technical basis for performance assessments. Tectonic events have such a potential at Yucca Mountain. Rates of displacement on the nearest potentially significant fault in the region average about 0.02 mm/yr. (DOE, Science & Engineering Report, 2002, p. 4-409, Docket No. EPA-HQ-OAR-2005-0083-0069) This means that in 10,000 years, there could be 20 cm (0.65 ft) of displacement, a relatively small change not likely to affect performance of the geologic system. However, in 1 million years, the same rate of movement results in 20 m (65 ft) of displacement on the fault. Using the larger estimates of movement within the range of potential movement, displacement could be as much as 30 m (100 ft) over 1 million years. Such changes in the geologic setting at Yucca Mountain have the potential to erode the scientific basis for performance assessment and possibly to affect the quality of the information the assessment can provide to decision-makers.

NAS also stated that "we see no technical basis for limiting the period of concern to a period that is short compared to the time of peak risk or the anticipated travel time." (NAS Report p. 56) This statement also suggests that the stability period must be long enough to allow FEPs that pass the probability and consequence screens to demonstrate their effects, if any, on the results of the performance assessments, even from waste package failures occurring relatively late in the period. In contrast to the accumulated small-scale changes discussed above, larger-scale seismic events are more likely to contribute directly to radionuclide releases through the effects of ground motion. Strong seismic events could damage waste package integrity by causing emplacement drift collapse or vigorous shaking of the packages themselves. It is known that damage to underground structures from seismic activity is significantly less than damage to surface structures for earthquakes of given magnitudes. Earthquake recurrence intervals for the site indicate that strong events could reasonably be assumed to test waste package integrity at various times within the 1 million-year period (Docket No. EPA-HQ-OAR-2005-0083-0374 and EPA-HQ-OAR-2005-0083-0379). The Yucca Mountain site is in a seismically active area and seismic hazard curves have been developed for the area (Docket No. EPA-HQ-OAR-2005-0083-0374). Studies of potential damage to emplacement drifts from seismic activity indicate that the threshold for damage lies at the mean annual exceedance frequencies between 10^{-4} and 10^{-5} per year (Docket No. EPA-HQ-OAR-2005-0083-0379). This means seismic events of sufficient magnitude to cause some damage to the repository itself have the probability of happening once over the course of ten thousand to one hundred thousand years. These exceedance probabilities correspond to earthquakes of approximately magnitude 6 and above (Fig 2-10, Docket No. EPA-HQ-OAR-2005-0083-0374), with ground motions varying between approximately 0.5 and 1.6 g (Fig. 2-12). Estimates of maximum earthquake magnitudes (magnitudes 7.5-8) in the area around Yucca Mountain (Fig 2-10) show that the annual exceedance probabilities for these high-end events are in the range of 10^{-5} and below. (Such an event would have the potential of happening on average once every 100,000 years.)

There is considerable uncertainty in estimating the annual exceedance probabilities for these very low probability, high-magnitude seismic events, and in estimating their actual potential for adversely affecting repository performance, as can be seen by inspecting Figures 2-10 and 2-12 from the DOE report cited above (Docket No. EPA-HQ-OAR-2005-0083-0374). We make no judgments on the evaluations of potential damage from these low-probability high-magnitude events. We do believe that, considering the high degree of uncertainty involved in evaluating their occurrence and effects, a 1 million-year stability period provides a time frame long enough for a reasonable test of their projected effects on waste packages and the overall performance of the disposal system.

In addition, we note that estimates of ground-water travel time from the repository to the RMEI location are on the order of thousands of years (see the BID for the 2001 final rule, Docket No. EPA-HQ-OAR-2005-0083-0050). At these rates, releases affected by disruptive volcanic and seismic events would not be delayed from reaching the RMEI location during the stability period, e.g., added releases from a low probability seismic event at 800,000 years would have ample time to be captured by the performance assessments. Based on these considerations, the 1 million-year period is a sufficiently long time frame to evaluate the potential consequences of both gradual processes and disruptive events on disposal system performance.

In summary, for regulatory policy as well as site-specific scientific considerations, we believe that fixing the period of geologic stability for compliance assessments at 1 million years provides a reasonable test for the disposal system performance. We believe a fixed time period is necessary both to provide a definitive marker for compliance decision-making and to prevent unbounded speculation surrounding the factors affecting engineered barrier performance and the ultimate timing of peak dose projections. Examination of site characteristics indicates that the influences of natural processes and events on release and transport of radionuclides would be demonstrated even for waste package failures occurring relatively late in the period. We believe that setting a 1 million-year limit is a cautious, but reasonable, approach consistent with the NAS position on bounding performance assessments for uncertain elements affecting disposal system performance. Finally, explicitly defining the period during which our standards apply will focus attention on times for which the geologic setting and associated processes are more quantifiable and boundable, rather than entering debate on disposal system performance in time periods where the fundamental geologic regime may have sufficiently changed so that the "scientific basis for performance assessment is substantially eroded and little useful information can be developed." (NAS Report p. 72)

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Section 11 Updating the Dose Methodology

Issue A: Agree with the proposal

1. I support the proposal to use radiation weighting factors and tissue weighting factors currently recommended by the ICRP to calculate the dosimetric quantity specified in dose criteria used in the regulations. EPA's justification for this change is technically sound. (Comment 0186-2)

2. NARUC agrees with updating the dose measurement methodology to current internationally agreed protocols as outlined in Section II.C.6. (Comment 0217-8)

3. We endorse EPA's proposal to use updated dose calculation factors…The National Commission on Radiological Protection (NCRP) has been urging the adoption of the newer dosimetry for years. The United States currently has no established policy regarding the updated dose conversion factors. Meanwhile, other nations have either wholly adopted the ICRP 60/72 approach or are in the process of doing so. The ICRP 26/30 approach is considered obsolete outside the US. Numerous countries have required the use of the most recent ICRP guidance in national legislation…Therefore, adoption of this methodology represents a good practice that will support a regulation that is both protective and stable that will not need to be adjusted in the future absent some major change in basic scientific understanding. (Comment 0298-23)

4. We also agree with revisions to the rule to be more current with international scientific protocols in dose measurement methodology. (Comment 0368.5-3)

Response to Issue A:

We have made some technical changes to the proposed methodology in response to comments addressed in Issues B and C below, but the same general approach has been followed.

Section 11 Updating the Dose Methodology

Issue B: EPA has misused the terminology – EDE and ED are not the same

1. As indicated in a previous comment, I support the proposal to update the tissue and radiation weighting factors used to calculate what EPA refers to as the annual committed effective dose equivalent. However, it seems silly to me to refer to this quantity as an "effective dose equivalent," rather than "effective dose," simply because the Energy Policy Act calls for use of the former quantity rather than the latter. Congress did not make a conscious choice here. EPA should be aware of two points concerning discussions of this issue in the Supplementary Information. First, ICRP Publication 26 does not use the term "effective dose equivalent." Rather, Publication 26 presents an equation to represent this quantity, but without giving it a name. The name "effective dose equivalent" does not

appear until Publication 28. What all this means is that the term "effective dose equivalent" refers only to the tissue weighting factors given in Publication 26. If any of the weighting factors are changed, the resulting quantity is not "effective dose equivalent. The second point is that the desire to avoid cumbersome terminology, such as "collective committed effective dose equivalent," was not the main reason for the ICRP's change to "effective dose" in Publication 60. The main reason was that the new quantity "effective dose" is quite different from the effective dose equivalent. Not only are the values of tissue weighting factors different, but they also have a different basis. Tissue weighting factors in the effective dose equivalent represent fatal cancers and hereditary effects in the first two generations only, whereas tissue weighting factors in the effective dose represent a combination of fatal cancers, non-fatal cancer incidence, length of life lost per fatal health effect, and hereditary effects in all generations. Thus, a different name clearly was needed to avoid confusion in communications. (Comment 0186-19)

Response to Issue B:

This comment is technically accurate in most respects, but a closer reading of ICRP 60 supports EPA's interpretation that effective dose equivalent (EDE) and effective dose (ED) are interchangeable concepts. ICRP defined two weighting factors in ICRP 26, the radiation quality factor, Q, and the tissue weighting factor, W_T. (Docket No. EPA-HQ-OAR-2005-0083-0425) In ICRP 60, the quality factor was replaced by the radiation weighting factor, W_R. Although defined somewhat differently, the value of W_R for alpha, beta and gamma radiation remained the same as for Q, i.e., 20 for alpha radiation and 1 for beta and gamma radiation. (Docket No. EPA-HQ-OAR-2005-0083-0421) In ICRP 26, the tissue weighting factor was presented as a rigid construct with *defined* values for specific organs. In ICRP 60, the tissue weighting factor was redefined as a set of *recommended* values for an expanded set of organs and it was explained that the attributes of the W_T include the components of detriment given by this commenter (fatal and non-fatal cancers, length of life lost, and hereditary effects). However, the ICRP makes a clear distinction between its renaming of the doubly weighted dose quantity from committed effective dose equivalent (CEDE) to effective dose (E) and its redefining of W_T. The association of EDE with the ICRP 26 tissue weighting factors is thus coincidental but not required. The following paragraphs from ICRP 60 support EPA's interpretation that CEDE and E are synonymous concepts:

> Para. 27: "…The weighted equivalent dose (a doubly weighted absorbed dose) has previously been called the effective dose equivalent but this name is unnecessarily cumbersome, especially in more complex combinations such as collective committed effective dose equivalent. The Commission has now decided to use the simpler name **effective dose**, E. The introduction of the name effective dose is associated with the change to equivalent dose, *but has no connection with changes in the number or magnitude of the tissue weighting factors. …*" [Italics added]
>
> Para. 31: "The values of both the radiation and tissue weighting factors depend on our current knowledge of radiobiology *and may change from time to time*. Indeed, new values are adopted in these recommendations. …It is appropriate to treat as

additive the weighted quantities used by the Commission but assessed at different times, despite the use of different values of weighting factors. The Commission does not recommend that any attempt be made to correct earlier values. *It is also appropriate to add values of dose equivalent to equivalent dose and values of effective dose equivalent to effective dose without any adjustments*. …" [Italics added]

In summary, EPA believes that the intent of Congress in specifying EDE is that the Yucca Mountain standards be based on a doubly weighted dose quantity, not that the assessment of that quantity be tied to old science. EPA uses EDE for consistency with the terminology used in the legislation, but adopts the current recommended values for W_T. Our approach is thus fully consistent with current ICRP recommendations.

Section 11 Updating the Dose Methodology

Issue C: EPA has omitted the dose coefficients in ICRP 72 making the proposed dosimetry update internally inconsistent

1. The Department recommends that EPA not specify weighting factors, but simply require that the calculation of doses be consistent with the International Commission on Radiological Protection (ICRP) 60 and 72 methodologies . The recommendation for the specific dosimetry system to be used needs to be internally consistent and include both radiation and tissue weighting factors. (Comment 0352-39)

2. EPA proposes "… to adopt updated scientific factors for calculating doses to show compliance with the storage, individual-protection, and human-intrusion standards…." EPA indicates that it accepts the ICRP 60/72 factors and any factors that may be produced in the future that are incorporated by EPA into Federal Guidance. EPA then proceeds to adopt the ICRP 60 radiation- and organ-weighting factors and give their values in EPA's Appendix A. By referencing ICRP 60 and ICRP 72, EPA gives an impression that it recommends that the Department use ICRP 60 radiation-weighting factors, organ-weighting factors, and ICRP 72 dose coefficients (which use radiation- and organ-weighting factors from ICRP 60). However, in its proposed rule and, in particular, Appendix A, EPA clearly recommends that only the new radiation and organ weighting factors be adopted, and makes no specific recommendation regarding the source of dose coefficients. EPA proposes to adopt the ICRP 60 and 72 radiation- and tissue-weighting factors and gives their values in EPA's Appendix A….NRC proposes to modify its rule "to include a definition for 'weighting factor' that conforms the weighting factors to be used in dose calculations to the values EPA proposes." In its rule, however, NRC proposes weighting factors "for an organ or tissue" (Part 63 .2, definition of weighting factor) and omits the radiation weighting factors that EPA proposes in Table A.1. (Comment 0352-40)

3. The set of tissue-weighting factors that EPA proposes in Table A.2 represents the most current recommendations of ICRP. It is based on recommendations of ICRP 60 with the addition of the extrathoracic region (ICRP Publication 66) and the clarification of tissue-weighting factors for colon and upper large intestine (ICRP Publication 69). The potential

problem is that dose coefficients (i.e., ICRP Publication 72 and Federal Guidance Report 13) consider a different set of organs. The Department, therefore, recommends that EPA not provide the list of tissues and organs but require that the calculation of doses be consistent with ICRP 60 and 72 methodologies. (Comment 0352-41)

Response to Issue C:

The comments suggest that the appendix should not include specific weighting factors, but state only that doses are to be calculated in accordance with the methods of ICRP 60 and 72. (Docket Nos. EPA-HQ-OAR-2005-0083-0421 and EPA-HQ-OAR-2005-0083-0427) The commenter believes this is appropriate because NRC's proposed licensing requirements specified using the tissue weighting factors, but did not mention the radiation weighting factors. (70 FR 53313, September 8, 2005) Further, the commenter points out that dose coefficients in ICRP 72 (and Federal Guidance Report 13, Docket No. EPA-HQ-OAR-2005-0083-0072) address a somewhat different set of organs than do the tissue weighting factors. We have not adopted the commenter's suggestion because we believe it could lead to questions regarding the appropriate factors to use. We note that ICRP 60, unlike ICRP 26, is not tied to a specific set of weighting factors, and allows for the possibility that users will substitute their own preferred set of factors. Stating only that the methods of ICRP 60 and 72 be used to calculate dose, without the additional stipulations in the appendix, would not provide sufficient clarity on this point. Therefore, we are adding language to the definition of "effective dose equivalent" in § 197.2 to the effect that NRC can direct that other weighting factors be used to calculate dose, consistent with the conditions presented in Appendix A. We believe this addresses the commenter's concern.

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Section 12 Ground-water Protection

1. The proposal abandons any long-term groundwater protection standard. (Comments 0103-2 and 0145-2)

2. At the time when the public faces the highest risk of radiation exposure, the EPA proposes easing the overall public health standard and throwing out the groundwater standard. Groundwater is acknowledged as the primary path of exposure; the time that exposure is at its greatest is after 10,000 years. (Comment 0111-3)

3. The ground water protection standard of 4 mrem per year should be extended to the time of peak dose. (Comments 0130-5, 0133-4, 0134-2, 0135-4, 0137-4, 0144-3, 0146-4, 0147-4, 0148-4, 0149-3, 0159-4, 0160-3, 0163-4, 0164-3, 0165-2, 0195-6, 0302-16, 0327-3, and 0341-9)

4. Although EPA will not consider comments on any aspects of groundwater protection standards in § 197.30 and § 197.31, discussions of those standards in the Supplementary Information surely must be open to comment. …. discussions in Section II.A.3 to support EPA's decision not to extend groundwater protection requirements beyond 10,000 years are weak on technical grounds. Furthermore, some of EPA's arguments are an affront to sensibilities of knowledgeable readers. For example, EPA claims that "protection of public health from releases to ground water over times beyond 10,000 years will be provided by extending the individual-protection standard to the time of peak dose." This essentially is an argument that EPA has rejected time and time again when NRC and DOE have used it to object to EPA's application of drinking water standards as groundwater protection requirements in regulating waste disposal or cleanup of contaminated sites. (Comment 0186-22)

5. In its earlier radiation rule for Yucca Mountain, EPA promulgated an independent groundwater protection standard that limits radiation in groundwater in an attempt to comply with safe drinking water standards established in the United States. In the proposed standard, EPA curtailed its groundwater protection after 10,000 years and subjects drinking and irrigation water in Amargosa Valley to unacceptable, dangerously high levels of radiation. Only through the abandonment of its responsibility to future generations is EPA able to forego protection of Nevada's groundwater. (Comment 0209.6-7)

6. In its earlier Yucca Mountain rule, EPA set a groundwater protection standard that limits radiation to groundwater available for human use, such as in Amargosa Valley, to levels required for safe drinking water throughout the country. In a proposed new standard, EPA ends that protection after 10,000 years leaving drinking and irrigation water with only the higher, unacceptable dose limit. Nowhere in its regulations or policies, except here, does EPA put a time limit on protecting the quality of our drinking water resources. And again, the collusion is obvious as DOE's performance models show Yucca Mountain will greatly exceed safe drinking water levels for radiation during the period of maximum releases. (Comment 0209.7-7)

7. Moreover, the logic of the Court's opinion, and the NAS recommendation upon which it is based, clearly indicate that EPA could not readopt the 10,000-year cutoff even if it did accept comment. The NAS rejected a 10,000-year cutoff because (1) it saw no scientific basis for drawing lines at 10,000 years; and (2) it realized that a 10,000-year cutoff would terminate the standards before the time of peak risk. That reasoning is just as applicable to groundwater protection as it is to individual exposure. The NAS already has concluded that the physical systems at the site, including all those that influence groundwater flow, are sufficiently predictable that there is no reason for cutting off compliance assessments at 10,000 years. And it has similarly noted that there is no sense in cutting off compliance assessments while the risk is just beginning to increase. Indeed, given DOE's assumption that no releases to groundwater will occur prior to 10,000 years, and EPA's ratification (through its agreement with DOE's assumptions about container corrosion) of that assumption, a 10,000-year-only groundwater standard would be nothing more than a public relations maneuver. For that reason, the NAS's recommendations and the Court's holding compel extension of the groundwater standard through peak dose. Indeed, the opinion is devoid of any suggestion that EPA, once it has decided it is necessary to provide a separate groundwater standard, could then adopt a period of compliance that the Court and NAS had expressly rejected. (Comment 0226-21)

8. EPA also fails to articulate any credible ground for terminating the groundwater standard that can be reconciled with its prior explanations of its groundwater protection policy, or with its statutory responsibility to promulgate standards protective of public health and safety…To excuse its early termination of groundwater protection, EPA insists in the proposed rule that public health protection from groundwater releases will be accomplished by extending the *individual protection* standard through peak dose. 70 Fed. Reg. at 49024. But, as discussed above, EPA's post-10,000-year individual protection standard is grossly inadequate. Application of the proposed 350-millirem (1000-millirem mean equivalent) standard to protection of public health from releases to groundwater would create the *lowest* level of protection, by far, ever proposed by a regulator, and would be contrary to the Agency's overall pollution prevention policies. EPA's explanation also cannot be reconciled with its responses to comments addressing earlier challenges to the separate groundwater standard. As EPA then explained, the individual protection standard is not a sufficient substitute for groundwater protection. Responses to Comment, 6-11, 6-12. As EPA counsel orally confirmed during the *NEI* litigation, EPA's separate groundwater standard "furthers the statutory goal of protecting public health and safety." January 14, 2004 Transcript at 59. And in *NEI*, as EPA correctly notes, the Court "concluded that [EPA's] reasoning for including such a standard as a means to protect the ground-water resource was sound and consistent with the Agency's overall pollution prevention policies." 70 Fed. Reg. at 49024. (Comment 0226-22)

9. By proposing to not establish a ground water protection standard after 10,000 years, the EPA is in violation of the NWPA requirement (above) to ensure that the environment is not adversely affected for future generations. (Comment 0263-5)

10. We urge EPA to adopt instead, a single, uniform protection standard for the entire projected life of the proposed repository, before and after 10,000 years, of 4 millirem for the groundwater protection standard. (Comment 0276-2)

11. The Safe Drinking Water Standard should also extend through this period [the period of peak risk, which is more like 300,000 years (according to DOE calculations)]. (Comment 0289-4)

12. The groundwater under Yucca Mountain provides drinking and irrigation water to the tens of millions of people who live in the Amargosa Valley and Southern California. (Comment 0293-3)

13. In its original rule, EPA's groundwater standard was set at 4 millirems per person per year for 10,000 years. The Court voided this standard. Yet, in its revised proposal, EPA leaves this standard in place, with no groundwater standard or protections after 10,000 years. (Comment 0293-4)

14. EPA has correctly concluded that "The Court's decision does not affect the ground-water protection standards" The court did not rule that EPA was required to promulgate a groundwater protection standard or that one was in any way necessary for consistency with the NAS recommendations, but rather that it was within the agency's discretion to decide whether or not to prescribe such a standard. EPA's proposal to not extend the existing groundwater protection standard represents an appropriate exercise of that discretion. (Comment 0298-22)

15. Under the new EPA proposed rules, it is not only 'permissible' to expose future generations to far higher doses of radiation than we would tolerate today, but it is also acceptable to deprive them of clean water. Compliance with the current Safe Drinking Water Act standard, which limits radiation in drinking water to 4 millirem/year, will only be required for the first 10,000 years if the rule is approved. In the period beyond 10,000 years, EPA switches to a 350 millirem/year all pathway exposure limit, which means that much higher levels of radiation could be allowed in drinking water. Water is a precious resource, especially in arid areas such as Nevada and southeast California, and will require more protection as time goes on. Yucca's radioactive wastes will likely leak into the underlying drinking water aquifer, which will become the primary pathway for harmful doses to people downstream. The Safe Drinking Water Act standard should be applied to protect Yucca's aquifer and the people downstream for as long as the high-level radioactive wastes remain hazardous, hundreds of thousands of years into the future. (Comment 0301-9)

16. Drinking water standards are based on people not drinking water (for one half of their daily liquid intake). How insane is that? Do the cows and pistachio trees, the jackrabbits and creosote brush which we use for anti-cancer medicine, all go to Safeway for Coca-Cola to drink every afternoon? (Comment 0306-4)

17. EPA posits that the Court ruling did not address the ground-water standard compliance period. The Court vacated the rule premised on a central point: “40 CFR 197 to the extent that it incorporates a 10,000 year compliance period because, contrary to EnPA section 801 (a), that compliance period is not based upon and consistent with the recommendations of the NAS.” The Court did not separate out the ground-water standard and its attendant compliance period for special, more lenient treatment in terms of consistency with the NAS recommendations. Refusal to take comment on the matter runs afoul of the Administrative Procedures Act to allow for public notice and comment. (Comment 0311.1-13)

18. In light of DOE’s conception that no waste will leak from the containers for the first 10,000 years, the provision of a ground water standard in the first instance is an apparition, and devoid of any meaning. EPA’s concession to the limits of the engineered barriers and the inherent weakness of the Yucca Mountain geology as a waste isolating system serves to highlight the absurdity of its draft rule. The performance assessments make it clear that the two-tiered approach is a mockery of the concept of protective standards by neutralizing the 15mrem/yr standard and the 4 mrem/yr ground-water standard prior to the time they are most needed, which also avoids their affecting the design of the site or threatening its viability. (Comment 0311.1-14)

19. Another casualty of EPA's proposed rule is the Safe Drinking Water Act equivalent standard limiting radiation in drinking water to 4 mrem/yr, which EPA would only enforce for the first 10,000 years, but would then replace with the 350 mrem/yr all pathway exposure limit. Water is a precious resource, especially in and areas such as Nevada and southeast California - Yucca's watershed -- which will require more, not less, protection as time goes on. Yucca's radioactive wastes will leak into the underlying drinking water aquifer, which will become the primary pathway for harmful doses to people downstream. The Safe Drinking Water Act standard should be applied to protect Yucca's aquifer and the people downstream for as long as the high-level radioactive wastes remain hazardous, hundreds of thousands of years into the future. The 4 mrem/yr radiation dose limit for Yucca's underground drinking water supply that EPA currently proposes to end at 10,000 years should be applied all the way out to peak dose, hundreds of thousands of years into the future. (Comments 0324-9 and 0324-14)

20. If, as EPA states on page 49018, column 3, that "There are two major aquifers beneath Yucca Mountain. Regional ground water in the vicinity of Yucca Mountain is believed to flow generally in a south-southeasterly direction," then the massively leaking dump would threaten Ash Meadows National Wildlife Refuge, an internationally recognized gem of biological diversity just 25 miles or so south/southeast of Yucca Mountain, home to several species of endangered desert pupfish (such as the Devil's Hole pupfish) found nowhere else on Earth. This would be in addition to the dangers presented by massively leaking radioactivity to the Amargosa Valley agricultural community south of Yucca, which utilizes Yucca's groundwater for drinking water and irrigation water. (Comments 0324-18, 0324-23, and 0324-24)

21. If the repository is licensed, a ground water monitoring program should be developed to evaluate potential impacts in California. In addition, a ground water contamination mitigation, clean-up and decontamination plan should be developed prior to beginning waste emplacement in the repository. (Comment 0326-4)

22. The proposed standards should be revised so that the time frame for the ground water protection standard is the same as the individual protection standard (at least 1 million years). However, since the individual protection standard includes the ground water pathway, the compliance period for both standards (individual protection standard and ground water standard) should be the same and should include the time period when maximum risk to the public and environment will occur. EPA should revise the proposed standards so that the separate ground water standard extends at least to 1 million years, in order to be consistent with the individual protection standard, and includes the period of maximum risk to the public and environment. The effect of this change would be to adopt a more scientifically acceptable and consistent standard to protect public health and the environment. (Comment 0326-8)

23. Section I.bb., Page 49020 - The Yucca Mountain site is in an area of numerous faults, that have had activity as recently at June of 1992 (5.6 magnitude earthquake, 12 miles southeast of the project site). The rule does not explain how the 10,000-year time frame is "within the period of geologic stability." Board staff is conceded that the rule terminates at the end of the 10,000-time period, and does not set any standard on the ease of radiation beyond the time frame. The rule basically sets a time period to protect water quality, and after that time period the proposed rule does not provide beneficial use protection. What problems will arise by setting the standard for a 10,000-year time frame, i.e., what will happen after 10,000 years? (Comment 0326-9)

24. Section II.A.1., Page 49023 - The proposed rule indicates that "Assumptions regarding the possible uses of ground water are quite speculative and have been avoided to the extent possible in the setting of the standards." Board staff is concerned that the possible uses of groundwater have not been addressed in the proposed rule. In a Regional Board letter to the California Energy Commission (dated January 10, 2000 - see Attachment), Board staff indicated that groundwater appears to move through the saturated zone from Yucca Mountain to the accessible environment (i.e. surface springs near the Death Valley region - 20-30 km away) in less than the 10,000-year regulatory compliance period. Regional Board staff comments on this issue have not been addressed. (Comment 0326-11)

25. lnyo County contends that the EPA's radiation protection standards for the proposed repository are unacceptable, since they would allow for the contamination of those aquifers that support human populations and federally protected natural habitat in both the Armargosa Valley and Death Valley National Park. (Comment 0326-13)

26. A major concern about these weakened standards is the issue of water. …. Yucca's radioactive wastes will leak into the underlying drinking water aquifer, which will become the primary pathway for harmful doses to people downstream. The Safe Water Drinking Water Act standard should be applied. (Comment 0349-5)

27. The actual effect of this rule is that while the 350 millirems per year is "'all pathways," the radiation will be in the water… [O]ne of [Yucca Mountain's] major weaknesses is that the radioactivity could be in the water and would not be diluted so that it could direct effect humans, unlike radiation leaking into a large river where the effects would be greatly diluted. EPA has not directly stated that the groundwater standard, which is 4 millirems *per* year prior to 10,000 years, will in effect jump to 350 millirems per year due to the nature of the site. The proposed EPA rule should explain why 4 millirems per year is protective up to 10,000 years, and then 350 millirems per year is protective, from just after 10,000 years to one million years. (Comments 0353-6 and 0361-6)

28. EPA chose to abandon its Safe Drinking Water Act standard for drinking water contamination (4 millirems per year) after 10,000 years. It set the maximum contaminant level at a dangerously high 350 millirems per year. The rationale which EPA uses to justify its rejection of drinking water standards is the fact that the Court did not *specifically* state that groundwater protection standards *must* extend beyond 10,000 years. EPA states that such a decision is solely at its discretion. Yet if the standard is 4 millirems per year for the first 10,000 years, it logically follows that this standard should continue or become more stringent during the time of peak risk after 10,000 years. For the health and safety of future generations, we urge EPA to include a radiation standard for groundwater which conforms to the standards of the Safe Water Drinking Act. (Comments 0360-5 and 0363-5)

29. Although radiation standards for groundwater contamination from Yucca Mountain are relevant to the health and safety of future generations, EPA refuses to consider any comments on groundwater protection standards. We also request that comments on the groundwater standard be accepted and considered in the Final Rule. (Comments 0360-6; 0363-6)

30. What is the groundwater standard for the first 10,000 years and why isn't there one after that? (Comment 0367.1-13)

31. What scientific justification is there for limits on radioactivity in water? (Comment 0367.2-2)

32. Again, we believe you should apply the "Safe Drinking Water Act" throughout if we imagine that human exposures will be the same whether you're in Nevada in our time or in future generations. … we also urge you to enforce a separate ground water protection standard of less than four millirem per year with a period beyond 10,000 years. (Comment 0368.2-4)

33. Incredibly EPA is proposing to arbitrarily abandon its ground water standard after 10,000 years at the point when the ground water will become increasingly contaminated according to DOE's models. The ground water standard is integral to the protectiveness of the overall radiation standard and EPA should extend the ground water standard to one million years and must take into consideration all public comments on this issue. (Comment 0368.6-5)

34. EPA has declared that since it is not modifying ground water standards that it does not have to consider public comment on this vital aspect of the proposed regulation. Simply because the court decision allows EPA to set a ground water standard does not mean the agency is exempt from considering public comment on its decision to not extend the ground water standard to one million years. (Comment 0368.6-6)

35. The "Safe Drinking Water Act" standard should be applied to protect Yucca's aquifer and the people downstream for as long as the high-level radioactive waste remains hazardous which, of course, is hundreds of thousands of years into the future. (Comments 0368.7-3 and 0368.13-6)

36. Now the EPA proposes a new standard which compounds this problem by doing away entirely with the water standard after 10,000 years and setting a radiation level that throws out decades of precedent-setting policy embedded in EPA's drinking water limit of four millirem, air emission of ten millirem, or Superfund cleanup to three millirem. The "Safe Drinking Water Act" standard should be applied to protect Yucca's aquifer and the people downstream for as long as the high-level radioactive wastes remain hazardous hundreds of thousands of years into the future. (Comment 0368.9-2)

Responses to Section 12:

Several comments expressed the opinion that we should take comment on the ground-water standard (Comments 0186-22, 0360-6, 0363-6, and 0368.6-6). We did not propose to extend the compliance period for the ground-water protection standard beyond the 10,000-year time frame in our 2005 proposed standards and explicitly stated, “We are not proposing to change any aspect of the ground-water protection standards….we are not requesting and will not consider public comment on either the storage standard or ground-water protection standards.” (70 FR 49022, August 22, 2005). Therefore, as these comments are outside the scope of this rulemaking, we are not responding to them. (We note, however, that we have addressed legal concerns related to this decision in Section 24 of this document.)

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Section 13 Tribal-related Comments

1. I ask you to reconsider and stop the recurrent disregard for the sovereignty of the Native American nation and the sanctity with which they regard this mountain. (Comment 0118-1)

2. Then there is the question/issue of damage to the First Nations near Yucca Mountain. Years ago, a stop was put to similar foolishness on First Nation's sacred ground in Nevada. Now is not the time to overturn those nobler motives. (Comment 0123-2)

3. I want to protest the Yucca Mountain nuclear waste disposal site since it is a sacred site to the indigenous people who live in the area. (Comment 0125-1)

4. The most egregious claim is the assertion that this proposed standard has no tribal implications. Executive Order 13175 forces the agency to develop a process to receive input from tribal governments on any potential impact this standard may have. The EPA arrogantly ignores this order by declaring the proposed rule will have no substantial effects on one or more tribal governments, or on the relationship between the Federal Government and Indian tribes. This is absolutely absurd. Yucca Mountain sits on the sacred land of the Western Shoshone people and WILL adversely affect the indigenous population in surrounding areas. (Comments 0130-8 and 0195-9)

5. The Yucca Mountain proposal is unsound and definitely has disastrous "tribal implications." (Comment 0140-1)

6. I believe that Native Americans have suffered enough without the dumping of toxic wastes on their land. (Comment 0162-1)

7. We believe the proposal to bury 77,000 tons of high-level radioactive waste on geologically unsuitable, sacred Western Shoshone Indian land at Yucca Mountain, Nevada, is dangerous and ignores the indigenous people on those lands. (Comment 0164-6)

8. There should be meetings held in their sovereign territory (Indian territories), especially on transportation issues. (Comment 0173–2)

9. Also, another thing that's occurred is the people that have come in from tribes to speak. I heard several times where you've said, Well, we can have a separate conversation with you about what's happening. Well, it's their land. I'm also told that they have radiation standards, and they have good ideas about how to manage the land, and they've never been spoken to. (Comment 0209.2-2)

10. I first want to request an additional 30 days to comment on behalf of the tribes. I would, myself, view that as an act of trust, responsibility exercised by the EPA. And no less is expected by the tribes, I'm sure, with ties to Yucca Mountain. (Comment 0209.5-1)

11. I think it's important that the EPA clarifies how it constructs risks so that it's culturally -- culturally appropriate context for risks, threat, or hazard to the vulnerable population that

is developed, as well as health communications strategy, to communicate those risks to the tribes in a way that they understand. I think that right now there's a particular class of individuals that are being disenfranchised and that is a vulnerable population. (Comment 0209.5-2)

12. Even though the EPA has spent a lot of time going around in having meetings with us, it doesn't sound like you did much on the American -- the Native-American front. So it appears that you're going to have to go out to Moapa. You may have to go to Duck Water. You may have to go to Death Valley. There are tribes and Indian nations here that need to be a part of this. And as been mentioned before, they need to be a big part of it, and it needs to be a government-to-government sort of process. And you may as well take the NRC with you as well because I don't think they've been out there either. And they're now in the process of revising their regulations too. (Comment 0209.14-3)

13. Down in the reading a little bit, in the paragraph that says: This proposed rule does not have tribal implication as specified in executive order. The rule proposals today will regulate only that DOE owns the land owned by the federal government. The rule proposed today does not have substantial direct affect on one or more Indian tribes.

Well, I wrote here two words. I strongly disagree with that because in the valley here, we have Las Vegas Paiute tribe, and close to us, we have Moapa Paiute tribe. And in this region, Region 9 of the EPA, we have 154 Indian tribes. Some of them close to Death Valley, some of them north of here. And if we consider the State of Nevada, according to the law, the Nuclear Waste Policy Act, as affected state, some of these tribes are affected tribes. (Comment 0210.5-1)

14. You need to start thinking about having public meeting with the governments of and the peoples of the Native American tribes. The U.S. government has a trust responsibility. (Comment 0210.5-2)

15. I'm from the Las Vegas Paiute tribe….Nobody knows, like we say, in a million years what's going to happen. And I know there's a lot of people who have -- who are educated and talk about this and that. But we don't know. I mean, no one knows in 100, 300, 400 years from now what's going to happen. Who knows if we'll all be here? But still, we need to protect the public plus the ground water that comes through the Test Site. It comes all the way to Vegas. So we need to make sure that that doesn't -- is polluted with radiation. And just thank you for letting us talk and letting me talk but, please, you know, help us and make it a better -- or make a very good judgment to all of us American people plus the natives too. (Comment 0210.7-1)

16. The government is doing what its always done; disregarding the Indians and breaking treaties. (Comment 0210.8-1)

17. The most egregious claim set forth by the EPA is their assertion that this proposed standard has no "tribal implications." Executive Order 13175 forces the agency to develop a process to receive input from tribal governments on any potential impact this standard may have. I have personally participated in annual Renewal Ceremonies on Yucca Mt.'s

western flank for many, many years. Native people continue to use medicinal plants from the region, to hunt and gather as they have for thousands of years. The EPA ignores Order 13175 by declaring the proposed rule will have no "substantial effects on one or more tribal governments, or on the relationship between the Federal Government and Indian tribes." This is absolutely unacceptable. (Comment 0306-13)

18. EPA also states "This proposed rule does not have tribal implications. . . and does not have substantial direct effects on one or more Indian tribes, [or] on the relationship between the Federal. Government and Indian tribes . . .". This is preposterous. Yucca Mountain is sacred and still used as a ceremonial site by the Western Shoshone Indians, who retain rights to the land under the Treaty of Ruby Valley signed by the US government in 1863. The Western Shoshone traditional lifestyle, lived at and near Yucca since time immemorial, may again return to that area someday. In fact, the Western Shoshone Indian traditional lifestyle was lived at and near Yucca for thousands and tens of thousands of years until contact with. European Americans in the late 1800s. Western Shoshone continued to hunt and gather at and near Yucca until the U .S. military and Atomic Energy Commission seized the land and established the Nevada nuclear weapons test site in 1951, just 55 years ago. How old is the "rural/residential" lifestyle near Yucca of which EPA speaks? 25 years old? The duration of the European American lifestyle as currently lived at and near Yucca is a mere blip in the history of the Western Shoshone people and their homeland. The Western Shoshone traditional lifestyle could mean far higher doses than EPA's "reasonably maximally exposed individual" living a "rural/residential" lifestyle would be exposed to. That EPA claims its proposal does not significantly impact Native American tribes clearly reveals its ignorance of the decades-long and extensive involvement of the Western Shoshone National Council, as well as other -federally recognized Western Shoshone tribes and bands and other tribes and bands, in. striving to protect traditional homelands and treaty-recognized lands against radioactive contamination due to nuclear waste dumping as well as other atomic activities in the Yucca Mountain area . This is a violation of the U.S. federal government's responsibility to relate with Native American tribes as sovereign governmental entities, on a government-to-government basis. (Comment 0324-11)

19. The EPA also asserts that this standard has no "tribal implications." Executive Order 13175 forces the agency to develop a process to receive input from tribal governments on any potential impact this standard may have. It appears as though the EPA has arrogantly ignored this order by declaring that this rule will have no "substantial effects on one or more tribal governments, or on the relationship between the Federal Government and Indian tribes." How can you say this when Yucca Mountain sits on the sacred land of the Western Shoshone people and WILL adversely affect the indigenous population in surrounding areas? (Comment 0328-8)

20. It (the standards) puts future generations at risk – especially Native Americans in Nevada. (Comment 0336-2)

21. The EPA is endangering our native people as well as all U.S. children for generations. (Comment 0342-2)

22. We would like to thank Betsy Fornash of EPA for responding to our request for consultation. Because of the lateness of EPA's attempts at consultation, we requested an extension of time for tribes to register their comments. It is also appreciated that Betsy Fornash responded by extending the comment period for tribes from November 21 to December 31, 2005. This is a good faith effort to make up for the lateness of the consultation process. This now provides the opportunity for actual government-to government consultation. We hope that in the future EPA will initiate consultation as early as possible when its actions may effect tribal ancestral territories as well as reservations. Even though (according to EPA) the proposed radiation standard does not apply to Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments"), EPA has now recognized that the more broadly worded EPA Indian Policy should be its guidance: "The agency, in keeping with the federal trust responsibility, will assure that tribal concerns and interests are considered whenever EPA's actions and/or decisions may affect reservation environments." (Comments 0360-1 and 0363-1)

23. Value Mountain on a spiritual level. (Comment 0367.1-16)

24. Tribal people nearby Yucca Mountain bear a disproportionate burden for the radioactivity that comes from the nuclear waste. (Comment 0367.2-18)

25. The Government does not protect Native Peoples from radiation. They cannot “just move away.” (Comment 0367.2-19)

26. There should be an additional 30 days for tribal people to consult with EPA – and a meeting in Elko. (Comment 0367.2-25)

27. The Federal Register states that this ruling does not affect tribes – which is wrong. (Comment 0367.2-27)

28. The comment period needs to be extended for a long time in order to engage tribes who don’t use the science that government uses. (Comment 0367.2-28)

29. Yucca Mountain is also located on native land, which is a particular concern to many of our constituents, which belongs to the Western Shoshone by the "Treaty of Ruby Valley." The Western Shoshone National Council has declared this land a nuclear free zone and has demanded an end to nuclear testing and the dumping of nuclear waste on their land. We support the claims of the Western Shoshone to their sovereign land which they hold as sacred and we believe that the revised radiation standard is a form of environmental racism that will disproportionately harm the lands and health of the Western Shoshone people. (Comment 0368.7-2)

Response to Section 13:

EPA recognizes the importance of government-to-government consultation with Tribes and the significance of the Tribes as sovereign nations. During the comment period, EPA believed that it was important to get input from the Tribes in Nevada and nearby States and contacted more than 20 Tribal governments to discuss the updated standard. At the Tribes' request, we extended the comment time for the Tribes from November 21 to December 31, 2005.

Comments 0173-2, 0209.2-2, 0209.5-1, 0209.5-2, 0209.14-3, 0210.5-2, 0210.7-1, 0210.8-1, 0360-1, 0363-1, 0367.2-25, and 0367.2-28 are concerned with EPA's interactions with the Tribes. In response to these comments, EPA held three conference calls in November 2005 with members of Tribal governments. Also, Tribal members testified during public meetings, and EPA received nearly 30 comments on Tribal matters.

EPA's role at Yucca Mountain is to set the radiation protection standards for the potential disposal system. Comments 0118-1, 0123-2, 0125-1, 0140-1, 0162-1, and 0164-6 imply that EPA has the ability to stop the potential siting and operation of Yucca Mountain. That is not the case. We have no authority to determine whether the Yucca Mountain disposal system is sited or licensed. The only authority that the Energy Policy Act of 1992 gave us was to establish radiation protection standards for Yucca Mountain. Siting and licensing are the responsibility of DOE and NRC.

We understand the concerns that Native Americans have relative to releases from Yucca Mountain (Comments 0336-2, 0342-2, 0367.2-18, 0367.2-19, and 0368.7-2). However, we have found no evidence that Native Americans would bear a disproportionate burden of the potential radiation exposure from releases from Yucca Mountain. EPA has set these standards to protect human health and the environment, including tribal members. We still believe what we stated in response to similar comments in our 2001 Response to Comments document (pp 1-39 to 1-40, Docket No. EPA-HQ-OAR-2005-0083-0043):

> "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. DOE has not resolved the question of whether the carbonate aquifer would be contaminated by releases from the Yucca Mountain disposal system. 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."

In addition to the concerns in Comment 0368.7-2 regarding "disproportionate harm" that is addressed above, it states that the standards are "a form of environmental racism." EPA takes environmental justice issues very seriously, and we believe that we have established these standards impartially and as we were directed by Congress when it specifically authorized and directed EPA to develop such site-specific standards for Yucca Mountain in the EnPA.

Comments 0130-8, 195-9, 0210.5-1, 0306-13, 0324-11, 0328-8, and 0367.2-27 take issue with the statement in the preamble to the proposed standards, "This proposed rule does not have Tribal implications, as specified in Executive Order 13175. The rule proposed today would regulate only DOE on land owned by the Federal government. The rule proposed today does not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes." We still believe that this is true; however, we want to ensure that we fully meet our trust responsibilities. Therefore, as stated above, we contacted more than 20 Tribal governments to discuss the proposed standards. Also, at the Tribes' request, we extended the comment deadline for the Tribes from November 21 to December 31, 2005. We also held three conference calls in November 2005 with members of Tribal governments. Finally, Tribal members testified during public meetings, and left us with nearly 30 comments on Tribal matters.

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Section 14 Public Process, Interactions, And Outreach

1. Request that the comment period be extended to 180 days in order to allow full public participation in this process and that additional hearings be held in other parts of the United States. (Comment 107-1)

2. EPA is also trying to silence voices of opposition by limiting the comment period. It took EPA more than a year to put together this proposal, but the agency is giving the public less than two months to review hundreds of pages of documents and put its concerns on record. (Comment 0111-4)

3. The comment period for this proposal must be no less than 180 days. The rule should be published, and the public should receive notice of the hearing, at least 60 days before the date of the hearing. We also encourage EPA to hold hearings in Reno and Amargosa Valley as well as Las Vegas. (Comment 0205–2)

4. We noted a 60 day comment period. In meetings between Clark County staff and your staff and public outreach consultants, I understand. a comment period of at least 180 days was recommended.

The promulgation of an adequate radiation protection standard for the proposed Yucca Mountain nuclear waste repository is vital to the public health and safety of Nevada residents and visitors. We believe the radiation standard is a primary factor in assessing the adequacy of the Department of Energy's license application to the Nuclear Regulatory Commission. We appreciate the fact that you plan to hold two meetings in Clark County, and have directed our staff to assist you in finding an appropriate location to facilitate broad public participation and to promote attendance at your meetings. In addition to providing that opportunity, it is imperative that sufficient time be provided, to Nevada stakeholders, including Clark County residents, to have sufficient time to review the revised standard and prepare meaningful comments. We respectfully request that you grant an extension of time to respond to the proposed revisions to the standard for a full 180 days. (Comment 0207-1)

5. Before discussing our preliminary views of EPA's proposal, I'd like to acknowledge EPA for at least partially honoring our and other's request to extend the originally announced 60-day public comment period. Although we requested 180 days, the 30-day extension has resulted in a total of 90 days for public review on this complex proposal. We're disappointed, however, that the request to hold additional hearings in Northern Nevada or other parts of the state was denied by EPA. (Comment 0209.7-1)

6. When your staff and public relations firm met with us as stakeholders, I believe we made it clear that, above all, this was to be a very open process. You can imagine our surprise when the rules of the game were published, and the process was far from open. I chose to play by your rules this evening.

In representing the citizens of the state, I tested your process. I have yet to see any advertisements in the paper. I heard no PSA's, either on the radio or television, but I did see a reported story that, indeed, there was going to be a hearing. And I believe the Sierra Club mailed out 5,000 postcards to let people know that this was happening tonight.

That's not something that's in my budget. Your budget is far greater than mine, and I believe that job of informing the public is your job, not mine. (Comment 0209.13-1)

7. I've looked at the draft. I've read it carefully. And I've listened to you two nights' worth of the roundtables. And what I see and hear are people who are here to defend what they've done. We started out a long time ago with the DOE talking about the DAD syndrome, D-A-D. Decide, announce, and defend.

There is a lot more of defense of what you've done than any sort of willingness to hear, it appears. And that's why I ask that your answers be as short as the questions that were asked. Because we hear a lot of people defending what they've done, and we don't see any of what we're putting in being reflected in your final standard. (Comment 0209.14-1)

8. Finish reading the Napa document. It's full of -- read the synthesis, Reference 3, which you mentioned. It's all process, openness, legitimacy. But you never touched those. You quote them, but you don't do it, you don't give us an open process. And you haven't done one in regard to the making of this rule. (Comment 0209.16-3)

9. The public needs surety that EPA fully understands the health and environmental consequences of exposure to various levels of radiation. The proposed public health and environmental radiation protection standards for Yucca Mountain, Nevada, which are subject to Docket ID OAR-2005-0083 serve to confuse rather than reassure the public. (Comment 0211.1-8)

10. [Congresswoman Berkley] was among those who had requested that EPA add this third day of hearings in Las Vegas to allow as many people as possible to attend. So we thank EPA. She thanks EPA for making that possible and is glad that we had this additional day to talk about this important subject. (Comment 0211.8-1)

11. Objections to the short public comment time. Nevada proposed 180 days to fully comment on very complex proposal. No reason was given by EPA not to extend. (Comment 0226-71)

12. Citizen Alert sees the methods and actions of the EPA regarding the public as insulting and inadequate. Offering a meer 60 days for public comments is ridiculous for a standard of such importance and impact. While we appreciate the extension to 90 days, the comment period should have been at least 120 days, and there should have been public hearings across Nevada. Many other communities outside of Nevada also have a stake in the Yucca Mountain project and we feel that the EPA was also remiss in not having any hearings outside of Nevada other than in Washington DC. (Comment 0268-9)

13. EPA's 90 day public comment period is objectionably short, given the million years of consequences it portends. NIRS, as well as many other public interest and environmental organizations and concerned citizens, requested a much longer public comment period, such as 180 days, but were rebuffed by EPA. We also requested additional hearings across

the U .S., especially considering the broad precedent EPA's revisions could set, for future repositories in addition to Yucca, as well as, for other radioactively contaminated or even non-radioactively but toxic chemical contaminated sites across the country. Again, EPA rebuffed our modest requests. We protest EPA's disinterest in providing more widespread, reasonable, and accessible public comment opportunities for such a significant proposed regulation.

It has also been objectionable that EPA has met behind closed doors with the likes of DOE and NRC beginning very shortly after the July 9, 2004 court decision striking down EPA's original Yucca regulations. Such secretive meetings violate transparency and democratic principles, and leave the concerned public with the unmistakable impression that the federal agencies are conspiring to "cook the books" on the Yucca Mountain Project and its regulations. (Comment 0324-1)

14. EPA's public accessibility under this rulemaking has not always been as advertised. For example, the toll-free information line advertised on page 49016, column 2 of the Federal Register Notice, contained no message -- thus, was not operating, on October 3rd, 2005 - the very time frame when most needed, given the hearings taken place in Nevada that week, and the hearing to be held in Washington, D.C. just one week later. (Comment 0324-16)

15. Eureka County attended the public meeting and hearing that EPA held in Las Vegas on October 4, 2005, and participated in the roundtable discussion with EPA officials. We appreciate that the agency extended the public comment period by 30 days, and note that the longer 180 day comment period requested by the State of. Nevada would have been more appropriate given the complexity of the regulations and their long term effects. (Comments 0353-1 and 0361-1)

Response to Section 14:

EPA has conducted a full, open and appropriate process in this rulemaking, and has placed all relevant information in the docket (EPA-HQ-OAR-2005-0083), including the scientific justification for the rule, and taken many actions to notify and involve the public. In response to comments, we lengthened the comment period for the general public. Given the narrow focus of the rulemaking, we did not believe that it was necessary to extend the comment period to 180 days, but we did extend it to 90 days. Similarly, with the narrow focus of the rulemaking, we did not believe there was a need to issue an advanced notice of proposed rulemaking.

Both before and after the proposal, we met with a wide range of stakeholders as we routinely do when developing rules. We met with Federal agencies, including NRC and DOE, industry and environmental groups, the State of Nevada, and affected counties in Nevada and California to share basic information about the development of the standards and to make sure we were taking into account the full range of views, concerns, and technical issues. Some meetings with Federal agencies were necessary. For example, the Federal government as a whole had to decide whether to appeal the lawsuit ruling. We coordinated with NRC as a fellow regulator and, in accordance with Executive Order

12866, the Office of Management and Budget (OMB) of the Executive Office of the President reviews significant rules proposed to be promulgated by Federal agencies. The OMB's role is to coordinate the agencies' budget and policy bases, so we met with DOE and NRC as part of OMB's process. We also met with DOE, as we often do with regulated parties in rulemaking to understand technical issues and views. Our reasoning and all data supporting our proposed approach are public information and in Docket Number EPA-HQ-OAR-2005-0083.We notified the public of the hearings by advertising in Nevada newspapers, placing a notice in the *Federal Register* (70 FR 54325, September 14, 2005), putting an announcement on our toll-free information line (800-331-9477), distributing an announcement via our listserv, and posting an announcement on our Web site(http://www.epa.gov/radiation/yucca/up-to-date). The hearings were held on October 3, 2005 in Amargosa Valley, Nevada; October 4-6, 2005 in Las Vegas, Nevada (the session on October 6 was added at the request of the public); and October 11, 2005 in Washington D.C. Fifty-three people testified at the hearings. We did not hold hearings in other parts of Nevada or in other parts of the country. To ensure that as many citizens as possible had the opportunity to comment, we provided many avenues to submit comments. Connected with the hearings we held public information sessions in each location where people could speak with EPA personnel and ask questions informally; they could also leave hand- or computer-written comments or comments on a tape recorder. In Amargosa Valley and Las Vegas, there were also roundtable discussions where anyone could participate in a facilitated conversation with EPA staff to discuss the standards and allow opportunities for the public to ask questions of EPA staff, and for EPA to respond. A summary of key points and questions was recorded for the record.

Overall, we received about 2550 sets of comments that amounted to about 3000 pages of comments and 1100 pages of attachments. Comments were from a wide range of individuals and organizations: Nevada Congressional members; the Nevada Governor's office; counties; tribal governments; the States of Maine, Vermont, and California; nuclear industry groups; environmental and public interest groups; and DOE. There were many methods for people to submit comments in writing: electronically, via surface mail, by fax, courier or personally. Specific instructions and addresses were contained in the proposed rule and on EPA's Yucca Mountain web site at www.epa.gov/radiation/yucca. We reviewed all comments and considered them as we developed the final rule.

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Section 15 EPA's Role and Responsibility

1. EPA "plays God" here as if you have the right to decide what doses future generations should be allowed to be exposed to. This is wrong. (Comment 0113-5)

2. It is the responsibility of EPA to promulgate a standard that assures that deadly high-level radioactive waste is truly isolated from the human and natural environment. (Comment 0209.6-9)

3. And I would just finish by saying that the EPA's job is not to worry about the performance of the repository, not to worry about DOE's uncertainty, not to worry about DOE's burden of getting a license. Your job is to protect the public health and safety. If Yucca Mountain doesn't make it, that doesn't make any difference to you. Your job is to do your job and to protect the public. (Comment 0209.14-7)

4. It is our hope that you re-examine this decision, focus on fulfilling your obligations of protecting public safety, and ignore the pressures of rubber-stamping this project. Is it too much to ask that you implement a rule that will protect the people of Nevada and of this great nation today and tomorrow? (Comment 0209.15-3)

5. EPA fails in its most basic mission of protecting human helath and safety and instead proposes to delegate this ahtority to NRC. (Comment 0275-5)

6. Citizen Alert is alarmed that the EPA would propose a radiation protection standard, which clearly reverses the path and ideals of environmental protection established over the past 35 years. We encourage you to revisit the reason for the creation of the EPA and its mission to the citizens of the United States. "The mission of the Environmental Protection Agency is to protect human health and the environment. Since 1970, EPA has been working for a cleaner, healthier environment for the American people." http://www.epa.gov/epahome/aboutepa.htm#history (Comment 0289-1)

7. It is not EPA's job and, in fact, is a violation of its statutory obligation and its public responsibility to create a standard that simply accommodates an unsafe site. Instead of joining the "save the dump" political effort, EPA must abandon this proposal and release a new draft for comment that provides real protection for public health and the environment for the dangerous lifetime of the waste. (Comment 0294-6)

8. EPA should only have burden to what is safe. (Comment 0367.1-21)

9. It is not EPA's job to ensure that Yucca Mountain can get licensed by the Nuclear Regulatory Commission. It is EPA's job to set a standard that will be protective of public health for all generations into the future. (Comment 0368.6-8)

Response to Section 15:

EPA's role relative to Yucca Mountain was established by the Energy Policy Act of 1992 (EnPA) and is consistent with EPA's overall mission. In the EnPA, Congress directed EPA to develop site-specific radiation protection standards for Yucca Mountain to protect public health and safety. Our final standards meet that mandate. The Department of Energy will be authorized to construct and operate the facility at Yucca Mountain only if it demonstrates to the Nuclear Regulatory Commission (NRC) that the disposal system will comply with EPA's radiological protection standards. EPA has not promulgated a standard with the intention of faciliting a positive licensing decision by the NRC.

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Section 16 FEPs and Screening Criteria

Issue A: General comments

1. Accordingly, both Lincoln County and White Pine Counties are particularly concerned with features, events, and processes which might result in unanticipated atmospheric releases of radiation and exposure consequences for residents living downwind of the Yucca Mountain site. Review by both counties of EPA's proposed radiation standards for Yucca Mountain has been focused largely upon the adequacy of EPA proposed multiple-dose standards regarding protection of public health and the implication of said standards with regard to how EPA's standards will affect the way the Department of Energy conducts performance assessments relating to seismic and igneous FEPs. (Comment 0211.1-1)

2. While some elements of the proposed rule might have been more appropriately left to the discretion of the Nuclear Regulatory Commission ("NRC"), NARUC agrees with those sections which cover seismic, volcanic, climactic and general corrosion features, events and processes (FEP's), as well as the 10^{-8}probability threshold set for very unlikely FEP's. (Comment 0217-2)

3. In its proposed rule, EPA has taken an active role in defining the FEPs that DOE must model. EPA proposes that DOE exclude numerous adverse scenarios from the modeling process, sometimes without specifying what those scenarios are or delineating the standard being used to exclude them. An entirely sensible initial EPA proposal that NRC would have authority to add additional FEPs for the 10,000-year period was unaccountably deleted (apparently at DOE's insistence), and replaced by a series of artificial and unfounded limitations that can have no purpose other than to make it easier for DOE to comply. (Comment 0226-73)

4. EPA repeatedly cites a perceived need to avoid uncertainties and over-conservatism as a reason for limiting the FEP-setting process. EPA posits that including all possible scenarios, even if highly unlikely, would prejudice the analysis towards excessive pessimism. Indeed, EPA even claims that its decision to include only scenarios that have at least a 1-in-10,000 chance of occurring over the 10,000 period, *and* that are likely to have "significant effects" (a term EPA never defines) is "extremely conservative." 70 FR 49049. But NAS's conclusions were to the contrary. Describing the basic approach involved in performing a probabilistic risk analysis, NAS wrote: [t]]o judge compliance against a risk-based standard of the type proposed, a risk analysis including treatment of **all** scenarios that might lead to releases from the repository and to radiation exposures is, in principle, required. To include them in a standard risk analysis, **all these scenarios** need to be quantified with respect to the probabilities of *scenario occurrence and* the probability of their *consequences* to humans, such as health effects of radiation doses. NAS Report at 72 (italics in original; bold text added). In other words, NAS recommended including a broad range of scenarios and accounting for the remoteness of the more unlikely scenarios by multiplying a scenario's impacts by its low probability of occurrence. Nothing in this passage, or anywhere else in the NAS report, suggests that such an approach would be excessively conservative. (Comment 0226-75)

5. A simplified mathematical example indicates why the NAS was correct that an inclusive analysis is, "in principle," appropriate rather than over-conservative, and why EPA's FEP approach is inherently *unrealistic* and *optimistic*. Suppose that events A, B, C, D, and E have probabilities of occurrence of 1%, 3%, 7%, 10%, and 12%, respectively, over the next year. Next, suppose that each event has a likelihood of producing 10 units of exposure if it occurs. The probable degree of exposures per year thus would be ((probability of A) (exposures per occurrence of A) + (probability of B) (exposures per occurrence of B)…. + (probability of E) (exposures per occurrence of E). Plugging the overall numbers into the equation produces an expectation of 3.3 units of exposure per year. There is nothing inherently conservative about this prediction; the inclusion of "unlikely" events A and B is compensated by discounting their effect by their likelihood of occurrence. The inclusion of unlikely scenarios thus does not bias the analysis because the unlikelihood of those scenarios is accounted for mathematically. (Comment 0226-76)

6. Now suppose, however, that the regulator has attempted to simplify the modeling by excluding from consideration all events with a less-than-5% chance of occurring. The modeler would then not consider events A and B at all—even though they do have a real-world possibility of occurrence—and would produce a prediction of 2.9 units of exposure per year. Although the change is not huge, defining FEPs to exclude certain scenarios has skewed the prediction toward excessive optimism. And the skewing will increase if, as EPA proposes, probable events with slight effects—for example, an event F which has a probability of 40% but a likely impact of only one unit of exposure—also are excluded (Comment 0226-77)

7. This example illustrates the fallacy of EPA's assertion that its prescribed FEP approach corrects supposed over-conservatism. In fact, unless compensating mechanisms are introduced, every exclusion of scenarios decreases the *realism* of the calculation, and skews the result toward optimism. The NAS report provides no support for such skewing, and instead endorses a methodology that provides more realism than that selected by EPA. (Comment 0226-78)

8. The NAS report recommends that, in principle, "all" scenarios should be addressed that "might lead to releases from the repository and radiation exposure." NAS Report at 72. Nevada understands that direction not to prescribe an infinite number of runs, but to ensure that EPA's methodology fully accounts for potential releases from the repository and radiation exposure. This NAS recommendation reflects EnPA's underlying statutory mandate for EPA to develop standards for the protection of the public health and safety. As noted below, key exclusions proposed by EPA appear to be inconsistent with the NAS-recommended approach. (Comment 0226-79)

9. EPA has excluded a series of events—many of them entirely unspecified—on the mostly unexplained rationale that their effects would be "insignificant." For example, EPA suggests that if criticality events are not addressed during the first 10,000 years (which DOE had proposed it would not do because it assumes that such failure is unlikely), they also need not be addressed in the post-10,000 year period because, oddly enough, criticality events at such later times would likely have lesser effects than the earlier criticality events

EPA already has excused DOE from analyzing. 70 FR 49051 (stating, without explanation, that "we do not believe such scenarios are either very likely or very important to performance"). As a consequence, EPA's proposed rule would completely excuse DOE from analyzing one of the most worrisome threats posed by the repository, at the very time when waste packages will begin to fail, emptying their fissile contents into pools and piles of unknown (but perhaps critical) geometries. EPA has also excluded engineering failures, such as localized corrosion, on the theory that their post-10,000 year effects would be insignificant. *Id*. Similarly, EPA apparently acquiesces in DOE's assumption that no manufacturing defects will exist, without ever considering whether this assumption is reasonable, let alone sufficiently certain to totally exclude such scenarios from analysis. Indeed, EPA never defines what its standard of significance is, or itemizes all of the FEPs that are being excluded, with the consequence that the rule never explains what events are being left out or how important they might actually be. (Comment 0226-80)

10. On similar grounds, EPA has excluded from consideration several other FEPs on the rationale that their effects will be, in EPA's words, "overwhelmed" by the influence of more important variables. 70 FR 49053; *see id.* at 49054. Again, EPA is inconsistent at best in defining what FEPs are being excluded on these grounds; while some, like seismic effects on hydrology, are specified, others are left unnamed. (Comment 0226-81)

11. Moreover, EPA never addresses the possibility that the comparatively minor FEPs' effects would occur *in addition* to those ostensibly more important ones represented in the scenarios that will be considered, and thus does not consider that this exclusion may well understate direct and cumulative effects. This approach is as irrational as a business declining to account for its smaller expenses on the rationale that they are "overwhelmed" by the larger ones. In reality, all of the expenses, large and small, influence the bottom line, and a failure to account for the small ones leave any budget projection overly optimistic. (Comment 0226-82)

12. EPA excludes from consideration FEPs that might be increasingly significant with the passage of time. Some FEPs, like general corrosion, may be of lesser importance during the first 10,000 years if DOE's sanguine predictions are realized, but could become increasingly important in the post-10,000 year period. EPA acknowledges this risk with general corrosion, and requires it to be addressed, but dismisses all other such time-sensitive effects (without even beginning to specify what they are) on the conclusory rationale that "the relevant FEPs are already captured within the 10,000 year screening process, and that any others would be overshadowed by other aspects of the longer-term modeling." 70 Fed. Reg. at 49055. As a consequence, EPA's rule proposes considering only the limited subset of FEPs that EPA believes, for largely unspecified reasons, to be worth modeling. Even if EPA was correct, and the FEPs DOE will consider turn out to be the most important ones, the collective impact of all the excluded FEPs could have a significant impact on the performance assessment. By categorically excluding those effects from consideration, EPA has departed from the NAS recommendation and introduced a potentially significant level of over-optimism into the assessment. (Comment 0226-83)

13. Those exclusions also exceed EPA's expertise. It would be one thing if EPA's cavalier exclusion of potentially key technical issues were in an area for which the agency has known and Congressionally delegated expertise, such as the health effects of radiation. It is another altogether when the issues concern metallurgy, nuclear physics, seismicity, and climatology. (Comment 0226-84)

14. The EPA proposal discusses screening out FEPs by probability and consequence within 10,000 years. To provide a realistic prediction of performance after 10,000 year EPA must consider all FEPs that provide significant consequences over the regulatory period of a million years. To protect future individuals in the Amargosa Valley, the EPA cannot limit consideration to only those FEPs that provide a consequence within 10,000 years. Furthermore the attempted screening of FEPs on independent probability and consequence arguments is totally fallacious. Screening for probabilistic risk analysis must be done on the product of these two factors (i.e., probability of occurrence multiplied by the consequence of the occurrence); otherwise important and possibly dominant contributors to annual dose can be erroneously excluded with the subsequent falsely optimistic estimate of performance. EPA must propose and then mandate an approach that correctly takes risk into account. (Comment 0263-16)

15. We agree with EPA's decision to limit consideration of FEP's after 10,000 years to those already required to be considered in the first 10,000 years. (Comment 0298-18)

16. EPA has overlooked important dynamics in the features, events, and processes (FEPs) and "reasonable expectations" approach. FEP occurrences that have been screened out or underestimated could very well increase rates of radionuclide exposure and contamination. Moreover, significant linkages to climate change, many which are not fully understood, are wholly ignored in this proposal. (Comment 0312.1)

17. White Pine County is concerned with features, events and processes (FEPs) which might result in unanticipated atmospheric releases of radiation and exposure consequences for residents living downwind of the Yucca Mountain site. Review by the County of EPA's proposed radiation standards for Yucca Mountain has been focused largely upon the adequacy of EPA's proposed multiple dose standards regarding protection of public health and the implications of said standards with regard to how EPA's proposed standards will affect the way the Department of Energy (DOE) conducts performance assessments relating to seismic and igneous FEPs. (Comment 0315-1)

18. Attachments A and B below are included to show that very real problems already exist with dry cask systems in, the U.S., so EPA cannot assume that there will be no design or manufacturing problems with waste burial casks at Yucca, as it attempts to do in its proposed rule. Under its FEPs section (Frequencies, Events, Processes), EPA seems to agree with DOE's highly unrealistic assumption that no manufacturing defects will exist in Yucca waste burial containers. This flies in the face of over 20 years of U.S. experience with dry cask storage, which has seen all too many instances of cask design, manufacturing, and operational problems. (Comment 0324-33)

19. Section 197.12: In order for EPA, NRC, or DOE to assess with reasonable accuracy all "features, events, and processes" that might affect the Yucca Mountain geological repository, the probabilities of human intrusion and consequences (e.g., compromised waste containers and radioactive releases) would have to be included in the analysis. If human intrusion is properly analyzed elsewhere in the requirements, it should be incorporated with naturally occurring events (e g., geological or climatological) that could compromise the repository performance in order to determine the likely performance. (Comment 0331-10)

20. The Department agrees with EPA's proposal regarding the treatment of features, events, and processes and supports EPA's approach to limit the inclusion of highly speculative features, events, and processes in the calculation of peak dose by defining the treatment of those specific processes to be included in the calculation. EPA's proposed approach for the treatment of features, events, and processes is a sound policy decision that avoids intractable speculation aimed at identifying all conceivable features, events, and processes that might possibly have an impact in a one million-year compliance period. The Department agrees that the probability cutoff for features, events, and processes should be the same as the cutoff originally established in Part 197 for the 10,000-year period, one chance in 100 million per year. The Department agrees with EPA's proposal that FEPs and scenarios not included in the 10,000-year analysis need not be considered in peak dose calculations. The Department agrees with EPA's proposal "that scenarios involving climate change, seismic activity, igneous activity, and general corrosion should be explicitly considered in the peak dose calculations"…The Department interprets EPA's proposed rule to mean that, with the exception of those specified processes, the calculation of peak dose will be based on the 10,000-year compliance demonstration. (Comment 0352-9)

21. The process of general corrosion of the waste packages in the evaluation of performance to time of peak dose is different in nature from the three natural system processes recommended by the Committee for inclusion in the evaluation of performance to time of peak dose (i e., climate change, seismic activity and igneous activity). This difference should be recognized. EPA should add the following sentence to 197.36(c)(3): The only subsidiary effects of general corrosion that need be considered are those that were previously considered in the TSPA for the 10,000-year period (that is, those features, events, and processes that would not affect 10,000-year performance need not be considered further)…There are specific limitations specified in section 197(c) for the first three of these analyses to ensure that the limitations of section 197.36(a) are applied properly such that unnecessarily detailed analyses of non-important features, events, and processes are not required for the peak dose analysis. A similar limitation should be applied to the corrosion analysis. (Comment 0352-10)

22. Extending the regulatory period to the time of peak dose has the potential to introduce arbitrary and unbounded speculation into the assessment of repository performance…EPA has prudently rejected the argument that a 100-fold increase in the time horizon for the performance assessment should be accompanied by a 100-fold reduction in the annual probability cutoff for the features, events, and processes to be considered in that assessment. Such a reduction in the screening threshold would require an attempt to

identify features, events, and processes of an inconceivably low probability, one chance in 10 billion per year, a level associated with literally end-of-the-world events. Making the compliance determination dependent on unbounded, and perhaps unboundable, speculation about events of an inconceivably low probability of occurrence theoretically would, at best, be placing the interests of distant future generations above society today and its descendants over the next 10,000 years. The one-chance-in-100-million cutoff itself is already extremely conservative, approaching the probability of a collision with an asteroid of the size associated with a major extinction event, or about 1/100 the annual probability of being struck by lightning. For perspective, the recent draft recommendations of the International Commission on Radiation Protection express skepticism about estimates of annual probabilities much below one chance in one million. (Comment 0352-11)

23. Explicit policy judgments are required to address extremely slow processes that should be excluded from 10,000-year performance assessments but that could affect the timing (and potentially the magnitude) of the peak dose…Physical-chemical processes that are not observable without accelerated testing should be excluded from the peak dose assessment. In the absence of direct observation of such phenomena, it is not possible to develop reasonable conceptual models of these phenomena or the parameters that describe them; nor is it possible to develop even cautious bounds on the uncertainty in the parameters. Because these long-term transient processes are unquantifiable, it is speculative to include them in any assessments of long-term performance. Undue speculation as to the appropriateness of a particular long-term transient conceptual model and the uncertainty in that model would not increase the ability of the regulator and the public to evaluate the ability of the Yucca Mountain repository to comply with the peak dose level of protection. Long-term calculation of peak dose should be consistent with and based upon the processes, conceptual models, numerical models, model parameters and boundary conditions included in the 10,000-year compliance evaluation. The calculation should not include unwarranted speculation about slow transient processes…This allows a more direct and representative comparison of the predicted dose to the target and avoids inappropriate speculation about unknown and uncertain rates of these transient processes. (Comment 0352-12)

24. The Department has identified FEPs that could potentially affect repository performance. The identification of these FEPs was not based on any compliance timeframe. These FEPs were then evaluated for inclusion in an assessment of repository performance over a 10,000-year period. The Department has subsequently re-evaluated the FEPs over the period beyond 10,000 years…The results of this evaluation support EPA's position "that FEPs and scenarios not included in the 10,000-year analysis because of limited consequence during that period need not be considered in peak dose calculations." This analysis indicates that the bases for excluding most of the FEPs are time invariant…some processes, such as erosion, are time dependent. However, these gradual and continuing processes will not have a significant effect on the projection of repository performance over the period beyond 10,000 years. (Comment 0352-13)

25. The Department agrees with EPA's proposal that the effects of seismic activity should be evaluated throughout the one million-year period but limited to those effects resulting in

damage to the engineered barrier system. FEPs that pertain to the effects of seismic activity on the Yucca Mountain repository natural barrier system have been excluded over a 10,000-year period based on low consequence. The justifications for excluding these FEPs for 10,000 years are also applicable to the period beyond 10,000 years because they do not depend on any time scale. It is, therefore, not appropriate to consider the effects of seismic activity beyond those that result in damage to the engineered barrier system. (Comment 0352-14)

26. The Environmental Protection Agency's ("EPA's) August 22, 2005 proposed amendments to 10 C.F.R. Part 197, "Public Health and Environmental Radiation Standards for Yucca Mountain, Nevada," include provisions at proposed section 197.36 designed to limit consideration of certain physical processes in the repository system safety performance assessment in the post-10,000 year performance period. These include a limit on the Nuclear Regulatory Commission's ability to take account of localized corrosion of the waste package. This limit is based on an EPA finding that the phenomena of localized corrosion of the waste packages at Yucca Mountain is sufficiently understood scientifically that the potential for significant new effects on public safety after 10,000 years should be ignored. In the proposed amendment EPA concludes these effects must be ignored unless they can be shown to be significant before then, which EPA seems to think is unlikely. See 70 Fed. Reg. 49053.

In its overly confident conclusions about localized corrosion processes, EPA is at odds with the experts in the field. In a December 30, 2005 letter to the Congress, the Nuclear Waste Technical Review Board advised that it "continues to be concerned about the potential for localized corrosion in deliquescent brines formed at temperatures between 160 C and 220 C from airborne dust that will be deposited on the surface of the waste packages." Further, in an October 6, 2005 scientific report (not released until late December), the Nuclear Regulatory Commission's Center for Nuclear Waste Regulatory Analysis concluded that "under a limited range of conditions, stress corrosion cracking of Alloy-22 has been observed in environments containing chloride and bicarbonate, which may be present in water entering the emplacement drifts."

It is clear from these sources, whose technical expertise on waste package corrosion far exceeds the EPA's, that the science of localized corrosion of the Yucca Mountain waste packages is still being developed, that significant technical concerns remain, and that more scientific work needs to be done before the matter can be resolved. Moreover, recent DOE initiatives to reexamine the waste package design for Yucca Mountain raise serious questions whether EPA's assumptions about the nature of the waste package subject to corrosion will comport with reality.

Given this, it is completely arbitrary for the Agency to issue a binding rule that limits the Commission ability to consider the matter. The licensing and regulatory process for Yucca Mountain must be based on sound science, but it cannot be if the Agency tells the Commission that it must willfully blind itself to significant new scientific information. The recent dramatic changes in DOE's program to develop Yucca Mountain also strongly counsels against an inflexible EPA rule that treats the Yucca Mountain Project as if it were frozen in the mid-2005 time frame. (Comment 0362.1-1)

27. The Environmental Protection Agency's ("EPA's") August 22, 2005 proposed amendments to 10 C.F.R. Part 197, "Public Health and Environmental Radiation Standards for Yucca Mountain Yucca, Nevada" include provisions at proposed section 197.36 designed to limit consideration of certain physical processes in the repository system safety performance assessment in the post-10,000 year performance period. These include a limit on the Nuclear Regulatory Commission's ability to take account of localized corrosion of the waste package. This limit is based on an EPA finding that the phenomena of localized corrosion of the waste packages at Yucca Mountain is sufficiently understood scientifically that the potential for significant new effects on public safety after 10,000 years should be ignored. In the proposed amendment EPA concludes these **e**ffects must be ignored unless they can be shown to be significant before then, which EPA seems to think is unlikely. See 70 Fed. Reg. 49053.

In its overly confident conclusions about localized corrosion processes, EPA is at odds with the experts in the field. In a December 30, 2005 letter to the Congress, the Nuclear Waste Technical Review Board advised that it "continues to be concerned about the potential for localized corrosion in deliquescent brines formed at temperatures between 160 C and 220 C from airborne dust that will be deposited on the surface of the waste packages." Further, in an October 6, 2005 scientific report (not release until late December), the Nuclear Regulatory commission's Center for Nuclear Waste Regulatory Analysis concluded that "under a limited range of conditions, stress corrosion cracking of Alloy-22 has been observed in environments containing chloride and bicarbonate, which may be present in water entering the emplacement drifts."

It is clear from these sources, whose technical expertise on waste package corrosion far exceeds the EPA's, that the science of localized corrosion of the Yucca Mountain waste packages is still being developed, that significant technical concerns remain, and that more scientific work needs to be done before the matter can be resolved. Moreover, recent DOE initiatives to re-examine the waste package design for Yucca Mountain raise serious questions whether EPA's assumptions about the nature of the waste package subject to corrosion will comport with reality.

Given this, it is completely arbitrary for the Agency to issue a binding rule that limits the Commission ability to consider the matter. The licensing and regulatory process for Yucca Mountain must be based on sound science, but it cannot be if the Agency tells the Commission that it must willfully blind itself to significant new scientific information. The recent dramatic changes in DOE's program to develop Yucca Mountain also strongly counsels against an inflexible EPA rule that treats the Yucca Mountain Project as if it were frozen in the mid-2005 time frame. (Comment 0365-1)

28. We agree with the sections of seismic, volcanic, climatic and general corrosion features, events, and processes, although we think the detailed requirements might have been better -- been included in the NRC implementation regulation as should the probability threshold for consideration of unlikely FEPs. (Comment 0368.5-4)

29. The proposed rule would apparently preclude the NRC from taking into account any corrosion of the waste package (or other engineered barriers) in the post-10,000 year period, other than "general corrosion." See proposed 40 C.F.R. § 197.36 (c) (3). This is based on EPA's apparent technical conclusion that other kinds of corrosion, for example

localized corrosion, would not under any circumstances contribute to risk after 10,000 years. The Nuclear Waste Technical Review Board's June 2006 annual report to Congress and DOE makes it clear that this conclusion has no scientific support. The Board advises Congress and DOE that whether a combination of salts known to be present in Yucca Mountain might cause localized corrosion in waste packages remains unanswered, and also that stress corrosion cracking of engineered barriers cannot be dismissed based on the current limited data. See Report at pp. 12-15. Given the scientific uncertainties cited by the Board, there is no adequate basis for the proposition advanced by EPA that the effects of localized corrosion and stress corrosion cracking will not be significant after 10,000 years. Thus EPA's proposed rule would unlawfully, and without sufficient scientific support, preclude the NRC from taking significant unresolved safety issues into account in its licensing decision. (Comment 0369-1)

30. The Board also raises questions in its June 2006 Report about the effectiveness of the drip shields, which DOE plans to put in 50-300 years after closure, and for which DOE takes credit in its safety calculations. The Board questions whether the drip shields along a tunnel would stay connected in the event of an earthquake. If they do not remain connected, then water could seep in and attack the waste packages. See Report at pp. 18-20. EPA's proposed rule would apparently limit the NRC's consideration of seismic events in the post-10,000 year period to "effects caused by damage to the drifts in the repository and failure of the waste packages." While EPA does not define "waste package," the NRC definition of the term seemingly does not include the drip shield. See 10 C.F.R. § 63.2 ("Engineered barrier system means the waste packages, inclusing engineered components and systems other than the waste package (e.g., drip shields)…." See also Fed. Reg. 55732, 55776, November 2, 2001. So, the combined effect of NRC's existing rules and EPA's proposed rule would again be that the NRC would be precluded from taking a significant unresolved safety issue into account in its licensing decision. (Comment 0369-2)

Response to Issue A:

Two comments addressed concern about airborne pathways (Comments 0211.1-1 and 0315-1). From our examination of previous performance scenarios proposed for the disposal system, we believe that in the post-closure period the ground-water pathway is the only pathway through which radionuclides could reach the RMEI for the expected case. Large amounts of airborne radionuclides would result from only a volcanic event; the probability of eruptive volcanic events is very small, but is considered in the final rule as a disruptive event that is to be considered in the performance assessments. (NAS Report p. 95)

Some comments expressed varying opinions on the probability limit we placed on FEP inclusion or exclusion in disposal system performance assessments. Some comments agreed with maintaining the probability limits from the 2001 rulemaking (Comments 0352-9, 0352-11, 0217-2, and 0298-18), while some comments proposed that all scenarios, regardless of probability, must be included in performance assessments (Comments 0226-75, 0226-77, 0226-78, 0226-79, 0263-16, and 0369-1). We believe that the probability limits used in the 2001 rulemaking are still appropriate even though we have constructed a compliance requirement for peak dose within the period of geologic stability. The previous rulemaking required a post-10,000-year performance assessment, even though no regulatory dose limit was applied to the results. Nevertheless, this requirement did not allow the assessments to ignore important scenarios that would significantly affect performance during the longer time frame. We believe the position we have taken in this rulemaking is consistent with our previous intent and the NAS direction concerning peak dose considerations. In light of the longer compliance period and the unavoidable uncertainties it brings into the task of making very long-term dose projections, we believe the probability limits are set to capture within the scenario development process a wide-ranging set of FEPs that potentially could affect disposal system performance and provides the foundation for a reasonable test of the disposal system.

Some comments argued that we are eliminating low-probability FEPs, even though they could contribute to releases that would compromise the performance assessments (Comments 0226-76, 0226-77, 0226-78, 0226-79, 0226-82, and 0263-16). We imposed probability limits on the FEPs selection process to eliminate potentially endless speculation on estimating exact probability numbers for very low-probability FEPs. The probability of FEPs is determined by examining the geologic record around the site as well as the body of technical information available from laboratory testing and real-world experience with engineered materials. We believe that scientific judgment may be used in assigning probabilities to FEPs, as well as evaluating their potential consequences under conditions at the site over the compliance period. Requiring that any conceivable FEP and any speculative prediction of its consequences be incorporated into the performance assessments, we believe, would make it impossible to perform the analyses or interpret the results sufficiently for regulatory decision-making, because of the unbounded speculation involved. ICRP's 2007 recommendations also support our conclusion that the 10^{-8} annual probability threshold presents a significant challenge to characterize FEPs with some degree of confidence, given the limits of today's science and technology, and will result in a wide-ranging set of FEPs:

> "The use of probability assessment is limited by the extent that unlikely events can be forecast. In circumstances where accidents can occur as a result of a wide spectrum of initiating events, caution should be exercised over any estimate of overall probabilities because of the serious uncertainty of predicting the existence of all the unlikely initiating events. In many circumstances, more information can be obtained for decision-making purposes by considering the probability of occurrence and the resultant doses separately."

(ICRP Publication 103, Docket EPA-HQ-OAR-2005-0083-0423, Paragraph 269. The term "accidents" in the quotation above also refers to releases that occur far into the future, i.e., releases from the disposal system).

Overall, we believe events with an annual probability lower than 10^{-8} would introduce speculation beyond what is appropriate to define a reasonable test of disposal system performance.

Further, in response to Comments 0226-75 and 0263-16, NAS itself suggested situations in which scenarios need not be quantified. NAS discusses, in the context of volcanism, a 10^{-8} annual probability of occurrence as a level that "might be sufficiently low to constitute a negligible risk" below which "it might not be necessary to consider" how the event might contribute to releases from the disposal system. (NAS Report p. 95) We believe this example is instructive, given that volcanism is the single scenario resulting in direct release of radioactive material from the repository into the biosphere, resulting in relatively immediate exposures. We believe it is reasonable to extend the concept expressed by NAS as "negligible risk" to FEPs whose influences are seen in the gradual release and transport of radionuclides over long periods of time. Therefore, we believe that lowering the probability threshold, or eliminating it altogether, would be inconsistent with the important NAS cautions to focus assessment efforts on FEPs that can be bounded within the limits of geologic stability. As a result, we believe that the probability limits we have established, and implemented in other applications of geologic disposal, are scientifically rigorous and consistent with a protective approach.

One commenter offered a simple example of the effects on dose calculations of excluding some scenarios (Comments 0226-76 and 0226-77). While the example is illustrative of the point about the possible effects of excluding some scenarios, the probabilities used in the example are equal to or significantly higher than those proposed in the rule – all these processes would be included, so the answer is not representative of the actual effect of excluding low-probability FEPs. In addition, the example is misleading in its simplified calculation. The elimination of a FEP on the basis of consequence would be based upon its effect on the overall results of the aggregation of scenarios, each of which includes multiple FEPs that make up the performance assessment. A FEP would not be eliminated on the basis of probability if its probability were as high as shown in the example. Another perspective on the consideration of low probability FEPs is the issue of uncertainties in performance due to expected variations in the major "driver" processes and the associated parameters in the performance assessments contrasted with the effects of low probability FEPs. If the variation of calculated doses from the major processes controlling dose extends over an order of magnitude or more, for example, a dose variation of only a percent or two due to the inclusion of a low probability FEP in question would be inconsequential in magnitude and not discernable within the variations due to other processes.

One comment (Comment 0352-12) proposed that FEPs whose effect could not be measured without accelerated testing should be eliminated from consideration in performance assessments. We disagree with this suggestion in that many important processes in the post-closure time frame cannot be quantified without some form of "accelerated" testing. For example, corrosion testing is usually done in an accelerated fashion to simulate in the laboratory in days to weeks what the actual in-service performance would be over much longer periods. We are aware of the limitations of such testing in terms of applying them in performance assessments and interpreting the results. One comment (Comment 0209.7-

4) also proposed that there may be earlier release scenarios than those resulting from failures caused by corrosion, but did not describe any of the scenarios alluded to in the comment. We cannot evaluate this comment further without additional explanation, but we believe the commenter should send any additional explanation to either the DOE or NRC for consideration in their efforts on safety assessment for the repository.

On a similar point, several comments characterized our proposal as assuming that no manufacturing defects will exist in the waste packages or that we are excluding the effects of localized corrosion from the analyses and preventing NRC from considering this process (Comments 0226-80, 0324-33, 0362.1-1, and 0365-1). On the contrary, our proposal makes no assumptions about the quality of construction or durability of the waste packages. Our standards provide the appropriate protections in the initial 10,000-year period, when such defects might result in releases earlier than expected. Should significant releases be projected to occur shortly after 10,000 years, NRC has stated (EPA-HQ-OAR-2005-0083-0376, p.49) that it would take such trends into account in its licensing decision, even if the standards beyond 10,000 years were not exceeded. We believe our peak dose standard appropriately considers the factors involved in conducting performance assessments covering the period up to 1 million years. Further, we are not limiting consideration of localized corrosion. Comment 0362.1-1 interprets our statements in the proposal as requiring that "the potential for significant new effects…must be ignored unless they can be shown to be significant before" 10,000 years. This is not the case. We explicitly recognized localized corrosion as a process that would operate during the early period of disposal, when temperature effects would be most significant (the commenter specifically indicates the potential for localized corrosion at temperatures between 160 and 220 ºC, or about 320 and 430 ºF). We contrasted that with general corrosion in the sense that the long-term effects of general corrosion are likely to be more significant to package failure. However, localized corrosion must be considered for the entire compliance period if it is included for the initial 10,000 years. It is unclear to what "significant new effects" from long-term localized corrosion the commenter is referring, but we are not limiting NRC's ability to examine the way that process is incorporated into the performance assessments. DOE will have to defend its assumptions regarding waste package performance in its license application.

These comments raise an important issue, which is the potential for FEPs, particularly seismic and igneous events, to cause direct damage to the engineered barrier system (e.g., repository drifts, drip shields and waste packages). Regardless of other effects of these events on the disposal system, the timing and degree of waste package degradation has a significant effect on peak dose. The longevity of waste packages, when considering periods of hundreds of thousands of years, is uncertain and dependent on a number of factors. Therefore, the aspect of primary interest in evaluating seismic and igneous FEPs is their potential to breach waste packages and make radioactive material available for transport by infiltrating water (or, in the case of volcanic events, for direct release into the biosphere).

Comments 0226-80, 0226-83, 0362.1-1, and 0365-1 criticize our approach to exclude FEPs on the basis of their significance to the performance assessment results. We recognize that setting forth the significance screening criterion in §197.36(a) of our proposal as pertaining to the 10,000-year period could be construed as creating a situation in which important long-term processes could be excluded altogether from the analysis if they were not significant in the earlier period. However, we do not believe it is reasonable to interpret the significance criterion in this way. We have taken specific steps to ensure that significant long-term FEPs will be considered in the assessments. Consistent with NAS, we have addressed the long-term effects of seismic, igneous, and climatic FEPs. In addition, as described below, we have directed that the effects of general corrosion on the barrier system be evaluated. Further, contrary to some comments, we explicitly required that FEPs included in the 10,000-year analysis must continue to be included for the longer-term (10,000 years to 1 million years) assessment. That is, FEPs included in the initial 10,000-year assessments will continue to operate throughout the period of geologic stability. These FEPs are already identified as appropriate for inclusion, and include fundamental physical and geologic processes that play roles in the release and transport of radionuclides, regardless of the time period covered by the assessment.

As noted above, to further bolster the significance screening criterion, in our proposal we considered whether some FEPs eliminated from consideration during the first 10,000 years should be included in the longer-term assessment if they would have a significant bearing on performance at later times, even if they could legitimately be dismissed for the initial 10,000-year period. We focused our attention on FEPs affecting the engineered barriers since, as noted above, waste package failure is the dominant factor in the timing and magnitude of the peak dose, and is the primary reason for considering time frames up to 1 million years. To illustrate one consideration, thermal conditions in the repository change dramatically within the initial 10,000-year period, affecting the relative importance of some FEPs during and after the thermal pulse. However, FEPs involved in release and transport of radionuclides would generally be the same, regardless of when the waste package fails. Further, while FEPs associated with the natural characteristics of the site are active today or can be observed in the geologic record, FEPs related to engineered barrier longevity involve extrapolation of shorter-term testing data. The degree to which natural FEPs can contribute to the breaching of waste packages is dependent to a large extent on the condition of those packages over time, making FEPs specific to the engineered barriers of particular importance. We took this approach for two reasons. First, we needed to clearly outline the reasons why a FEP that could be excluded on the basis of significance from the performance assessments for the initial 10,000-year period might potentially need to be re-considered for the lengthened compliance period. Second, we wanted to further our goal of issuing an implementable standard by eliminating potentially unconstrained speculation over the longer compliance period. By discussing the considerations involved in evaluating FEPs that could be previously excluded, we hoped to lay out clearly the reasoning that could be used to justify inclusion of additional FEPs beyond those identified by the NAS committee.

We explicitly addressed general corrosion of the waste packages and engineered barriers in our proposal because it is likely to be a significant degradation process at later times. This FEP is significant at times greater than 10,000 years because we believe it is the principal process FEP that could lead to "gross breaching" of the waste package over those extended time frames. Processes and events that could lead to "gross breaching" are of greatest significance to long term performance because, as noted by the NAS, "canisters are likely to fail initially at small local openings through which water might enter, but out of which the diffusion of dissolved wastes will be slow until the canister is grossly breached." (NAS Report p. 86) It is the time of "gross breaching" that determines the time of more rapid release of dissolved wastes from the repository and hence may have a significant effect on the time and magnitude of the peak dose within 1 million years. Although the general corrosion process is slow, tends to decrease with decreasing temperature, and may not lead to significant releases for the first 10,000 years (depending on DOE's design of the waste package), we believe this FEP is significant enough over the long term to require inclusion in the assessment of performance during the time of geologic stability, regardless of the screening decision in the first 10,000 years. Further, consideration of the uncertainties involved in extrapolating general corrosion data for the proposed waste package materials supports the inclusion of this potentially highly significant process ("Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments," Docket No. EPA-HQ-OAR-2005-0083-0085, Section 5.4.1). Therefore, we believe that general corrosion, as well as those FEPs related to seismicity, igneous activity and climate change identified by NAS, require explicit inclusion in the assessments during the time of geologic stability. In fact, general corrosion is a process that will take place from the time of repository closure onwards and would be included by the probability screen and included based on its consequences over the very long term.

We did, as Comment 0226-73 pointed out, consider providing NRC more latitude to identify FEPs if they would significantly affect the peak dose. We view the requirement to include general corrosion, as well as the climate, seismic, and igneous scenarios identified by NAS, as leading to an effective and extensive assessment, which can fairly be represented as a reasonable test of the disposal system. As we discussed in our proposal, the search for additional FEPs that might be argued as significant at some point beyond 10,000 years can rapidly become highly speculative and bounded largely by the limits of the imagination and of limited in benefit if the speculation cannot be removed. Therefore, we continue to believe that our approach represents "informed judgment" and a reasonable test of repository performance over time frames as long as 1 million years.

Most commenters who disagreed with our proposal cited the limited data available on various corrosion mechanisms that could affect the waste packages (e.g., Comments 0362.1-1, 0365-1, and 0369-1). Many of these commenters seem to believe that we have excluded all corrosion mechanisms except general corrosion. This is not the case. We have explicitly directed that general corrosion be considered because it is likely to be the most significant such process at longer times; however, other corrosion mechanisms (such as localized corrosion) are more likely in the early period after disposal when temperatures inside the repository are high. For example, Comment 0369-1 cites the Nuclear Waste Technical Review Board (NWTRB) as concluding "that stress corrosion cracking of engineered barriers cannot be dismissed based on the current limited data." The NWTRB states in its June 2006 Report to the U.S. Congress and Secretary of Energy: "Alloy-22 has been shown to be very resistant to, but not immune from, SCC under many Yucca Mountain conditions at temperatures below approximately 160ºC. Although Alloy-22 can exhibit SCC under these conditions, very high stress intensities induced by pre-cracking are required, and even then cracks propagate very slowly. However, for Yucca Mountain environments above about 160ºC, only limited SCC data exist for Alloy-22. Given that the susceptibility of metals to SCC generally increases with temperature, the Project will have to obtain relevant data under higher-temperature conditions, assume that SCC will occur, or use a different approach." (Docket No. EPA-HQ-OAR-2005-0083-0395) If DOE determines these processes to be insignificant within 10,000 years, when thermal effects are at their highest, they are not likely to be more significant than general corrosion at later times. If they are included in the 10,000-year analysis, they must be included in the longer-term assessments.

Comment 0226-80 highlights our discussion of criticality as excluding one of the "most worrisome threats to the repository" over the long term. We cited an NRC technical study to support our conclusion that such an event is unlikely to be significant to the results of the assessments (70 FR 49054). Further, the DOE reference cited above concludes that all criticality scenarios fall below the probability screening threshold. We do not believe it is necessary to specify that criticality be evaluated.

Comment 0369-2 again cites the NWTRB in charging that we have "precluded NRC from taking a significant unresolved safety issue into account in its licensing decision" by limiting the scope of seismic analyses beyond 10,000 years to "effects caused by damage to the drifts in the repository and failure of the waste packages." The commenter views this as excluding the potential for displacement of drip shields through ground motion, an issue raised in NWTRB meetings. The commenter correctly notes that drip shields are not part of the waste package. However, we do not view the "drifts in the repository" as being limited to the emplacement tunnels themselves. We consider that this provision also applies to the loss of functionality of structural components of the engineered barriers, including the drip shields and the inverts supporting the waste packages. Effects of seismic events on the drip shields could include both physical damage (e.g., through rockfall) and loss of function without physical damage through displacement. Displacement could allow water to contact the waste packages and contribute to waste package failure. The June 2006 NWTRB report indicates that DOE has evaluated this possibility (Docket EPA-HQ-OAR-2005-0083-0395, p. 19).
An alternative view on our FEPs screening process was expressed in a report by the Electric Power Research Institute (EPRI): "Thus, the current EPA screening limit is very conservative compared to the [Negligible Incremental Dose] level suggested by [NAS]. It is likely that there are many FEPs that DOE has already included in their analysis using the EPA approach that would not have been included if the [NAS]-recommended approach had been followed. Given that many additional FEPs are already included, it should be unnecessary to include any additional FEPs if the regulatory compliance period is extended beyond 10,000 years." ("Yucca Mountain Licensing Standard Options for Very Long Time Frames," April 2005, pp. 3-5 and 3-6, Docket No. EPA-HQ-OAR-2005-0083-0087) Taking all of this information into account, we continue to believe that our approach to assigning probabilities to FEPs and the screening process is sufficiently rigorous to capture all the pertinent FEPs for a reasonable test of the disposal system performance over the compliance period.

Comment 0331-10 made the argument that human intrusion should be included in the naturally occurring events. For the Yucca Mountain standards, the NAS specifically recommended that the treatment of human intrusion be addressed stylistically and evaluated separately from the post-closure performance assessment for the individual-protection standard (NAS Report p. 104), therefore, we have remained consistent with the NAS recommendation for treatment of intrusion as the compliance period has been extended. NAS concluded that institutional controls could not eliminate the possibility of human intrusion, nor could the probability of intrusion be predicted. NAS therefore recommended that the intrusion be assumed to occur (i.e., assigned a probability of one). (NAS Report pp. 11-12)

Comments 0368.5-4 and 0217-2 expressed agreement with the specifications for FEPs described in the proposal, in terms of their substantive merits, but expressed an opinion that NRC is the authority that should make these stipulations for the treatment of FEPs in the safety assessments. We believe that NRC will critically evaluate the manner in which DOE performance assessments treat FEPs in the analyses and make any alternative treatments they deem appropriate to evaluate the projected performance of the disposal system.

Section 16 FEPs and Screening Criteria

Issue B: Seismic FEPs

1. EPA proposes that only seismic effects on the engineered barriers should be considered. While conceding that seismic events also could affect the natural system— particularly by affecting fluid transport pathways—EPA is "proposing that DOE's analysis for seismic events may exclude the effects of seismicity on the hydrology of the Yucca Mountain disposal site." 70 FR 49056. EPA based this exclusion on two rationales: first, that predicting alterations in flow would be "highly speculative," and second, that any effects of seismic events would be overshadowed by the effects of climate change. (Comment 0226-85)

2. These rationales are wholly inconsistent with the NAS's determinations. Rather than suggesting that seismic effects on hydrology could be excluded from analysis, NAS wrote that "[w]ith respect to the effects of seismicity on the hydrologic regime, the possibility of adverse effects due to displacements along existing fractures *cannot be overlooked*." NAS Report at 93 (emphasis added). NAS did also state, as EPA selectively notes, that favorable alterations in the hydrologic regime were possible, but then went on to conclude that "the consequences of these events are boundable for the purpose of assessing repository performance." *Id.* But NAS never qualified its admonition that seismic effects on hydrology "cannot be overlooked" by suggesting, as EPA does now, that climate change might have similar but larger effects. That rationale is patently flawed, for it overlooks the realistic possibility that adverse hydrologic effects arising from seismic events would compound the adverse effects of climate change; there is no reason to assume that adverse climate change effects would preclude adverse seismic effects from occurring. (Comment 0226-86)

Response to Issue B:

After considering public comments, we are adding a provision to address a potential effect of seismicity on hydrology that was identified by NAS. The final rule now requires DOE to assess the potential effects of changes in the ground-water table as a result of seismicity.

We noted in our proposal (70 FR 49055-49056) the NAS statement that "[w]ith respect to the effects of seismicity on the hydrologic regime, the possibility of adverse effects due to displacements along existing fractures cannot be overlooked" but that "such displacements have an equal probability of favorably changing the hydrologic regime." (NAS Report p. 93) We argued that these effects would likely be minimal given the many small-scale changes that would be possible in the connectivity of the fracture networks, and that these effects would likely be small compared to the effects of climate change on the hydrologic behavior of the disposal system. We did not mean to imply that the seismic and climate events would involve the same hydrologic characteristics and processes or produce the same effects on the ground-water flow regime, but that the effects of one were likely to outweigh the effects of the other. While we still believe that is likely, we have concluded, after further consideration, that the issue of hydrologic effects resulting from seismic events needs to be examined in sufficient detail to address the point made by NAS. We believe the effects of fault displacement on the hydrologic regime will be adequately addressed by the variation in parameters such as hydraulic conductivity (i.e., evaluating reasonable variation in ground-water flow parameters, whether seismically-induced or not, will illustrate the range of effects that might result from seismicity). However, NAS also identified another seismic effect on hydrology, namely the potential for transient rise in the ground-water table. In this instance, NAS did not simply state that such potential could be bounded, but noted site-specific studies suggesting that such a rise would be "on the order of 20 m or less" (NAS Report p. 94). Therefore, the final rule requires the potential effects of a rise in the ground-water table as a result of seismicity to be considered. NRC may determine the magnitude of the elevation of the water table rise and its significance on the results of the performance assessment, or NRC may require DOE to demonstrate the magnitude of the elevation of the water table rise and its significance during licensing. If NRC determines such effects to be significant to the results of the performance assessment, it shall specify the extent of the rise for DOE to assess.

We believe deferring to NRC on this point is the appropriate approach. The above quote from page 94 of the NAS Report makes it clear that changes to the hydrologic regime from seismic events would be equally likely to enhance or reduce transport of radionuclides. However, we believe these seismically induced changes are likely to be approximated by the normal variation in flow parameters. It may be that changes in the hydrologic system from climate change, including elevation of the ground-water table, may be quantitatively more significant than such changes resulting from seismic activity. We believe NRC is better positioned to make judgments regarding the extent of such changes. We note that a dozen years of site characterization, scientific study, and performance assessments have been conducted since the NAS Report in 1995. NRC has conducted its own analyses as well as participated in ongoing technical exchanges with DOE over this period. We view deferring to NRC's judgment in this case as comparable to the approach we have taken with climate change. In that instance, we outlined the primary issues and overall approach, but specified that NRC would establish the details required to implement our standard.

Section 16 FEPs and Screening Criteria

Issue C: Volcanism and igneous events

1. Lincoln County agrees with EPA's proposal to require DOE to consider the exposure consequences of igneous events during the 10,001 to 1,000,000 regulatory compliance periods. Further, EPA's proposal to limit said analyses to volcanic events that intersect the repository, damage the waste packages, and cause releases of radionuclides either directly to the atmosphere and biosphere or to the groundwater appears reasonable. (Comment 0219-4)

2. EPA states that DOE need only consider as FEPs volcanic events that have occurred, or may reasonably be inferred to have occurred, during the Quaternary Period, which includes approximately the last 1.6 million years. 70 FR 49052. The rationale, apparently, is that if events haven't occurred during the last 1.6 million years, the probability of their occurrence within the next million years is negligible. For events likely to occur on a shorter time cycle (e.g. climate shifts), this might be a reasonable assumption, since a 1.6 million-year period is long enough to encompass numerous climate cycles and provide a sense of the full range of possibilities. Volcanic eruptions in the Yucca Mountain area, however, occur infrequently and irregularly, and the activity in one 1.6-million year period—a long period by human standards, but a short one for many geologic processes—may not be an accurate preview of future activity. To assume that the volcanic events of the next million years are bounded by the events of the previous 1.6 million years is somewhat like assuming that Chicago's weather tomorrow can be predicted, with certainty, by reviewing the weather reports from the previous two days. (Comment 0226-89)

3. EPA's own consultant's report concedes that during the Pliocene Epoch (5.2 million years before present to 1.6 million years before present), several larger-scale eruptions occurred at the site. Cohen Report at 10-1 to 10-2. Moreover, EPA's own rule acknowledges that the type of eruptions that formed the tuffs at Yucca Mountain is not the same as the type of eruptions that are known to have occurred more recently. EPA at 70 FR 49058. The difference is important; in comparison to most basaltic eruptions, the eruptions that produce welded tuffs generally are gigantic. (Comment 0226-90)

4. In requiring that DOE model only events that occurred during the Quaternary period, EPA is excluding possible volcanic events from analysis. Moreover, it isn't excluding just any events, but instead is selectively leaving out larger events. While such events have low probabilities, since volcanic events in the region are infrequent, their effects, if they do occur, could be major, and there is no foundation for EPA's rationale for screening them out entirely. (Comment 0226-91)

5. White Pine County agrees with EPA's proposal to require DOE to consider the exposure consequences of igneous events during the 10,001 to 1,000,000 regulatory compliance period. Further, EPA's proposal to limit said analyses to volcanic events that intersect the repository, damage the waste packages, and cause releases of radionuclides either directly to the atmosphere and biosphere or to the groundwater appears reasonable. (Comment 0315-4)

6. Section 197 .12: The duration of geologic stability is at best guesswork, although the presence of comparatively recent volcanic activity and record of seismic activity in the vicinity of Yucca Mountain should receive heavy weighting in the analysis. (Comment 0331-11)

7. We wish to call EPA's attention to a possible drafting problem. Proposed 40 C .F.R. § 197.36 (c) (1) (ii) states that the "igneous event may be limited to that causing damage to the waste packages directly . . . ." This might (but need not) be read to preclude consideration of any igneous events that are projected to occur after waste package failure. We assume no such interpretation was intended since the preamble has no discussion that could serve to justify the exclusion of such a large category of potentially significant events. (Comment 0357-3; 359-3)

Response to Issue C:

First, in order to prevent confusion, we will provide some definitions of the major terms we use in this response. The Pliocene Epoch was a subdivision of geological time from approximately 5.3 million years ago to approximately 2 million years ago. (Source: University of California, Berkeley, (http://www.ucmp.berkeley.edu/tertiary/pli.html). The Quaternary Period is a subdivision of geological time which covers the last two million years up to the present day. (The exact duration is a matter of debate with estimates of the onset of the Quaternary Period placed between 1.8 million years and 2.6 million years ago by different authors) The Quaternary can be subdivided into two epochs; the Pleistocene (two million years to ten thousand years ago) and the Holocene (ten thousand years ago to the present day) (Source: Quaternary Research Association, http://qra.org.uk/what.html).

EPA agrees with the commenter (0226-90) who states that evidence of past volcanic events in the Pliocene Epoch should also be considered in determining the probability of igneous FEPs for performance of the repository out to 1 million years. As we stated in the preamble to the proposal (70 FR 49056), we agreed with NAS that the probability of igneous events may be great enough, and the potential consequences significant enough, that they must be considered over the period of geologic stability.

Concerning which events to consider for the igneous FEPs, we looked at the geologic record of the area. Over the past 11 million years there has been a shift in the types of igneous events that have taken place in the Yucca Mountain vicinity. The repository block tuffs are in the age range of approximately 11–12 million years old and were generated by the large-scale volcanism mentioned by the commenter (0226-90), and involved a large area around the site. Information compiled by the NRC (ACNW Meeting, 2004, Docket

No. EPA-HQ-OAR-2005-0083-0373, 0378) concerning basaltic igneous activity around the site shows that this type of activity has been the only activity around the site through the Pliocene, and that volume of eruptive activity (both tuff and basaltic material) has decreased continually over the last ten million years (Compton et al., 2004, Docket No. EPA-HQ-OAR-2005-0083-0377). From the identification of surface as well as indicators of buried remnants of past volcanic activity, the episodes of basaltic activity around the site can be shown to have occurred in clusters of events around one million and four million years ago (Hill, 2004 Docket No. EPA-HQ-OAR-2005-0083-0373). The occurrence of these clusters indicates that the nature and extent of past volcanic activity can be reasonably well characterized and that annual probabilities for such events can be reasonably estimated from the geologic record around the site. Annual probabilities of volcanic disruptions of the repository have been estimated by various workers, and range from as high as 10^{-6} to as low as 5.4×10^{-10} (Compton, et. al, 2004, Docket No.EPA-HQ-OAR-2005-0083-0377). These probabilities fall across the 10^{-8} probability cut-off limit and indicate that intrusions of this type would have to be considered in DOE's performance assessments. The site evidence and history of volcanic activity indicate that the nature of this potentially disruptive event can be reasonably characterized both in terms of probability and consequences for repository performance, based on the number of events that have occurred in the past.

Basalt volcanism, exemplified by the Lathrop Wells scoria cone, and other features near the repository, appears to be the type of igneous activity, though unlikely, that has some probability of occurring within the period of geologic stability. By specifying a probability threshold, we focus the analysis on the type of events most plausible during the period of geologic stability. Statements made by the commenter (0226-90) in which it was suggested that DOE consider eruptions that produce welded tuffs (of the type produced 11-12 million years ago) which "generally are gigantic" shows a lack of understanding for the concept of geologic stability as it pertains to performance assessment. Volcanic events as large as the ones that produced the Yucca Mountain area can change the landscape entirely and create a situation in which site characteristics could be far different from those seen today. For time periods where conditions at the site would change dramatically in a relatively short time, projections of site conditions would be highly speculative, and consequently performance assessments would have very limited if any validity. It would be unreasonable to require any repository to be designed to withstand catastrophic events having such far-reaching consequences. The potential for such large-scale events would more appropriately be addressed during site selection.

It is important to understand that "stable" in this context is not synonymous with "static and unchanging." Rather, NAS recognized that many "physical and geologic processes" are characteristic of any site and have the potential to affect performance of the disposal system. NAS concluded that these processes could be evaluated as long as "the geologic system is relatively stable and varies in a boundable manner" (NAS Report p. 9). Thus, the site itself could be anticipated to change over time, but in relatively narrow ways that can be defined ("bounded"). Implicit in the NAS recommendation is the idea that the maximum risk might occur outside the period of geologic stability, but assessments performed at that time would have little credibility and would not be a legitimate basis for regulatory decisions: “After the geologic environment has changed, of course, the scientific basis for performance assessment is substantially eroded and little useful information can be developed.” (NAS Report p. 72).

Comments 0357-3; 359-3 state that our proposal states that the "igneous event may be limited to that causing damage to the waste packages directly . . . ." This might (but need not) be read to preclude consideration of any igneous events that are projected to occur after waste package failure.” The comments are correct, and we did not assume such an interpretation. We note that NRC has defined “waste package” to include the waste form (10 CFR 63.2), which is not inconsistent with our intent.

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Section 17 Reasonable Expectation/Implementability

1. However, if my interpretation of language in the Proposed Rule is correct, I basically disagree with how EPA has attempted to incorporate the concept of "reasonable expectation" into regulations for Yucca Mountain. On the basis of discussions in the Supplementary Information, language in the Proposed Rule, and language in other parts of 40 CFR Part 197 that are not subject to change in the Proposed Rule, it seems to me that the only way EPA has incorporated the concept of "reasonable expectation" in these regulations is by specifying that the mean or median of probability distributions of projected doses must not exceed specified dose criteria .The description of "reasonable expectation" in § 197 .14 notwithstanding, I do not see any other way that "reasonable expectation" is incorporated in the regulations in regard to how that concept can be used by the NRC in evaluating DOE's license application for Yucca Mountain.

…It seems to me that a reasonable interpretation of the proposed wording in the regulations noted above [§ 197.13, § 197.20, and § 197.25] is that NRC must render its licensing decision on the basis of objective comparisons of means or medians of probability distributions of calculated doses with specified dose criteria, even though the standard of proof of compliance is one of "reasonable expectation." If my interpretation is correct, the wording in the regulations indicates to me that EPA has misinterpreted the concept of "reasonable expectation" and applied it inappropriately.

The basic idea behind the concept of "reasonable expectation" is that decisions … cannot be based solely on objective comparisons of results of performance assessment … with specified numerical criteria (e.g., a limit on dose). Rather, the concept of "reasonable expectation" requires that licensing authorities exercise subjective scientific judgment … the essential point being that subjective scientific judgment necessarily involves important qualitative considerations that are not captured in quantitative probability distributions of projected doses. Indeed, discussions in the Supplementary Information concerning "reasonable expectation" and the importance of uncertainties at far future times emphasize that regulatory decision making over time frames out to one million years involves important qualitative considerations. However, it appears that EPA has not properly accounted for this essential aspect of the concept of "reasonable expectation" in formulating its decision rules concerning compliance with dose criteria in these regulations.

The essence of my concern boils down to two simple questions that EPA must clearly address in developing its regulations for Yucca Mountain:

- Is NRC required to reject a license application if means or medians of probability distributions of projected doses exceed specified dose criteria, without regard for any other considerations?
- Is NRC required to issue a license if means or medians of probability distributions of projected doses do not exceed specified dose criteria, without regard for any other considerations?

If the answer to both of these questions is "yes," then EPA has improperly applied the concept of "reasonable expectation" in formulating its decision rules in the regulations. If the answer to both of these questions is "no," then EPA has recognized what "reasonable expectation" means and how it should be applied in regulatory decision making, but what is missing from the regulations is some discussion of conditions under which NRC can reject a license application if specified dose criteria appear to be met or issue a license if not. I appreciate that specificity about such conditions is inappropriate, but the basic idea must be clearly stated.

The essential point of these comments is that NRC must have the flexibility to evaluate the totality of information in deciding whether or not to license the Yucca Mountain facility. For example, NRC must be allowed to reject a license application that indicates compliance with specified dose criteria if, in NRC's judgment, important factors that could lead to substantially higher projected doses have not been properly accounted for in DOE's performance assessment that supports the license application. Conversely, NRC must be allowed to license the facility, even though a license application may indicate noncompliance with specified dose criteria under some conditions, if, in NRC's judgment, assumptions in performance assessments that led to an appearance of noncompliance are not credible. Thus, the regulations must be written in such a way that these kinds of decisions by NRC clearly are allowed. I do not believe that EPA's proposed wording in the regulations meets this crucial test. (Comment 0186-6)

2. Requiring absolute assurance of dose rates less than a tiny fraction of natural background, even for only a small number of people, over a timeframe extending from 10,000 to a million years, is not only infeasible, but it is indefensible and completely inconsistent with all other environmental regulations ever promulgated. (Comment 0201-2)

3. We agree with the discussion in Section II.A.4 on reasonable expectation, especially the contention that “proof” of disposal system performance in the traditional sense of the word cannot be attained for periods extending hundreds of thousands of years. That is why we did not agree with extending the dose limit period beyond 10,000 years. (Comment 0217-9)

4. EPA's final justification for its rule is the concept, originated by DOE, of "implementability." EPA believes, reasonably enough, that the standard it selects should be usable by the NRC to distinguish an adequate repository design and site proposal from an inadequate one. But EPA offers no proof that its proposal will accomplish this result. A standard must be “implementable” in the sense that the application of the principles of sound science should enable a regulator to decide whether or not compliance is achieved. But EPA's conclusion that only a lax standard is "implementable" in this sense is inconsistent with the findings and recommendations of the NAS. The NAS clearly determined that EPA's standard should apply at peak dose, and that physical processes affecting the site were sufficiently predictable to allow such a peak-dose compliance assessment. As EPA itself previously recognized, NAS recommended a methodology for setting the standard, and that methodology would produce dose limits in the 15 millirem/year range. *See* EPA, Response to Comments at 4-5 to 4-6 (rejecting a 70 millirem/year standard because it would be "well above the NAS-recommended level"). Those determinations clearly indicate that, in the NAS's view, a 15 millirem/year standard is "implementable." Moreover, EPA has produced nothing but speculation to suggest that only a higher standard is "implementable." Nor could it, for DOE's current modeling results show a clear and certain *failure*, by almost any statistical measure, when compliance is measured against a consistent 15 millirem standard. *See* TSPA graph reproduced in Appendix C) (showing that at peak dose, almost 100% of the model runs predict doses

exceeding 15 millirem/year). Any test that shows such certain failure obviously would be implementable; NRC quite clearly can determine what the outcome would be. (Comment 0226-68)

5. To escape this obvious problem with its implementability rationale, EPA vaguely implies, notwithstanding the NAS's clear determinations, that inherent uncertainties would make compliance with a 15 millirem/year standard difficult at any site, and that a 15 millirem standard therefore is not "implementable" because it cannot distinguish good sites from bad. Yet EPA supplies absolutely no empirical support for this speculative statement. (Comment 0226-69)

6. EPA's "implementability" rationale is suspect for another reason: it already has been rejected by the Court. As the court noted, EPA's core rationale for its prior 10,000- year cutoff was that post-10,000-year analyses were "not practical for regulatory decision-making." *NEI*, 373 F.3d at 1268 (66 FR 32097). EPA had reached this conclusion after considering "comment on whether it is possible to implement the NAS-recommended compliance period…." EPA's conclusion was that it was not. The Court specifically rejected this rationale, concluding that it was inconsistent with the NAS report. As the court noted, NAS specifically warned against calculational approaches that make "compliance rather easy" and "simplify licensing," but fail to uphold the core duty to ensure "no unreasonable risk to the health and safety of the public." 373 F.3d at 1271. Yet, EPA now proposes to resurrect a similar rationale to severely loosen its peak dose standard. As discussed *infra*, what EPA really means by "Implementability" is that DOE is entitled to a standard that Yucca can pass. But that determination is not EPA's to make. It is charged with promulgating a standard that protects public health and safety, and must do so consistent with the findings and recommendations of the NAS. It may not flout those recommendations and deviate from thirty years of practice by invoking "Implementability" as an excuse to promulgate what is, in effect, a best available or best practicable technology standard, rather than a health-based standard, so as to grant Yucca an easy pass. (Comment 0226-70)

7. EPA's heavy reliance on the concept of "Implementability" is the first indication of EPA's prejudgment, for EPA has defined its "Implementability" goal in such a way that it assumes a license must be granted. EPA's proposed rule suggests that a standard must be "implementable," ostensibly meaning that it must provide a measure capable of distinguishing a good repository license application from a bad one. *E.g.* 70 FR 49029. This definition is reasonable enough; a standard against which compliance could not be measured might as well be no standard at all. Yet the manner in which EPA applies this concept reveals, for numerous reasons, that EPA misconstrues it by deciding that any standard that might cause Yucca to fail is not implementable. First, EPA impliedly defines an "implementable" standard as a standard that some repository somewhere could pass. Without offering any basis for this conclusion—and without acknowledging that it is directly contrary to the conclusions of the NAS, which determined that a traditional apportioned standard could be used through the time of peak dose—EPA then suggests that because of inherent "uncertainties," no repository anywhere could pass a traditional, 15

millirem/year standard, and that such a standard therefore is not implementable for longer-term compliance assessment. (Comment 0226-97)

8. EPA has no basis for assuming that a "safe" repository could not pass a traditional 15 millirem/year standard and that such a standard therefore is not implementable. The NAS came to no such conclusion, and instead determined that current site characterization capacities are sufficient to project compliance with a traditionally apportioned standard through the time of peak dose. Moreover, EPA's rule does not consider experience at other actual repository sites, and EPA therefore lacks any basis for asserting that no site could pass a 15 millirem standard. Another location with true geologic isolation—a site without permeable, fractured rock that allows ground water to flow through the repository—might well pass the traditional 15 millirem standard even at peak dose. DOE's WIPP repository -- the only operating repository in the world -- is just such a location. Having considered only Yucca Mountain in assessing whether 15 millirem/year is "implementable," EPA has no basis to suggest that the standard is universally impossible to meet. Because EPA's "Implementability"-based rejection of a traditional standard is based solely on its review of Yucca Mountain, that rejection is in reality a prejudgment that the only "implementable," and thus acceptable, standard is one that Yucca Mountain could meet. Implementability thus is only an excuse for setting a standard that allows Yucca Mountain to be licensed, regardless of its safety, and EPA's use of that concept betrays its procrustean attempt to predetermine the outcome of the licensing process. (Comment 0226-98)

9. EPA's treatment of supposed "uncertainty" further evinces prejudgment. Under EPA's reasoning, uncertainty and implementability are closely connected; because of compounding uncertainties, EPA believes, a low standard is not implementable for long-term compliance assessment, and a higher standard must be used. This reasoning amounts to a predetermination that Yucca Mountain should be licensed. First, EPA's relaxation of standards betrays a prejudgment that the repository should be licensed even if DOE and NRC cannot determine whether it will work. Even if uncertainties do make predicting compliance with a traditional standard difficult regardless of site-specific characteristics, that does not mean that the standard is not implementable, for there is nothing unimplementable or unreasonable about a standard that requires the applicant to bear the burden of addressing uncertainty. Just as the FDA does not license drugs until it has some certainty about how they will perform, and does not consider rules requiring such demonstrations "unimplementable," EPA cannot alter its standards to facilitate the licensing of a repository with uncertain prospects of success. Indeed, that uncertainty may reflect flaws in the siting or design of the repository, or may simply reflect the fact that DOE's modeling and site characterization capabilities are not sufficiently advanced for it to demonstrate whether or not a repository will perform adequately. Under such circumstances, uncertainty provides a reason *not* to license repositories, not an excuse to consider traditional health-based standards unimplementable. Relaxing standards to accommodate uncertainties indicates an unlawful predetermination that repositories should be licensed. (Comment 0226-99)

10. Second, because the key uncertainties EPA cites as affecting DOE's long-term performance assessment are *specific to Yucca Mountain*, EPA's implementability/ uncertainty rationale betrays EPA's attempt to predetermine licensing by tailoring the standard to accommodate the known *weaknesses* of the Yucca Mountain site. Uncertainty exists at Yucca Mountain primarily because water naturally percolates through the repository due to fractured geology. For two primary reasons, that water flow makes engineering uncertainties crucially important. First, it promotes corrosion, which EPA has observed is "exactly the critical element in estimating the timing and magnitude of peak dose." 70 FR 49026. Second, because it negates the existence of geologic containment, it places increased importance on the engineered barrier system, and while it is undisputed that those barrier systems will eventually fail, no one is certain when that failure will occur. Additionally, because water flow rates may vary, water infiltration creates some uncertainty about the rate at which radionuclides will move through the subsurface environment. (Comment 0226-100)

11. These uncertainties are not inherent in all potential repository sites. Instead, they are peculiar to the permeability and fractures of Yucca Mountain's rock. At a site providing true geologic barriers—such as the WIPP site, where the geology provides total containment—neither source of uncertainty would exist. Water would not enter or leave the system, and inevitable failures of the engineered barriers would be compensated for by the impermeability of the surrounding geologic formation. EPA's reliance on uncertainty as the basis for its lax standard therefore constitutes EPA's determination that the standard should be tailored to accommodate the flaws in the Yucca Mountain site. That rationalization and the resulting lax standard completely undermine the integrity of EPA's rulemaking by basing the standard on non-health related factors that EPA has no power to consider. Additionally, that rationalization usurps the NRC's jurisdiction to determine whether or not the license should be issued by crafting a standard to *ensure* that a license will issue. A standard designed to *measure* whether a repository protects public health cannot be tailored to the weaknesses of that very repository without tainting the entire licensing process with prejudgment. (Comment 0226-101)

12. EPA's current proposed rule is a radical departure from the advertised bases of both the Reasonable Expectation and the Reasonable Assurance concepts, in that EPA's proposal (1) fails to focus performance assessments and analyses on the *full range of defensible and reasonable parameter distributions*; and (2) seeks to invade the jurisdiction of NRC as the implementing authority for licensing of the proposed Yucca repository. In its analysis of DOE's Yucca Mountain performance assessments, predating the EPA proposed rule, Cohen & Associates noted that: "Inappropriate simplifications can mask the effects of processes that will, in reality, determine disposal system performance, if the uncertainties involved with these simplifications are not recognized." OAR-2005-0083- 0085, at 12-2. "If the uncertainties in site characterization information and the modeling of relevant features, events, and processes are not fully understood, results of bounding analyses may not be bounding at all." *Id*. "The Reasonable Expectation approach is aimed simply at focusing attention on understanding the uncertainties in projecting disposal system performance so that regulatory decision making will be done with a full understanding of the uncertainties involved." *Id*. In sum, to the extent EPA's discussion, reasoning, and application of a new

"Reasonable Expectation" standard can even be understood, it appears vaguely to apply a set of criteria that together amount to far less than the simple and well-understood concepts of either Reasonable Assurance or Reasonable Expectation. (Comment 0226-109)

13. 40 CFR 191 was "implementable" but Yucca Mountain could not comply. The second rule cannot be implemented because it did not pass the legal test. So, EPA could either write an implementable rule that will protect the public, not the site; or write one that again fails legally. Yucca Mountain fails a protective test so EPA has proposed a new 40 CFR 197 that is accommodating, not legally "implementable." EPA should establish a rule that is "implementable;" meaning one that is understandable, directly complies with the order of the Court, and has protective limits against which Yucca Mountain can be tested. (Comment 0257-2)

14. EPA is trying to bring back "reasonable expectation" even though in the Court arguments it became clear that "reasonable expectation" and "reasonable assurance" are the same. However, the general public thinks that "reasonable expectation" is the weaker of the two. (Comment 0257-5)

15. EPA retains numerical criteria of any magnitude for the post 10,000 year period, EPA should further address the uncertainty aspects of using such a value in NRC adjudicatory regulatory proceedings. The specification of the median value in the proposed standard is a step in the correct direction, but more should be done. NRC proceedings are traditionally conservative and that is likely to continue despite EPA and NRC intentions for a "reasonable expectation" evaluation. NRC processes will likely turn more toward their traditional conservative "reasonable assurance" approach which is often not much different than the most stringent "beyond reasonable doubt" approach that is used in judicial trials. EPA should include language in the final standard that would level the playing field and specify that multi hundred thousand year dose projection criteria can be achieved "with a reasonable doubt", not just "reasonable expectation" criteria. (Comment 0264-5)

16. The of the stated goals for the standard in the preamble for the Individual-Protection Standard is that it be " implementable by NRC in its licensing process." This caveat is clearly the cornerstone upon which the EPA as built a case for the relaxing the standard after 10,000 years, which is arbitrary in the first place. Here, the EPA is doing the NRC's job, and paving the way for the DOE to make its case for Yucca Mountain. By saying that the standard needs to reflect the uncertainties and lower confidence of projected doses past 10,000 years runs contrary to the concept of a standard in the first place. A standard is codified to assure a certain level of protect regardless of how well we can estimate future impacts; in fact, increased uncertainty is all the more reason not to relax the standards. A more stringent standard protects the public in the future from failures in our understanding of how the repository can contain the radionuclides. The "added" margin is critical as a compensatory measure against likely error. Of course 15 mrem/yr and the Safe Drinking Water Standard can be implemented, i.e., used as a measure of how well the repository needs to perform to protect the public. Failure of the DOE to demonstrate compliance is not a failure of the standard, but rather an illustration of deficiencies of the repository, which underscores the purpose of the standard: Will the repository protect the public from

radiation exposure to a level deemed acceptable? 350 mrem/yr and no groundwater standard is not acceptable: period. You at the EPA know that. The EPA must not heed concerns over compliance, but rather stay the course of protecting the public. (Comment 0268-12)

17. EPA has exhausted its bag of tricks to justify this outlandish standard by trying very hard to bring back "reasonable expectation" even though it was made clear, during the arguments in the Court that "reasonable expectation" and "reasonable assurance" are no different. However, the words ARE different in the understanding of the general public and it appears that they have different meaning for EPA as well – otherwise they would not make such a concerted effort to have this rule morph back to "reasonable expectation." It is the weaker of the two. (Comment 0294-2)

18. EPA should establish a rule that is "implementable;" meaning one that is understandable, directly complies with the order of the Court, and has protective limits against which Yucca Mountain can be tested. Unlike this current draft, a proposed rule that is "based upon and consistent with" the National Academy of Sciences report and simply complies with the order of the Court would be straightforward and transparent. (Comment 0294-5)

19. Yet, efforts to evaluate the consequences of this diminished hazard out to a million years, even in a conceptually sound manner, inevitably give rise to issues that, in practice, would become problematic. Such issues, involving large long-term uncertainties, would be difficult to resolve in the adjudicatory setting of an NRC licensing process. What results is a safety assessment wherein several assumptions necessarily underlying applicable model(s) can be subjected to extensive second guessing due to their inherently speculative nature. (Comment 0298-5)

20. It is this growth in uncertainty that underlies the point that long-term projections of repository performance should not be viewed as predictions of what will happen, but simply as indicators that can inform but not dictate a decision about whether the repository provides adequate protection…In short, the issue to be resolved in establishing a peak dose standard is not whether such long-term calculations can be made, but rather what degree of confidence can be placed in them and how they should be used in determining the acceptability of a repository…In commenting on EPA's original proposal for Part 197 in 1999, the Department agreed with EPA's statement that there was no policy basis for the acceptable level of confidence necessary to determine compliance using long-term projections going far beyond 10,000 years . While there is international agreement that long-term projections should be prepared as part of the process of regulating radioactive waste disposal, there is no consensus about how those projections should be made or how they should be used in regulatory decision making. (Comment 0352-8)

21. It would be helpful for EPA to restate the point that it has made repeatedly in the past that reasonable expectation is different from reasonable assurance as it has traditionally been applied, and to include a statement, similar to the one used in promulgating Part 197 in 2001, that "whatever approach is implemented must incorporate the aspects of

reasonable expectation we have described in the standards and amplified upon in our proposal." Such clarification is particularly important in view of the fact that EPA has not proposed any changes to the definition of reasonable expectation in the regulation itself that would explicitly recognize the difference in its application at the time of peak dose compared to 10,000 years. In this context, it would be helpful for EPA to point out that the "… body of experience in applying the 'reasonable expectation' concept for 10,000 years..." referred to in the proposed rule must be interpreted with caution in applying the concept at the time of peak dose because the difference in time periods of application and in the resulting uncertainties is so great. (Comment 0352-38)

Response to Issue 17:

A number of comments focused on our discussions of implementability in the preamble to the proposed rule. These comments expressed a belief that our goal to have an implementable standard served as the driving force behind what some comments perceived as a loosening of the health protection standards (Comments 0226-68, 0226-69, 0226-70, 0226-97, 0226-98, 0257-2, 0268-12, and 0294-5). Related comments discussed concerns about uncertainty and its relation to the standards (Comments 0226-99, 0226-100, and 0226-101), and comments on our discussions of the reasonable expectation approach (Comment 0226-109). We believe these comments are closely intertwined and not easily discussed in isolation. The general thrust of the comments is that we did not apply these ideas and goals in an appropriate manner, i.e., what some commenters perceive as a loosening of the standards for the proposed peak dose limit in order to ensure the disposal system can be licensed.

This perception is incorrect. The three issues of implementability of the standard, the role of uncertainties in making compliance decisions over the period of geologic stability, and our reasonable expectation approach to decision making, are intimately related. Our intent for the peak dose standard is that the licensing authority should have sufficient information in the licensing process to evaluate the level of confidence that can be placed in the analyses presented by the applicant. Making a compliance decision for peak dose calculations that extend into the many hundreds of thousands of years must of necessity consider the uncertainty involved in such calculations. For a standard to be implementable requires that these uncertainties also be considered in framing the standard. This goal imposes significant burdens on the implementing authority to identify and evaluate the uncertainties in the applicant's safety assessments during the regulatory process and in the final compliance decision. It also imposes a heavy expectation on the applicant to provide sufficient information supporting the safety assessments to allow the regulator to make judgments about the credibility of the assessments in light of the uncertainties involved. We agree with Comment 0226-99 to the extent that it would be appropriate and reasonable for DOE to identify uncertainties, and its methods for addressing them, in its license application. However, we disagree with Comment 0268-12, which argues that standards should be determined "regardless of how well we can estimate future impacts." Standard-setting agencies have traditionally been cognizant of the limitations in the methods available to show compliance with those standards. For example, standards for cleanup or treatment of toxic materials, including radionuclides, depend heavily on the sensitivity of instrumentation or the capabilities of technologies to destroy, separate, or neutralize toxic constituents. As another example, it makes little sense to set standards for maximum contaminant levels in water or soils at levels where the technology for determining these levels cannot distinguish between different analytical results. We have examined the types of uncertainties, i.e., modeling and data uncertainties, involved in the Yucca Mountain site assessments (EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429) to gain insights into the interplay of uncertainties in processes that control the timing and magnitude of the peak dose. These insights lead us to conclude that small differences in mean dose levels (a few tens of mrem/yr or less) observed for different sets of numerical simulations of the disposal system may not be statistically distinguishable. Such small differences represent the limits of the performance assessment tool rather than a meaningful difference in the dose assessments. Similarly, in judging compliance with a dose standard over periods as long as 1 million years, it is necessary to recognize that such a standard cannot be viewed in the same way over that entire time. The limitations in projecting doses become more pronounced at longer times, as does the ability of regulators to assess the importance of variation in various parameters to the overall safety of the disposal system. In our view, performance assessment is one of many elements that contribute to safety. The uncertainty in these assessments must be recognized and factored in to decision-making using this technology.

We reiterated our reasonable expectation approach to focus the compliance process on a full consideration of all relevant uncertainties and the limits in reliability of numerical performance projections that must extrapolate data and conceptual models over time frames that are unprecedented in the waste disposal arena. We believe that uncertainties in describing the characteristics of the site increase with time because natural conditions and processes will modify these characteristics over time, and this uncertainty also contributes to the degree of confidence we can place in assessing the processes within the disposal system that control containment and isolation of the wastes. We agree basically with the NAS opinion that bounding performance assessments can be performed, but as we explained in the preamble text, care must be exercised in doing such assessments and using the results in compliance decision making. These bounding assessments, as we discussed, adopt conservative assumptions as a common practice to bias estimates to high-end releases and doses when significant uncertainties exist in the site data. An assessment that is heavily populated with deliberately conservative assumptions and data can in fact give results which are in reality an extreme performance cases and not truly representative of the full spectrum of possible performance. We intend that the licensing process consider the entire spectrum of projected results – both optimistic and pessimistic and not be biased by the inclusion of only "worst case" assumptions and data selection.

Contrary to some comment, we have not defined a "new" reasonable expectation to accommodate the extended compliance period. We used the reasonable expectration term in our 40 CFR part 191 generic standards, illustrating its consistent use in EPA regulations for deep geologic disposal. We maintained the description of our reasonable expectation approach unchanged for the proposed standards since we believe these principles remain valid. With the extension of the regulatory compliance period beyond 10,000 years and into the period of geologic stability, the issue of the degree of confidence that can be placed in the results of numerical assessments is of primary importance in decision making. It is simply a matter of degree relative to the magnitude of uncertainties within the 10,000 year period, and later through the period of geologic stability. (Comments 0226-68 and 0226-109)

Comment 0226-99 argues that uncertainty was the sole rationale for our selection of a dose limit above the 15 mrem/yr limit in today's action relative to the 2001 standards for the 10,000-year period. While we believe that uncertainty is an inherent part of making performance projections over many tens to hundreds of thousands of years, we believe that these projections still have value, which is why we required them to be performed and presented in the environmental impact statement. We believe there is a fundamental point going unrecognized in these comments. When the 15 mrem/yr standard for 10,000 years was framed in 40 CFR part 191 it was never intended to suggest that the disposal system would remain unchanged for extremely long periods of time, i.e., periods of hundreds of thousands of years. Nor did it imply that the engineered barriers should be expected to provide a fixed and very high level of containment of the wastes for unlimited time periods. It is simply unreasonable to expect that engineered materials will remain unchanged and impregnable for periods of many tens to hundreds of thousands of years. The purpose of the engineered barrier system is to provide containment for as long as practical, after which the natural barriers are intended to provide controlled release at acceptably low levels, i.e., not permit catastrophic releases when the engineered barriers degrade. In framing the original standard in 40 CFR part 191, it was stated that uncertainties beyond 10,000 years made the level of confidence in longer projections unmanageable.

One comment requested that we specify conditions under which NRC could license a disposal system that did not meet the dose limits, or could deny a license even if there were dose assessments that show compliance with the standards (Comment 0186-6). We do not believe that making such specifications in our standards is appropriate or could be done in a reliable way without an exhaustive review of DOE's licensing assessments, which is clearly not our mandate under law. To specify conditions where we believe the DOE licensing case dose assessments are not credible for a meaningful comparison with our dose limits would be highly speculative on our part, and would inappropriately intrude into the licensing process that is NRC's responsibility. We believe that it is NRC's responsibility to make the licensing decision based on the complete body of evidence placed before it by the applicant – only part of which will be numerical dose assessments, as described within NRC's regulation (10 CFR part 63). Further, it may be reasonable for NRC to focus on the assumptions and construction of those assessments, while attributing less importance to the projected dose values. The approach we took in our 2001 rulemaking was intended to avoid this very dilemma, allowing NRC to make judgments regarding the overall safety of the disposal system while being informed by long-term projections, but without giving undue emphasis to any particular projected dose levels, when we believe such emphasis is less supportable . NRC staff is on record (EPA-HQ-OAR-2005-0083-0376) to the effect that overall trends in projections may be given special attention even if the standard is not exceeded, such as if significant increases in projected doses are seen at times relatively soon after 10,000 years.

Comment 0226-99 contains the assertion that our treatment of uncertainty considerations in the proposed rule indicated a "prejudgement" on our part of the Yucca Mountain disposal system and an effort to set a standard that would assure the site would be able to show compliance. We do not believe that we are prejudging the acceptability of the disposal system. The preamble to the final rule explains the rationale used to develop the peak dose limit, a rationale that also recognizes the role of increasing uncertainty in dose assessments performed for very long time periods and a consequent lessening of reliance that should be placed on such analyses. We have performed some site-specific modeling to examine the effects of uncertainties in the natural barrier on dose projections for a hypothetical disposal system performing at the "edge-of-compliance" at 10,000 years (EPA-HQ-OAR-2005-0083-0386). The modeling is described in these reports and also described in Section 6 of this document. The intent was to explore the propagation of uncertainties in the natural barrier system around the repository on a reference disposal system created for the analyses. Results showed a two order of magnitude increase in the spread of dose projections compared to the initial reference case (a mean dose of 15 mrem/yr at 10,000 years). These results indicate that, with longer time frames for dose projections, the ability of such projections to meaningfully distinguish between alternative assumptions about characteristics of the disposal system as they may affect performance would become more difficult as the overall uncertainty in the system performance increases. Additional modeling we performed (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429,) illustrates the types of uncertainties involved in performance assessments and the limitations of these assessments to distinguish between alternate conceptualizations of the disposal system. If legitimate alternative conceptualizations involving differing assumptions, data distributions or repository designs, cannot be meaningfully distinguished because their specific effects are overwhelmed by larger uncertainties for the disposal system as a whole, the degree of confidence in the usefulness of the assessments lessens for decision-making. We believe that these results illustrate the need and meaning of reasonable expectation as applied to evaluating the weight to be given to long-term dose projections in reaching compliance decisions. Reaching a compliance decision using the results of such numerical dose projections is a major, if not the major, factor in decision-making and must consider the effects of increasing uncertainties on the projected doses. The regulator must also determine the degree of weight these projections should be afforded considering how mounting uncertainties can cloud the interpretation of results. For these reasons we have retained the concept of reasonable expectation as an important component of the standard.

Comments 0298-5 alluded to the difficulties of handling uncertainties in an adjudicatory licensing process. We agree that the treatment of uncertainties in dose projections is an important component in reaching compliance decisions in a regulatory proceeding. That is why we use the term reasonable expectation in the standards to provide guidance on how such uncertainties should be approached. A similar point was made in comment 0352-8, which focused on the degree of confidence that can be placed on long-term dose assessments in reaching a compliance decision. We agree that this is an important question and reiterate that was the reason for incorporating the reasonable expectation concept in the standards.

We have retained the text describing reasonable expectation unaltered even though the compliance period is considerably increased in the final standards. We did this because we believe that the principles remain the same regardless of the time frame for the decision-making. The difference between the expression of reasonable expectation in decision-making for the 10,000-year versus peak dose time is a matter of degree only (Comment 0352-38), the principle remains the same.

Commenter 0226 makes a number of other comments that flow from the position that we have prejudged the outcome at Yucca Mountain in favor of licensing. First, the commenter cites the NAS Report as supporting a "traditionally apportioned standard" of 15 mrem/yr through the time of peak dose (see Comments 0226-68, 0226-69, 0226-97, and 0226-98). As we have stated elsewhere, however, NAS acknowledged that "determining what is acceptable is not ultimately a question of science but of public policy" and did "not directly recommend a level of acceptable risk," but identified a range of risk that "could therefore be used as a reasonable starting point in EPA's rulemaking," (NAS Report p. 49) In identifying current domestic and international regulations that have applied for as long as 10,000 years, NAS noted that the apportionment approach has been widely accepted, but did not recommend that EPA adopt it in establishing the peak dose standard, nor did NAS suggest that the "traditional" apportionment approach would be appropriate for a standard in the extreme far future. The commenter also criticizes our statements that the standard we issue must be implementable by NRC in its licensing process. The commenter interprets our position as equating an implementable standard with one that DOE or "some repository somewhere" can meet (see Comments 0226-68, 0226-70, 0226-97, and 0226-98), and as "implying" and "suggesting" that "no repository anywhere could pass a traditional, 15 millirem/year standard" (see Comments 0226-69, 0226-97, and 0226-98). However, our direction in the EnPA is not to develop standards for "some repository somewhere," but to develop standards specific to the Yucca Mountain disposal system that NRC can use to judge the overall safety of that system. Many factors affect the projection of doses from a repository, including site characteristics, radionuclide inventory, engineered barrier design and longevity, and choice of receptors (see previous paragraph). It would be indefensible to say that "no repository anywhere" could meet a 15 mrem/yr standard – and Yucca Mountain itself may in reality perform to that level (note – the Final Supplemental EIS issued by DOE shows mean dose values within 1 million years well below the 15 mrem/yr. level). However, we have consistently stated our belief that, when accounting for very long times, the complexity of the system, increased uncertainty in projections, and increased difficulty in interpreting those projections, a 15 mrem/yr standard would not represent a reasonable test of the capabilities of the Yucca Mountain disposal system. The commenter goes on to question our "assumption" that "a 'safe' repository could not pass a traditional 15 millirem/yr standard." We would re-frame the question to: "Is a repository "safe" only if dose projections for the next 1 million years do not exceed 15 mrem/yr?" We disagree with this proposition in general, and would not consider it a responsible exercise of our authority to set such a standard in the specific case of Yucca Mountain.

Finally, this same commenter considers our emphasis on uncertainty to be insufficient justification for a higher peak dose standard (see Comments 0226-99, 0226-100, and 0226-101). The commenter suggests that uncertainty may reflect flaws in the site, design, or DOE's modeling capabilities. In such a case, the logical conclusion would be to deny the license. As stated earlier, we agree with the commenter's position that DOE should be expected to address uncertainty in its license application. However, one could easily interpret this position as concluding, for example, that the license cannot be issued if DOE has not accumulated a body of knowledge demonstrating that waste packages could unequivocally resist corrosion at least for periods stretching into the hundreds of thousands of years, which is clearly unrealistic (as the commenter points out elsewhere, the advanced materials in DOE's design have been in existence for less than one hundred years). The commenter compares this situation to the Food and Drug Administration's review of pharmaceutical applications, noting "FDA does not license drugs until it has some certainty about how they will perform, and does not consider rules requiring such demonstrations "unimplementable." We would point out, however, that FDA does not then require applicants to project the potential health effects over multiple generations on a wider population (in terms of age, gender, ethnicity, and other characteristics) than may have been represented in drug trials. For this analogy, there is a fundamental mismatch that makes the comparison very questionable. Drug testing can be done to a large extent in real time to verify the drug's efficacy, whereas the repository disposal system is a passive system, intended to perform without the ability to verify in real time the projections of actual performance. Factoring in uncertainties in the performance projections is a fundamental requirement for deciding what the dose limit must be and determining whether the system can meet the compliance requirements.

The commenter also makes the point that "the key uncertainties EPA cites as affecting DOE's long-term performance assessment are *specific to Yucca Mountain*" [emphasis in original] and "[t]hese uncertainties are not inherent in all potential repository sites. Instead, they are peculiar to the permeability and fractures of Yucca Mountain's rock." It should not be surprising that the content of a standard being developed to apply to Yucca Mountain may be affected by consideration of features specific to that site, but not features found at other sites. The commenter neglects to note that other repository sites have their own inherent uncertainties (one of which, climate change, will manifest itself in different ways at different sites, including Yucca Mountain). We cited extensive literature in our proposal to the effect that increasing uncertainties will render dose projections less meaningful beyond 10,000 years, and cautioning against relying solely on such projections for regulatory decisions. For example, we note that both France and Sweden include statements in their guidance to the effect that "uncertainty concerning the evolution of the repository increases progressively with time" and dose assessments should "tak[e] into consideration the increasing uncertainties over time." Neither of these countries is considering sites with characteristics similar to Yucca Mountain. We have not identified guidance on this topic stating that dose projections are credible except at sites with fractured volcanic tuff, such as is found at Yucca Mountain; rather, the general approach is to make the long-term standards less definitive and more reliant on qualitative judgment.

Comment 0352-38 has the suggestion that we restate the point that reasonable expectation differs from reasonable assurance as it has been traditionally applied, i.e., in the area of power reactor licensing. We agree in general with the thrust of this comment, in that as the time period for safety assessments stretches into the many tens to hundreds of thousands of years, the degree of confidence that can be placed in the values of parameters used in numerical assessments must of necessity decrease. We have added some additional text to the preamble to the final rule discussing the general increase in uncertainty in safety assessments for 10,000 years and those extending through the period of geologic stability.

Another comment (Comment 0264-5) made the suggestion that the language in the final rule be stated so that compliance could be met with “reasonable doubt” as well as reasonable expectation. We believe this idea is adequately expressed in our descriptions of the reasonable expectation approach. With an understanding of the gradual decreases in confidence that should be placed in numerical assessments over long time periods, we do not believe that characterizing the compliance decision with the term “reasonable doubt” is necessary.

Comments 0294-2 and 0257-5 stated that reasonable expectation is a weaker term than reasonable assurance. We maintain the position expressed in our 2001 rulemaking that the term reasonable expectation was preferable to the term reasonable assurance. Reasonable assurance is a concept well established and understood in the context of reactor licensing. Our point of emphasis was that NRC had not defined reasonable assurance in the context of geologic disposal, nor previously indicated that any difference in the approach taken to reactor licensing might be warranted. By contrast, our term of reasonable expectation has been used since the promulgation of 40 CFR part 191, has been extensively discussed in several rulemakings, and was implemented in the certification process for WIPP. The primary difference between reactor licensing and disposal system licensing is one of extrapolation times. Most of the projections of reactor performance can be verified in real time through testing and reactor operation, and the extrapolation of geologic conditions bearing on reactor safety involves periods of decades. For repository performance projections, essentially all the performance projections cannot be verified in real time. It is this difference we attempted to highlight when we preferred to keep the reasonable expectation term in our rule. We believe the reasonable assurance term should be left in the reactor-licensing arena where it is well understood. We believe that the equivalent of reasonable assurance applied to the repository safety assessment area would be reasonable expectation, because of the nature of evaluation. Projections of disposal system behavior over tens- to hundreds-of-thousands of years are inherently unverifiable and uncertainties in these projections take on a higher level of importance than in reactor licensing where uncertainties can be reduced more definitively. We noted in our Response to Comments document for the 2001 rulemaking that NRC had acknowledged, in its comments on our 1999 proposal, a need to re-examine “its reactor-based reasonable assurance approach…to adapt the approach to the unique aspects of repository performance" (Docket No. EPA-HQ-OAR-2005-0083-0043, p. 2-4). We further stated our belief that "whatever approach NRC adopts for implementation would at least incorporate the principles described for our reasonable expectation approach" (p. 2-7). NRC has adopted reasonable expectation in its proposed regulations (as indicated in the D.C. Circuit Court statements raised by the commenter).

Comment 0217-9 agreed with our discussion of reasonable expectation, but voiced opposition to extending the compliance period beyond 10,000 years. We believe extending the compliance period is the most appropriate way to address the Court decision and we believe that the reasonable expectation approach is equally valid, and perhaps more so, for this very long time frame. While we still required safety assessments beyond 10,000 years in the 2001 rulemaking, no regulatory requirement was applied to these assessments. The present rulemaking requires a compliance decision by the implementing regulator, and we believe that NRC must, and will, consider the inherent uncertainties involved in performance projections over these extremely long time periods. We do agree on the observation offered by one comment (Comment 0298-5) that long-term uncertainties could be difficult to resolve in an adjudicatory licensing process. Without a process that lets the decision-maker fully consider uncertainties and the degree of confidence that can be placed in the safety assessments, the licensing process could become hopelessly tangled in second-guessing and disputes about uncertainties that cannot be eliminated or reduced meaningfully because of the extrapolations involved in the safety assessments. This is why we believe that the reasonable expectation approach is critical to the regulatory process and decision-making for the peak dose standard.

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Section 18 Performance Assessment

1. The Nevada (Test Site?) monitors radiation releases, in the air and water, over 41 years, should be a factor in setting radiation standards on Yucca Mountain. As we discussed, there has been a radiation plume detected at a monitoring well outside of the test site boundaries. (Comment 0173-1)

2. The container integrity lifetime will be the primary determinant as to the protection afforded by the engineered barriers and this lifetime should be estimated through the TSPA modeling process. (Comments 0180-2 and 0181-2)

3. Water flow inside the mountain could ultimately cause radiation to leak out of the repository. (Comment 0210.1-2)

4. Population is growing all the time here in Nevada. So, although Yucca Mountain is a hundred miles from Las Vegas, there are more and more people that will be subjected to radiation closer to the mountain. (Comment 0210.3-3)

5. A calculation should be performed that would account for all the pollution coming from the Test Site, and that should be included in any calculations used at Yucca Mountain. (Comment 0210.3-4)

6. I'm the one that believes what were doing is doable. (Comment 0210.4-1)

7. You're writing a Yucca Mountain-specific standard. But I think it's more accurate to say that you're writing this standard specific to what you refer to as the RME, the reasonably maximally exposed individual, which is a resident of Amargosa Valley. And we talk about deep geologic disposal. And, yes, the waste would be a thousand feet below the surface, the very top of Yucca Mountain. But it sits a thousand feet over the heads of the people who live in Amargosa Valley. They live at an elevation of about 2,000 feet. The waste is buried at an elevation of about 3,000 feet. So when the waste comes down and gets into the water table, which everyone knows that it will -- the question is when -- it goes to Amargosa Valley where the water table is very close to the surface. And, in fact, at some times, like in the spring, that water comes to the surface, and the Amargosa River runs. And we have pictures from this previous spring in which many roads were closed, washed out, and a lot of problems occurred out there because the Amargosa River was running and looked just like an all-the-time, everywhere river. But at this time of the year, you can't find it except for the trees. You see the green line that goes along where things are growing, and that means the Amargosa River is underneath it. But there was a question raised by a man out at Amargosa Valley, and who's a resident out there, who knew about background radiation because he does a lot of monitoring. And he asked you to check with on the ground, what they -- what they know about that. But you really need, because you're writing an area-specific standard, you need to understand that area very well and realize that the groundwater is the transport mode for this waste and just how that works. And just the groundwater, which we think of as being somewhere way, way down at the end of a well,

sometimes joins the people and the animals and everything that's out there. (Comment 0211.11-1)

8. While I agree with the proposed amendments that one shouldn't consider events such as that one that wiped out the dinosaurs, I disagree that other sorts of estimations could reasonably go way past the 10,000 year mark, even up to a million years. If a need is perceived to project situations up to 1 million years hence (and I believe it rightly is perceived), the fact will have to be faced that this need cannot be realistically met because the variables inserted by human manipulation of the environment cannot be realistically estimated. (Comment 0216-1)

9. However, much more needs to be done to explain to the lay public what the relationship is between dose limits proposed for a “Reasonably Maximally Exposed Individual” (“RMEI”) and the health effects on the general public. The explanation of the comparison to average annual exposure in Colorado included in the draft proposal is a first step. Such plain language explanations help the public put in perspective inaccurate statements by repository opponents about the so-called “great danger” Yucca Mountain could pose to future generations. Specifically, the final rules should include more discussion about the difference between peak radiation intensity and peak dose. Once the repository receives its last waste package, it will be at its peak radiation intensity, but it is contained. As the radioactivity of the spent fuel decays over time, the radiation at the source (contained within the manmade and geologic barriers) will continue to diminish. Computer models forecast estimates of dose received by the RMEI. The relevant inquiry is at what point after waste packages are emplaced will the RMEI 18 kilometers away from the repository perimeter be exposed to a dose that exceeds the standard in this revised rule? Preliminary computer models estimate that the dose level will be below the 15 *mrem*/year limit for the first 10,000 years. (Comment 0217-1)

10. Presumably at the direction of DOE, the Office of Management and Budget ("OMB") instructed EPA to remove a provision from the draft proposed rule, circulated for comment to OMB, providing that "NRC may specify, in regulation, additional features, events, and processes ["FEPs," *see* Section XIX below] that DOE must consider because they may significantly affect the magnitude of the peak dose." EPA obliged, and that provision, which would have confirmed NRC's authority to apply traditional principles of performance assessment in its licensing review, was removed. As a result the rule is not risk informed. It arbitrarily eliminates factors that could significantly affect the calculation of the peak dose. (Comment 0226-8)

11. Section 197.15: It would be extremely imprudent for DOE, NRC, or EPA to assume that future civilizations, if faced with repository control failures and need for remediation, will possess either the natural resources (e.g., iron ore and other metals), availability of energy sources required to fabricate materials into replacements for failed equipment, or the technological knowledge and competence comparable with or superior to ours. Therefore, full consideration of radical changes in society, knowledge, energy sources, and technology most certainly must be included in DOE's analyses -- and in those of EPA. (Comment 0331-13)

12. 197.20: See comments above concerning the inadequacy, the unacceptability, of EPA's proposed annual CEDE doses and comments on RMEI. The history of DOE performance with respect to "reasonableness" -- not to mention the inaccuracies of its claims throughout the decades of Yucca Mountain repository development thus far -- should warn that DOE's assessments are not trustworthy. However, if DOE is charged with undertaking performance assessment, that assessment must include all potential pathways of transport and exposure, both in the controlled area and the accessible environment beyond. (Comment 0331-14)

13. 197.25: In this regard, human inattentiveness and all-too-common other failings (i.e., sleeping on the job) must be included in the analysis. (Comment 0331-16)

14. 197.36: No, there should be no limits. The possibility of factors that have not been considered, or are believed at this time by EPA, NRC, or DOE to irrelevant, should require that highly improbable matters and events may later be understood to be extremely important to assurance of sequestration and appropriate protection of future human beings. (Comment 0331-17)

15. How well can it be demonstrated that the facility will actually meet the limits? (Comment 0367.1-7)

Response to Section 18:

Some comments voiced opinions that changes in technology, resource availability and human error should be included in projections of repository performance (Comments 0210.3-3, 0331-13, and 0331-16); whereas Comment 0216-1 agrees that “human manipulation of the environment cannot be realistically estimated.” NAS addressed this issue when discussing framing performance assessment scenarios, i.e., “we believe that no scientific basis exists to make projections of the nature of future societies to within reasonable bounds” (NAS Report pp. 10, 96, and 122). We have always held the position that predicting future states of society and technology is too speculative to permit the use of such predictions in regulatory decision making. This position is also described in the responses to comments for the 2001 rule (EPA 402-R-01-009, Docket No. EPA-HQ-OAR-2005-0083-0043, pp.7-16 through 7-18). Consequently, we have always adhered to the position that current conditions relating to society and the biosphere should be used to frame repository performance scenarios, and we still believe this position presents the only approach that can be implemented without introducing irresolvable speculation in regulatory decision making. The question of human error also fits within this category of overly speculative scenarios. Although human error in some form is almost a certainty (Comment 0331-16), the range of potential effects and consequences is unfortunately again unavoidably highly speculative. For these reasons we do not agree that these highly, and unavoidably, speculative, subjects should be included in repository performance projections. Comment 0331-13 expresses a common misconception about geologic disposal, which is that assessment of a potential disposal system is in some way dependent on the ability of people in the future to perform maintenance or remediate contamination.

On the contrary, the concept of geologic disposal rests on the assumption that the system as implemented will perform adequately to protect public health and the environment in the absence of active maintenance or remedial measures, and even if all knowledge of the repository is lost. The disposal system is designed to be a passive system, i.e., one that will operate as expected without human intervention during its operational lifetime. This fundamental premise for deep geologic disposal has been implemented in all previous regulatory actions concerning deep geologic disposal.

Comments 0173-11 and 0210.3-4 stated that repository releases should be combined with projected releases from other radioactively contaminated areas around the Nevada Test Site (NTS). We do not support this idea for a number of reasons. The specific intent of the standards, and our direction in the EnPA, is to address potential releases from the Yucca Mountain repository and the licensing decision is intended to address how well the site's projected performance meets the EPA standards. We addressed the issue of other sources of contamination in our 2001 Response to Comments document on pp. 1-12 through 1-14 (Docket No. HQ-OAR-2005-0083-0043). On another point raised in comment 0173-1, we have examined the results of monitoring around the Test Site in the estimation of background exposure levels in Amargosa Valley (Docket No. EPA-HQ-OAR-2005-0083-0387).

Comment 0226-8 stated that the proposed standards omitted a provision for the NRC to specify additional FEPs. We have put some specifics into the proposal concerning how some FEPs should be evaluated for the period beyond 10,000 years. We did this for two reasons, (1) in an effort to limit the potential for unwarranted speculation to produce scenarios that have no significant bearing on very long-term dose assessments, thereby focusing the analyses on less speculative FEPs that would be consequential, and (2) to assure that certain FEPs not considered in shorter-term assessments because they would not be significant in the first 10,000 years are in fact included in the post-10,000-year assessments, where they have the potential to significantly affect the assessment results. We believe NRC would still have the flexibility to require the analyses they feel necessary to properly execute the licensing process, and that stakeholders can introduce other FEPs provided they have sufficient evidence to substantiate the addition.

Two comments focused on the need to examine and understand the movement of ground water through the repository and into the surrounding hydrologic flow system down gradient of the site (Comments 0210.1-2 and 0211.11-1). We agree that the ground water pathway is the most important pathway for potential releases to the accessible environment. We believe that our standards are consistent with that fact and address protection accordingly, by both the all-pathways individual protection standard (§197.20 in the final rule), and the separate ground-water protection standards. We also agree with the comment that the repository safety assessments can be performed with sufficient confidence that the regulatory process can be successfully implemented (Comment 0210.4-1).

Comment 0331-17 stated that there should be no limits placed on scenario development. We do not agree because, from practical standpoint, the possibilities for postulating performance scenarios, using highly improbable features, events and processes is limited only by the imagination. A regulatory decision process cannot be practically implemented unless the performance assessments can be reasonably bounded. We believe that the comment's point about evolving understanding revealing that previously dismissed ideas and assessments could later be recognized as important is valid. This is why we considered whether FEPs that may have been excluded from a 10,000-year assessment based on probability or consequence should be re-examined for the extended compliance period, as described in the preamble to the proposed rule (70 FR 49053-49055). However, we believe the performance assessment must be structured around FEPs as we understand them today, rather than hypothesize as to how we might understand them better in the future. Our current understanding is necessarily imperfect when considering periods approaching 1 million years, therefore, a degree of conservatism in constructing scenarios is reasonable, but taken to its extreme conclusion, the commenter's point would foster an ultra-conservative approach to defining performance assessment scenarios contrary to our approach to reasonable expectation. We believe that the details of the licensing process, as explained in NRC's rulemaking, allows for periodic re-examinations of the repository safety assessments and a performance confirmation period that would function to test the foundations of the safety assessments, and would provide confidence that understanding of the site is at its best before the repository is closed and the license terminated.

NAS examined this question in its report and concluded that the site is sufficiently stable that the uncertainties in projecting future conditions of the natural barriers could be bounded. (NAS Report p. 7) NAS also recommended the use of probabilistic performance assessments as a means of addressing uncertainties in projecting performance (see Section 6 of this document for more discussion of uncertainty). (NAS Report pp. 78 – 80) The question of whether the repository will perform to meet the limits in these standards is a matter for the licensing process decision-making, we do not speculate on the outcome of that process since it is only our responsibility to establish standards. The NRC will have the final authority for the licensing decision (Comment 0367.1-7).

Two comments pointed out that waste package container integrity is the primary determinant to releases (Comments 0180-2, 0181-2). We agree with this observation and the comment's conclusion that the container lifetimes should be evaluated in performance assessments. Waste package behavior is an integral part of DOE's and NRC's performance assessments of the disposal system, and we are confident that they will remain so. We have examined the effects of various waste package corrosion rate assumptions, and assumptions about other important parameters (Docket Nos. EPA-HQ-OAR-2005-0083-0414 and EPA-HQ-OAR-2005-0083-0429). Results of our assessments confirm the importance of waste package failure rates on the magnitude and time frame of the peak dose.

Comment 0217-1 asks several questions about the relationship of doses to health effects along with the relationship of the dose projections to background levels and the timing of doses to the RMEI and the regulatory limits. The 100 mrem/yr. peak dose limit we have established is similar to the measurements of outdoor cosmic plus terrestrial annual exposures in Amargosa Valley. The health effects of such exposures are discussed more fully in Section 2 of this document. The timing of the peak dose to the RMEI during the geologic stability period is a major part of the licensing decision to be made by the NRC.

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Section 19 Human Intrusion

1. I do not take issue with the proposal to revise the performance standard that applies to a specified human intrusion event essentially in the same manner as the proposed revision of the performance standard that applies to normal (undisturbed) performance. (Comment 0186-4)

2. Section 197.25: Potential actions that accomplish the effect of human intrusion and/or waste package degradation, but without the observable physical presence of intruders or of their intrusion, must be taken fully into account in assessment of earliest intrusion time post-disposal. (Comment 0331-15)

Response to Section 19:

We stated in the preamble to the proposed standards that we are not changing the scenario for human intrusion and would neither take comments nor respond to comments on that issue.

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Section 20 Comparison to WIPP is Inappropriate

1. EPA's attempt to analogize the Yucca situation to that of DOE's repository site for the Waste Isolation Pilot Plant ("WIPP") in Carlsbad, New Mexico, is grossly misplaced. EPA certified the WIPP site under 42 C.F.R. Part 191. The compliance standard for that site was a wholly appropriate 15 millirem/year, and the compliance period was 10,000 years. EPA attempts to suggest that the Yucca situation is "unprecedented" relative to WIPP because at Yucca, EPA is now required by the Court to evaluate performance out to a time period of one million years. For several reasons, this suggestion is a distortion of the facts and could not be more wrong. (Comment 0226-110)

2. The WIPP repository is a site for medium-level transuranic radioactive waste, while the Yucca repository must handle the much more radioactive high-level radioactive waste and spent nuclear fuel. (Comment 0226-111)

3. The WIPP repository is sited not in fractured volcanic tuff but in a large, stable, and fully isolating salt deposit. The NAS has recognized since 1957 that salt deposits provide the safest possible site for a repository because water can neither get into the repository nor get out of it as a result of the well-known absorptive characteristics of salt. *The Disposal of Radioactive Waste on Land,* Publication 519, NAS (1957), at 3-4. NAS noted that a salt deposit provides a stable, isolating geologic setting because "no water can pass through salt" and its "fractures are self-sealing." *Id.* at 4. Yucca's billions of known fractures are clearly not self-sealing. In connection with judicial review of WIPP, the D.C. Circuit Court noted that "[s]alt formations ... should prove suitable for disposal of radioactive waste because their low permeability serves to prevent leakage and the plasticity in response to pressure allows fractures in the formations to heal themselves. The salt ... will gradually encase the waste deposited in the underground rooms ... *isolating it* from the accessible environment." *New Mexico v. Watkins,* 969 F.2d 1122, 1125 (D.C. Cir. 1992) (*per curiam)* (emphasis added). For that reason, EPA's 15 millirem/year compliance standard was referred to as the "no migration rule" *Id., citing* 42 U.S.C. § 10141(a); 40 C.F.R. §§ 191.11-.18. That name could of course never be applied to Yucca. (Comment 0226-112)

4. In *NEI,* the Court did not require EPA to extend the compliance period at Yucca to one million years. Rather, it required EPA to extend the compliance period to the time of peak dose/risk, whenever that is expected to occur. It is presumed that this is within one million years, but it could be longer (there is no reason to prejudge this fact in the EPA rule). At Yucca, an untenable peak dose is expected to occur in the accessible environment around the site very shortly after the waste packages fail. That is because Yucca's fractured geology is non-isolating, making the repository more like a septic field than a geologic vault. At WIPP, peak dose never occurs (or it remains at zero) because the geologic medium is perfectly isolating. Another way of stating this is that peak dose occurs at a time period of infinity. And indeed, had EPA specified an "unprecedented" *infinite* compliance period for WIPP, this would not have hindered its licensing or increased its performance uncertainty in any way. (Comment 0226-113)

5. At WIPP, the geology was known by DOE and EPA to be so perfectly isolating that *no credit whatsoever was given to man-made waste packages* in that repository's total system performance assessment. *See* 63 FR 27,354-27,369 (1998). A 10,000-year compliance period therefore allowed performance modelers ample time to test the geologic integrity of the site, because it assumed, essentially, that the waste packages had failed in year 1. Nevada would be completely satisfied for DOE and EPA to make the assumption that all of the waste packages at Yucca fail in year 1, and to require modelers to ensure compliance for only a 10,000-year period thereafter. That is because the same analysis done at Yucca as that done at WIPP would show the Yucca repository to grossly fail a compliance standard of 15 millirem/year during the first 10,000 years in that situation. At Yucca, the man-made waste containers provide 100% of the repository's performance during the first 10,000 years, assuming DOE's optimistic assumptions about container life are accepted. But as soon as those containers are presumed to have failed, the repository flunks any compliance standard even remotely similar to that used at WIPP. (Comment 0226-114)

6. Big difference between WIPP and Yucca: no one drinks from groundwater at WIPP, and Yucca has large dairy and wells. (Comment 0367.1-25)

Response to Section 20:

Commenter 0226 suggests that we have inappropriately compared the proposed repository at Yucca Mountain with that at the Waste Isolation Pilot Plant (WIPP) in New Mexico. The commenter clearly believes that WIPP is a much better site than Yucca Mountain, and takes issue with implications that the sites are equally well-suited for geologic repositories. We made no statements of this nature in our proposal. We referred to WIPP only in the sense that the individual-protection standard implemented at that site for a 10,000-year compliance period is the same as the individual-protection standard we have established for Yucca Mountain for the same period. The relative merits of the two sites are not relevant, as both were designated by Congress (in the WIPP Land Withdrawal Act and the NWPA Amendments of 1987, followed by approval of the Presidential recommendation in 2002, respectively). Our purpose is to establish standards that protect public health and safety while providing a reasonable test of the Yucca Mountain disposal system for up to 1 million years. We do not believe it is appropriate to speculate as to whether WIPP could perform better or meet a more stringent standard than Yucca Mountain; such a conclusion would have no bearing on the ability of the Yucca Mountain disposal system to comply with an appropriate standard.

Nevertheless, we believe it is necessary to address several points on which the commenter appears to have misinterpreted our standards and regulation of the WIPP, as well as reached questionable conclusions regarding matters of regulatory approach. Comment 0226-112 cites the Nuclear Waste Policy Act and 40 CFR part 191 in referring to the individual-protection standard implemented at WIPP as the “no migration rule,” concluding that this terminology acknowledges the superiority of the salt environment at WIPP. The commenter is incorrect. The standards in 40 CFR part 191 have never been known as “no migration” standards. The term “no migration” applies to the variance sought by DOE to allow the disposal of waste containing chemically hazardous constituents regulated under the Resource Conservation and Recovery Act (RCRA). Such a variance requires the petitioner to demonstrate "to a reasonable degree of certainty, that there will be no migration of hazardous constituents from the disposal unit or injection zone for as long as the wastes remain hazardous." 40 CFR 268.6 Because Congress subsequently exempted WIPP from compliance with the RCRA land disposal restrictions, DOE was not required to obtain a variance and withdrew its petition to EPA. (Section 9(a) of the WIPP Land Withdrawal Act, Public Law 102-579, as amended) The commenter also ignores the fact that the radiation protection standards promulgated by EPA in 40 CFR part 191 were intended to apply to radiological disposal sites in any geologic setting (Yucca Mountain was later explicitly excluded by statute), and were not restricted to salt sites in general or the WIPP in particular.

Comment 0226-113 postulates that an infinite compliance period at WIPP would pose no problems for compliance, while at Yucca Mountain the peak dose is highly dependent on the timing of waste package failure (see Section 10 of this document for discussion of the compliance period). The commenter suggests that it is misleading for us to characterize a 1 million-year compliance period at Yucca Mountain as "unprecedented" because of what could have been done at WIPP. The commenter misunderstands the important difference between what might be true for individual sites and what is reasonable to regulate. In developing our generally applicable standards in 40 CFR part 191, we did not dismiss the possibility that some sites could essentially provide infinite containment by virtue of their natural characteristics alone. It was not, however, considered necessary for sites to exhibit such characteristics in order to be considered as potentially suitable for geologic repositories. As discussed in Section 2, Issue B of this document, early studies of the geologic disposal concept (including EPA's original rulemaking for 40 CFR part 191) concluded that doses in the range of several rem per year would be possible in the event of consumption of ground water near the repository. In both our 1985 and 1993 rulemakings for 40 CFR part 191, we emphasized that the 10,000-year compliance period for both the containment requirements and individual-protection limit would lead to a combination of site characteristics and engineered barriers that would be capable of providing containment and isolation of the waste for these long periods of time. We did not, however, anticipate that such performance could be maintained indefinitely. Our generic technical analyses, in fact, suggested that significant releases and doses to individuals could result at later times, depending on the characteristics of the site in question and the presumed location of the receptor (to help mitigate such a possibility, we included the concept of a controlled area, which is considered part of the natural geologic barrier and inside which compliance with dose standards will not be assessed and need not be demonstrated).

Sites whose natural features alone would not provide total containment were not necessarily considered unsuitable, but we recognized that in those instances, the focus would have to be on "the design of more robust engineered barrier systems capable of significantly impeding radionuclide releases," which is consistent with the concept of a multi-barrier system. (58 FR 66401, December 20, 1993) We believe that it is unrealistic to assume that these sites would then exhibit better performance after the failure of those barriers than they would in the initial 10,000-year period. Consequently, we believe the potential for doses higher than 15 mrem/yr to individuals in the far future has always been implicit in the concept of geologic disposal, although in the Yucca Mountain case the issue is more related to uncertainties in projecting the characteristics and behavior of the disposal system over extremely long time periods. We disagree with the commenter's view that establishing an infinite compliance period for the WIPP would be a trivial matter, and further disagree that there is no increase in "its performance uncertainty in any way." We have consistently expressed our concern, and the concern of the international community, that the uncertainty in performance projections over long time periods makes the use of quantitative performance measures as a basis for regulatory decisions more questionable. This was the primary reason for limiting the compliance period in 40 CFR part 191 to 10,000 years, and no exception was made for salt sites. We are establishing standards specifically for the Yucca Mountain disposal system that address the question of uncertainty and are consistent with the recommendations of the NAS and the decision of the D.C. Circuit. We do not find it useful to speculate about what we might have done if faced with the prospect of establishing a site-specific standard for the WIPP.

Comment 0226-114 suggests that since waste packages were not considered barriers to release in the WIPP compliance assessments, the same assumption should hold true at Yucca Mountain. The commenter misconstrues the differing nature of the regulatory situations in reaching an unwarranted and untenable conclusion. As noted above, geologic disposal has been premised on the expectation that engineered barriers would be provided to supplement the site's natural characteristics. The NWPA requires NRC to "provide for a system of multiple barriers in the design of the repository" in its licensing criteria. (42 USC 10141(b)(1)(B)) Our generally applicable standards require the use of both engineered and natural barriers. (40 CFR 191.14(d)) The use of engineered barriers is thus in no way illegitimate or to be interpreted as an indication that a disposal system will perform inadequately. While the commenter is correct that the waste packages at WIPP were not designated as an engineered barrier, this decision was made by DOE, not EPA. Waste packages at WIPP are essentially standard steel 55-gallon drums, and were not relied upon to provide containment. Further, the primary mechanism for release of radionuclides at WIPP is intrusion through drilling, which is not the case for Yucca Mountain. Given the long and extensively-documented history of drilling and mining around the WIPP site, the waste packages provide little resistance to penetration. By contrast, the waste packages at Yucca Mountain are intended by DOE to provide an important barrier to release of radionuclides. If, as the commenter asserts, "the man-made waste containers provide 100% of the repository's performance during the first 10,000 years," that is exactly their purpose, unlike the waste packages at WIPP. This approach is completely consistent with the multi-barrier concept. Also unlike WIPP, where EPA is the implementing agency, it is up to NRC, as the implementing agency at Yucca Mountain, to determine whether and to what extent DOE's "optimistic assumptions about container life are accepted."

Comment 0367.1-25 states that ground water at the WIPP site is not used by people whereas the ground water down-gradient from Yucca Mountain is used. We are aware of this difference and point out that the same ground-water protection standards were included in both the WIPP certification requirements and the Yucca Mountain standards to address protection of the ground-water resource.

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Section 21 Miscellaneous Comments

1. A commitment should be instituted whereby the repository standards are scheduled to be renormalized every 10,000 years. If the repository does not meet the new standards in the future, then the industry shall be required to retrofit the repository to meet the new standards. (Comment 0095-3)

Response: We disagree with this comment concerning reevaluation of the standards at some point in the future. We find it impossible to assume that any regulatory process established in our time can be "scheduled" to be re-evaluated every 10,000 years, in light of the uncertainty in predicting the course of society over such time spans. In addition, NAS stated, "…we believe that no scientific basis exists to make projections of the nature of future human societies to within reasonable limits of certainty." (NAS Report p. 9) We agree and, therefore, to attempt to require a future society to "renormalize" the standards every 10,000 years is infeasible.

2. These requirements would probably be successful if human civilization declines and the use of high technology is discontinued. However, the Agency should also consider the human factors of future generations interacting with the Yucca Mountain disposal site. Historical and social science insights suggest that future generations will not leave the waste disposal site undisturbed. It is likely that people in the coming decades and centuries will mine Yucca Mountain. This human incursion will be more than a simple bore hole through the volume of the waste site. Indeed, the more primitive our future, the more necessary the EPA standards are. (Comment 0099-1)

Response: NAS, in its recommendations to EPA, set a stylized scenario for inadvertent human intrusion. (NAS Report p. 108) NAS stated that "there is no scientific basis for estimating the probability of intrusion at far future times." (NAS Report p. 106) We believe that our rule is consistent with this recommendation. We also agree with NAS that deliberate intrusion to recover the wastes ("mining" as described by the comment) is not appropriate for our rulemaking because the intruders would be aware of the risks and would have made a decision that the risks were acceptable. In order to meet the NAS recommendations, we specified sufficient details concerning the stylized intrusion to assure that it is assessed as we (and NAS) intended, but we left considerable flexibility to NRC in further defining the details of the assessment. We believe that our standard sets the context in which the intrusion assessment analyses and decision-making should be implemented.

3. Technological capability will be lost more than once over the long time frame under consideration. The non-technological future societies and their environment will be protected by the containment technology forced by the planned EPA standards for radiation protection. Long after the EPA and the USA are gone, the mandated containment could be protecting human cultures from harm. (Comment 099-2)

Response: We agree that the intent of the standards is to provide containment of the wastes for very long periods. By imposing protective standards for releases we believe that we encourage robust engineering design and rigorous scientific analyses of the design's performance under the conditions reasonably expected to occur at the site over very long time frames.

4. Any standard EPA sets must be accompanied by an economic study as to costs, etc. and a true risk assessment; justification of limits is a necessity. The major risk here has to be ingested radiation and there is little evidence of any real problem here. I see none of this your report. What you have done is laughable if it were not serious and fraught with major cost effects. (Comment 0100-2)

Response: EPA did produce an Economic Impact Analysis for the revised 40 CFR part 197. This document is found in Appendix A of "Assumptions, Conservatisms and Uncertainties in Yucca Mountain Performance Assessments" (Docket No. EPA-HQ-OAR-2005-0083-0085).

5. My objection to the Proposed Rule for Yucca Mountain is that EPA has not discussed anywhere in the Supplementary Information whether EPA performed analyses to indicate that the proposed standards at times beyond 10,000 years should be reasonably achievable or whether EPA took results of DOE's performance assessments into account in developing the proposed standards. For example, EPA performed its own analyses in developing standards for disposal of spent fuel, high-level waste, and transuranic waste in 40 CFR Part 191. Those analyses were largely generic, but they indicated that EPA believed that those standards were reasonably achievable at well chosen sites. Indeed, I thought EPA generally was required to perform its own analysis of impacts of its regulations, but I find no such analysis in the Proposed Rule. (Comment 0186-14)

Response: The Energy Policy Act of 1992 (EnPa) set forth our responsibilities as they relate to Yucca Mountain. In the EnPa, Congress directed us to set public health and safety radiation standards for Yucca Mountain. Specifically, section 801 (a)(1) of the EnPA directed us to "promulgate, by rule, public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site." That is our mission, as directed by the Congress. We must determine what standard should be set, and then DOE must show to the NRC a reasonable expectation that the standard will be met. The disposal system must contain the waste to the levels at or below those that are prescribed in the standards. It is EPA's responsibility to establish standards that protect public health and safety from releases from the facility. However, it is not EPA's responsibility to determine how the repository will function over the regulated period, that is left to NRC and the licensing process as directed in the Nuclear Waste Policy Act. It is DOE's responsibility to show that the repository will meet our standard, and to determine the projected performance of the natural and engineered barriers at the site.

The analyses conducted to support 40 CFR part 191 were focused on the containment requirements (release limits), which limited the cumulative radionuclide releases from the disposal system. EPA concluded, as the commenter states, that these requirements were technically achievable through a combination of good site characteristics and engineered barriers. The Agency did not, however, conduct similar analyses to evaluate the individual-protection standard of 15 mrem/yr, and reached no such conclusions regarding its achievability.

6. I support these proposed amendments for their ability to direct better radiation containment. (Comment 0104-1)

7. You say "you recognize that a standard based on variations in natural background radiation would be higher than previous non-occupational standards in the U.S." (Fed Reg p 49038) 1st col). I see no reason why a standard for Superfund should not be the same for a repository. Why is it all of a sudden OK to expose people more than allowed before? (Comment 0113-6)

Response to Comments 6 and 7: As we stated in the preamble to our proposal (70 FR 49038), we believe the circumstances involved in this final rule are significantly different from the situations addressed under Superfund or any other existing U.S. regulatory program, and that it should be clear that comparisons between the two are inappropriate.

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

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

We continue to believe that references to natural sources of radiation can provide useful insights into the "significance of" projected doses (in IAEA's words) over hundreds of thousands of years. For example, as noted above, 100 mrem/yr is roughly the value reported by the Desert Research Institute for cosmic and terrestrial radiation at Amargosa Valley (unshielded). When shielding from buildings is considered and indoor radon doses are estimated using a more conservative conversion factor suggested by some commenters, 100 mrem/yr is at the low end of overall background radiation estimates in Amargosa Valley and nationally. Within the State of Nevada, the difference in average estimates of background radiation for counties is greater than 100 mrem/yr. This suggests that 100 mrem/yr can be considered to be a level such that the total potential doses incurred by the RMEI from the combination of background radiation and releases from Yucca Mountain will remain below doses incurred by residents of other parts of the country from natural sources alone. It may also be noted that the 100 mrem/yr public dose limit recommended by ICRP is itself related to background radiation. However, in the absence of compelling reasons for selecting specific background radiation estimates and points of comparison, we conclude that comparing background radiation estimates from specific locations does not provide a clear or sufficient basis for a regulatory compliance standard applicable to the Yucca Mountain disposal system. For further discussion on the factors related to our decision, please refer to Section 3 of this document.

8. EPA often mentions the need to address policy concerns in developing a standard for Yucca Mountain. Although EPA may believe that it is obvious what its policy concerns are, I think it would be very helpful to list and summarize them all in one place. (Comment 0186-21)

Response: There is a significant amount of uncertainty involved in establishing standards for such an unprecedented length of time , and that is where we turn to sound, technical policy. The NAS has given us guidance on how to lessen the amount of uncertainty involved in this process, but the committee did not (and cannot) provide all of the "answers" necessary to eliminate all risk and uncertainty in developing a standard for such an unprecedented time period. Therefore, we have had to use our best judgment (policy) in areas for which there is little technical precedent, with the overall goal of establishing a reasonable test of the disposal system. These areas include defining a context for public health protection and setting the dose standard to 1 million years, delineating an approach for evaluating that the standard has been met, defining a period of geologic stability, and determining which features, events and processes are most important for the functioning of the disposal system. At the same time, we have tried to lessen the amount of uncertainty involved by assuring that our actions are not unreasonable, and can be implemented by NRC.

We have outlined and summarized all of our general policy considerations in the preamble to this final rule, and in the preamble to the final rule we promulgated on June 13, 2001 (66 FR 32075).

9. The NRC should revise 10 CFR Part 63 to include these proposed rules. (Comment 0401-3)

Response: The NRC proposed to modify 10 CFR part 63 on September 8, 2005 (70 FR 53313) and we anticipate it will make its licensing requirements consistent with our standards as required by the EnPA.

10. We adamantly oppose skirting the issues by subverting health standards, not now, not in ten thousand years, not in one hundred thousand years. You and we have known for decades that this radioactive material must be kept completely isolated from the environment for at least one hundred thousand years, more likely actually two hundred fifty thousand years. (Comment 0143-1)

Response: We agree that the waste proposed for disposal in the Yucca Mountain repository should be isolated as well as can be reasonably done. We believe our peak dose standards protect human health throughout the period of geologic stability, which may be up to 1 million years.

11. In my opinion, discussions in Section II.C.3 about EPA's risk-management policies in the Superfund cleanup program don't quite give the right idea about what CERCLA and what implementing regulations do and do not require in regard to achieving certain levels of health risk (this is hardly the first time EPA has misrepresented cleanup requirements under CERCLA). Therefore, for EPA to say that Superfund does not apply to the present situation as a way of justifying a high dose criterion at times beyond 10,000 years seems to me to be a faulty argument for dismissing approaches to risk management in cleanup of contaminated sites under CERCLA. (Comment 0186-23)

Response: Even though CERCLA itself does not apply to this situation, the CERCLA risk range is a guideline that is typically applied across EPA programs. The Agency recognizes the implications of establishing a public health and safety standard that is outside the CERCLA risk range and does not “dismiss” it lightly. However, we believe that our final standard presents a reasonable approach to risk management and appropriately takes into account the unique circumstances involved in extending the compliance period to 1 million years.

12. NARUC respectfully submits that the EPA revised rule successfully meets the goals set for revising the individual protection and other standards because it) responds to the court ruling, (ii) protects public health and safety, (iii) reflects the best science and is cognizant of the limits of longterm projections, and (iv) can be implemented by NRC in its licensing process. (Comment 0217-10)

Response: This comment requires no response.

13. EPA is encouraged to incorporate into the final rule requirements for compliance monitoring and measures to be taken in the event of non-compliance. (Comment 0219-5)

14 White Pine County notes that EPA's proposed rule does not appear to address requirements for compliance monitoring and related measures to be taken in the event said monitoring demonstrates noncompliance with established standards . EPA is encouraged to incorporate into the final rule requirements for compliance monitoring and measures to be taken in the event of non-compliance. (Comment 0315-5)

15. Section II.B, Page 49027 - The proposed rule states that " . . .the projections of the disposal system's long-term performance cannot be confirmed. Not only is the projected performance of the disposal system not subject to confirmation, the natural conditions in and around the repository site will vary over time and these changes are also not subject to confirmation, making their use in performance assessments equally questionable over the long-term." If the long-term performance of the disposal system cannot be confirmed, then how is the proposed project going to properly monitor the facility for potential discharges? (Comment 0326-12)

Response to Comments 13, 14, and 15: There are requirements in the NRC regulations for monitoring, both during the operation of the repository and for a period after closure. We do not believe it would be appropriate for EPA to specify particular monitoring requirements in advance of the licensing process since we would not have the information to determine what monitoring would be meaningful.

16. Actinides such as plutonium and neptunium 237, as the time progress, will be converted to lead; therefore, the standard must be set on the big -waste standard. (Comment 0209.1-1)

Response: The commenter is correct that, given enough time, most transuranic radionuclides will decay into stable lead. However, EPA was directed in the EnPA to set radiation standards for the Yucca Mountain repository, not a standard for non-radioactive materials.

17. I think we've heard that word about ten times tonight -- this is unprecedented, we've never had to do anything like this. So you say that on one hand, but then on the other, you

say, but we've worked with other nations and look. So it's not unprecedented. You know, there are other nations that are handling this problem. Some of those industrialized nations are putting in one million year, zero-dose standard. So, you know, there's looking at those regulations that are those other countries. (Comment 0209.2-1)

Response: The commenter correctly notes that we did consult guidance and regulations from numerous international organizations (such as the IAEA) and individual countries (such as Sweden and France). We found it useful to examine the ideas of those faced with a similar situation. In general, they reinforced two points we emphasized throughout our proposal and final preambles. The first is that uncertainties generally increase with time. The second point is that projections at those longer times cannot be viewed with the same level of confidence as shorter-term projections, and may, in fact, be viewed as more qualitative indicators of disposal system performance. It is because our standards contain a quantitative standard that applies through a compliance period of 1 million years that we stated that the standards are unprecedented for U.S. regulations. Most other countries that have considered time periods beyond 10,000 years begin to look at performance in these long time periods with a more qualitative view. In addition, we are unaware of any country that has established a zero-dose standard. Again, we have stated that the action we are making final today is unprecedented precisely because the United States Congress, unlike the majority of the international community, has directed us to set a numerical dose limit that applies for a period up to 1 million years rather than move to a more qualitative-type standard.

18. Applying the same dose limit to both the individual protection and human intrusion standards makes sense. (Comment 0217-6)

Response: We have adopted the same dose limits and compliance period for both standards. This is also consistent with the NAS recommendation, “We recommend that EPA require that the estimated risk calculated from the assumed intrusion scenario be no greater than the risk limit adopted for the undisturbed-repository case….” (NAS Report p. 12)

19. Had the Department of Energy (DOE) in 1995 applied the recommendations offered by the NAS then it is likely that the process would be further along today. It is also probable that the Yucca Mountain site would have been discarded and the nation would be well on the path to selecting a more suitable site or crafting a better strategy for disposing of this highly dangerous waste. The frame of reference for the protection standards, one million years, is, of course, impossible to contemplate let alone reasonably plan. The time period of the risk is well beyond recorded human history and undoubtedly beyond our current capability to develop engineered barriers that would protect the public and environment for the period of the risk. Because of the extensive time periods of the risk, almost infinite for some of the components of the nuclear waste, it was Congress’ expressed wisdom in the original Nuclear Waste Policy Act of 1982 to acknowledge that man-made engineering barriers would fail long before the danger was eliminated. Congress’ original objective,

therefore, was to ensure that the geology of a selected repository site wou [comment ends here] (Comment 0266-1)

Response: We agree with the commenter that it is unreasonable to expect the engineered barrier system to continue to function completely undegraded for the entire 1 million year period. We also agree that the disposal system must contain the waste to the levels at or below those that are prescribed in the standards. It is EPA's responsibility to establish standards that protect public health and safety from releases from the facility. However, it is not EPA's responsibility to determine how the engineered barrier system will function over the regulated period; that is left to NRC and the licensing process as directed in the NWPA. It is DOE's responsibility to show that the repository will meet our standard, and to determine the projected performance of the natural and engineered barriers at the site.

20. EPA has proposed regulations on National Repositories for nuclear waste, specifically Yucca Mountain, but intended to apply in general. (Comment 0275-1)

Response: This comment is incorrect; EPA has both Yucca Mountain-specific standards and generic standards. The EPA standards for Yucca Mountain, being promulgated under 40 CFR part 197 and the subject of the current action, are site-specific, not generic. There are generic EPA standards that apply to most facilities, except Yucca Mountain, for the management, storage, and disposal of spent nuclear fuel (SNF), and high-level (HLW), and transuranic (TRU) radioactive wastes (40 CFR part 191, 50 FR 38066, September 19, 1985; amended at 58 FR 66398, December 20, 1993).

21. EPA states on page 49026, column 2 that "It is self-evident and non-controversial that the engineered barrier system cannot be expected to last forever." This is a highly significant admission. DOE, on 1/25/99, in a presentation to the U .S. Nuclear Waste Technical Review Board, admitted that 99.7% of radiation isolation at Yucca would be provided by the waste package itself. An additional 0.2% would be provided by the irradiated fuel cladding, the all-too-thin and oft-failed metal sheaths enclosing the high-level radioactive waste pellets and loose solid particle, gases, and liquids. Thus, 99.9% of the radiation barrier at Yucca would be provided by the "engineered barrier system." Only 0.09% of radiation isolation would be provided by Yucca's overburden and only 0.008% by Yucca's geology. Thus, a mere 0.098% of radiation isolation at Yucca would be provided by the geologic setting. So much for "geologic isolation"! EPA must establish the strictest of protective standards to guard against the licensing of a dump in an unsuitable geologic setting. To do otherwise would guarantee catastrophic radiation releases and the consequent public health disasters downstream. (Comment 0324-21)

Response: We reiterate what we discussed in the preamble to the proposed rule (70 FR 49026) that it is self-evident and non-controversial that the engineered barrier system cannot be expected to last forever. We point out that the estimates given above were in the context of compliance with the 10,000-year standard. Through the 1 million-year period of geologic stability the engineered barrier system degrades and radionuclides could be released into the natural barrier, which then plays a more prominent role than within the initial 10,000-year period after disposal. The disposal system must limit the releases for 1 million years to a mean dose rate that is no greater than 100 mrem/yr. Therefore, we believe that we have crafted a standard that is protective of public health, and it is now up to DOE to demonstrate that it can meet that standard.

22. Section I.c., Page 49021 - The proposed rule indicates that the primary means for demonstrating compliance with the standards is the use of computer modeling to project the performance of the disposal system under the range of expected conditions . The rule also states that the model involves extrapolations that involve inherent uncertainties. Board staff is concerned that using a model with "inherent certainties" could lead to erroneous results, thus not really identifying the "real" performance of the disposal system. Additionally, the "range of expected conditions" is not specified in the rule. Board staff would like to see an explanation of what the expected conditions were for the proposed model (i.e. does it include all potential geological conditions - earthquakes, volcanism, etc.). (Comment 0326-10)

Response: The purpose of a performance assessment is to project the performance of the disposal system under a range of expected conditions, with reasonable variations (see our discussion in the preamble to the proposed rule at 70 FR 49047). The NAS has also stated that such a performance assessment is the tool generally proposed for evaluating such performance. (NAS Report p. 28) One cannot unequivocally predict what the natural conditions at the repository will be over the next 1 million years. Consequently, one cannot predict with absolute certainty what the projected performance of the disposal system will be, and therefore it is reasonable to assume a set of conditions, and then model those conditions to determine projected performance of the repository. However, it also means that extremely unlikely or speculative features, events, and processes (FEPs) should not play a prominent role in the assessment. As a result, we specified a probability level (an annual probability of 10^{-8}) for determining which FEPs are to be included in the assessment and to provide a sufficiently inclusive list of FEPs while reducing unbounded speculation on FEPs. Regarding time frames out to peak dose, or on the order of about 1 million years, we have used NAS's recommendation of including FEPs for climate change, igneous events, seismic events, and clarified the approach to general corrosion. NAS stated that the first three are boundable to about 1 million years for the Yucca Mountain site. We believe that use of these parameters will provide a reasonable test of repository performance over a range of expected conditions.

23. The standard addresses human exposure to radiation, it does nothing to quantify or to address the exposure and contamination to the water, soil, air, rock strata, plants, or animals in the desert surrounding Yucca Mountain. There is no attempt to understand the legacy of toxic pollution within the environment that is being created. (Comment 0209.12-7)

24. 197.36: It should also be noted by EPA that there is an almost total inattention to providing protection for other forms of life. Their protection should be required. (Comment 0331-18)

Response to Comments 23and 24 Our policy on this issue is that by protecting humans to an acceptable level, we are protecting the rest of the biosphere (see 41 FR 28409, Docket No. EPA-HQ-OAR-2005-0083-0385).

25. The release limits in the original promulgation of EPA regulation, 40 CFR Part 191, were scaled to the size of the radionuclide inventory. In other words, larger repositories were accorded higher release limits. Yucca Mountain would be a large repository and would contain primarily spent nuclear fuel. Repositories in other countries typically are planned to be much smaller, or would be for high-level radioactive waste. It is not appropriate to compare levels of protection for these different repositories without taking this into consideration. (Comment 0352-24)

Response: The commenter is referring to our 40 CFR part 191 standards first promulgated in 1985 and amended in 1993. 40 CFR part 191 contains generic standards for the management, storage and disposal of SNF, HLW and TRU radioactive wastes. As noted by the commenter, the release limits in those standards are scaled to the projected amount of radioactive waste proposed to be emplaced in a repository. The risk objectives for the containment requirements had a level of health impact of 1,000 fatal cancers over 10,000 years for a repository containing 100,000 metric tons of heavy metal. However, that same scaling does not apply to the individual-dose limit in 40 CFR part 191. Since we are following the NAS recommendation not to use release limits (NAS Report p. 2) and complying with EnPA to set an individual-protection standard, we are consistent with 40 CFR part 191 in using a fixed limit for the individual-protection standard. To reiterate, the dose limit has no correlation with the size of the repository, the risk is independent of size.

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Section 22 EPA Should Balance the Risks from Storage with the Risk Near Yucca Mountain

1. Based on a risk informed approach (recommended by the NAS), it is puzzling to me that the EPA does not take into account the increased risk which is being put upon the sights which must ship waste to Yucca Mountain. This increased risk is real and is the result of having to store nuclear materials in a less than ideal environment while the courts, the EPA and the NRC quibble over 10,000 or 1,000,000 year standard. The uncertainties associated with 10,000 vs 1,000,000 year risk assessments are infinite. The real question is "Is it safer where it is or in Yucca Mountain?" (Comments 0101-1 and 0102-1)

2. “The amount of exposure also depends on how the source is arranged. For example, whether the source is concentrated in one place, or more evenly distributed.” By consolidating radioactive waste from all over the country to the Yucca Mountain site, how much dose that increase the containment risk? It would appear from the statement above (taken from the EPA website) that concentrating the radioactive waste at Yucca Mountain exposes Nevada to greater exposure risk then lower exposure risk at the current diversified locations. Concentrating at Yucca Mountain also appears to increase the effort needed for containment. (Comment 0109-1)

3. Per E. Spence comment on 9/19/05, are you proposing that we retain the spent fuel above grade in thin metal containers exposed to the elements for one million years, just so that it remains well distributed across the country and not concentrated in Nevada? Naturally, a strong, well-guarded, underground containment is necessary. Yucca Mountain is the perfect location. Evacuation of the Nevada area in the unlikely event of a breach of containment is much easier there than at many of the current sites (near Manhattan, near Philadelphia, etc.). I personally would much rather have a very large radiological event in the Nevada location rather than a smaller radiological event at Indian Point in New York. I personally trust the DOE to provide much better containment services for one repository below ground as compared to the nuclear industry for dozens of smaller storage facilities above ground near urban centers. (Comment 0112-1)

4. The States of Maine and Vermont would like EPA to consider that the safety of Yucca Mountain should not be viewed in a vacuum. Rather, EPA should weigh the safety of the Yucca Mountain repository relative to the safety of the over one hundred sites, including sites in Maine and Vermont, where spent nuclear fuel is presently stored and will likely continue to be stored pending the licensing and construction of the Yucca Mountain repository. It has been estimated that over 161 million Americans live within 75 miles of one of these sites. Maine and Vermont ask EPA to please consider these people when considering the comments of parties concerned about the safety of Yucca Mountain especially those who question the safety of this depository more than 10,000 years in the future…Compared to the Maine Yankee ISFSI the Yucca Mountain repository is much more protective of the human health, safety and the environment…It has been years since the Department of Energy was due to begin removal of spent fuel rods from Maine. DOE has failed to perform and has blamed its failure on the unavailability of the Yucca Mountain repository. Vermont faces the same prospect when the Vermont Yankee Nuclear

Power Plant is decommissioned. Whatever action EPA chooses to take should not extend the period of time that the citizens of Maine and Vermont as well as the millions of Americans living near an ISFSI are exposed to the hazards posed by these storage sites for high level nuclear waste. (Comment 0297-1)

Response to Section 22:

The comments under this heading deal with questions about alternatives to geologic disposal. In the findings and purposes of the Nuclear Waste Policy Act of 1982 (NWPA), Congress established its policy that it would be safer to dispose of the waste rather than keep it in temporary storage over time. In Section 114(f) of the NWPA, Congress specified that alternatives to geologic disposal would not be considered in the process of establishing a repository for spent nuclear fuel and high-level radioactive wastes. This is the reason there are not analyses of the relative risks of alternatives to geologic disposal. In addition, the authority given to EPA by Congress in the Energy Policy Act of 1992 (EnPA) gave EPA only the authority to develop site-specific standards to address releases of radioactive material stored or disposed of in the Yucca Mountain repository and require those standards to be based on and consistent with the NAS recommendations (EPA-HQ-OAR-2005-0083-0076). Neither the EPA nor the NAS addressed in any form a comparative study between the relative risk among disposal and storage alternatives to use as a basis for determining the future of the Yucca Mountain disposal system. Therefore, such a comparison is outside our authority for this action.

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Section 23 Add further criteria

1. The International Peer Review of the Yucca Mountain Project noted (at Section 5.1.3) that the compliance requirements proposed by EPA places far greater emphasis on probabilistic assessment than equivalent programs in other countries. To ensure a robust regulatory requirement, the EPA should propose additional criteria to evaluate performance at all times. One possible approach would be to follow the example of nuclear reactor safety analyses by defining a set of design basis events and evaluating the consequences for each. Such an approach could be designed to demonstrate "defense in depth", thereby providing confidence that DOE has selected a site that is geologically suitable for a repository and prove that they are not attempting to engineer compliance of a totally unsuitable site. (Comment 0263-7)

Response to Section 23:

The commenter suggests that probabilistic performance assessments may not adequately capture the impacts of significant events, and believes this perceived deficiency may be addressed by specifying the magnitude of events (e.g., seismic events) to be analyzed deterministically. It is unclear whether the commenter is suggesting that we should establish additional standards to apply to these design-basis assessments, or whether we should apply the same standards to the deterministic and probabilistic analyses. In the probabilistic performance assessments, the consequences of an event are weighted by its probability of occurring. (The International Peer Review referred to in the comment was conducted by the OECD/NEA and the IAEA, and is in the docket at EPA-HQ-OAR-2005-0083.)

Using design-basis events for safety analyses is a well-established concept and used in the engineering and licensing of constructed facilities such as nuclear power reactors and spent fuel storage facilities. Its equivalent in the areas of geologic disposal systems is the examination of alternate conceptual models for disposal system performance assessments and the process of scenario development for the assessments. DOE and NRC have been examining multiple scenarios and alternative conceptual models for their assessments for many years and will continue to do so through the licensing process. We have addressed the issue of scenario development and performance assessment in the context of our rulemaking (e.g., specifications of FEPs screening). We believe the rulemaking and licensing process being executed, with the spectrum of scenarios that must be considered, will capture events of concern for the disposal systems and, therefore, will resolve the concern in the comment.

Another approach could be to add qualitative elements. 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 qualitative measures called assurance requirements. The assurance requirements in 40 CFR Part 191, however, do not apply to facilities that NRC regulates, for example, 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. But, based on the public comments on the 1999 proposed standards 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 unnecessary 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 regulations for Yucca Mountain.

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Section 24 Legality of the Standards

Issue A: General comments

1. The proposed change to Part 197.35 can be issued as a final rule immediately. (Comment 0084-1)

2. I seriously believe that the nuclear industry would have a strong legal case against the EPA, arguing unequal protection under the laws, and outright discriminatory regulation. The good news is that I doubt they'll sue, as long as EPA proceeds with Yucca standards that are actually possible to meet, such as the ones recently proposed. They'll probably let the unnecessary 60 billion dollar cost "slide". (Comment 0201-9)

3. I think what's important is, in addition to talking about radiation and its effects on human beings and the potential that Yucca Mountain has to create harm to those living in Nevada, I think it's important that, also, the record reflect what the law requires the Environmental Protection Agency to do in this case and to look at the reason that we're here today. And that's because of a Court ruling that said that EPA failed in its first attempt to satisfy the requirements set down by Congress to address the issue of radiation contamination that would be released by Yucca Mountain. The reason EPA failed the first time out is because its standards were ruled to be arbitrary and not in keeping with the recommendations made by the National Academy of Sciences, as required by Congress, under the law which created Yucca Mountain. Again, what we're faced with is a move by the Environmental Protection Agency to ignore the words that were set forth by the National Academy of Sciences in its report on this -- the activities that are supposed to take place at Yucca Mountain. (Comment 0211.8-2)

4. The idea expressed by NAS was that the standard would be protective over the course of the repository's life span and with particular attention being paid to the maximum radiation doses and when they would be released. And if that's not to occur for the first 300,000 years or more, it's impossible to believe that EPA would set a standard which would suddenly, after the first 10,000 years, allow for an enormous increase in the amount of radiation that would be emitted from the site. That 10,000 years, again, seems to be an arbitrary standard not in keeping with the idea that it will be another 290,000 years before we even hit the maximum dose. So if we're protecting at a level of 15 millirem for the first 10,000 years, there seems to be no logic, especially in keeping with the advice of the National Academy of Sciences, that the radiation standard take into account the entire life cycle of the waste. (Comment 0211.8-3)

5. And I would think that a single standard that was offered the maximum protection and that would cover the entire million years that you now propose would be in keeping with what the National Academy of Sciences said was required under the law. (Comment 0211.8-4)

6. And so, again, if you said what is called a bifurcated or a dual standard, you are again ignoring the directions of what are our formal -- some of the formal scientists in this field

who were employed by the National Academy to make that determination. And it was important enough that Congress required that in the law. And for EPA not to, again, turn to those -- to both the guidance of Congress and to the guidance of the scientists seems to be inviting additional Court action and, perhaps, this new standard being tossed out and having to start all over again. So in terms of the process being one that looks at what's happened in the past and tries to take into account mistakes that were already made, I would encourage you and those who have a say in this to think about what happened the last time, and make sure that you're following the law and following the scientific guidelines. (Comment 0211.8-5)

Response to Issue A:

Notwithstanding whether it would have been acceptable under the Administrative Procedure Act to promulgate this rule immediately and without opportunity for comment, the Agency has chosen not to do so; therefore, this is a moot point. We disagree that remedy on equal protection grounds is available to any party on the basis of today's final rule amending 40 CFR Part 197. We similarly disagree that today's rule somehow "ignores" the words of the NAS Report. Pursuant to our statutory obligations under the EnPA, today's revised standards are based upon and consistent with the findings and recommendations of the NAS Report. As recommended by NAS, the revised public health and safety standards for protection of the public from releases of radioactive materials stored or disposed of in the Yucca Mountain repository apply at the time of peak dose, within the period of geologic stability, bounded by a time period of 1 million years. For a number of reasons, discussed both in the preamble to today's rule and in response to other comments, EPA determined not, in revising the Part 197 standard to be unambiguously consistent with the express recommendations of the NAS, to eliminate the requirement that releases of radioactive materials from the repository not exceed 15 mrem at 10,000 years. This requirement at 10,000 years, however, is <u>not</u> the peak dose standard required by the EnPA and recommended by the NAS. That standard (i.e., the peak dose standard required by law and recommended by the NAS) is found at 40 CFR 197.20(a)(2). It is neither violative of the EnPA, nor inconsistent with the NAS's recommendations, for EPA to, in addition to the § 197.20(a)(2) standard, impose additional requirements at 10,000 years to be further protective of public health and safety (197.20(a)(1)).

Section 24 Legality of the Standards

Issue B: EPA's rule is inconsistent with the D.C. Circuit decision

1. Nevada is mindful that EPA, in its proposed rule, has attempted to construe the NAS recommendations as a "starting point," and to portray its proposed rule as a reasonable modification based upon policy grounds. But while the Court recognized EPA had "some flexibility" to craft standards in light of NAS's findings, it warned that "EPA may not stretch this flexibility to cover standards that are inconsistent with the NAS Report." NEI, 373 F.3d at 273. The proposed rule has done precisely that. (Comment 0226-3)
2. EPA's proposed rule would abandon the well-established and universally accepted principle of apportionment. That abandonment departs, without any credible justification,

from the consensus position embodied in the NAS's recommendations and in EPA's own prior statements and practice. NAS Report at 4; see also id. at 40-41. Using this approach, each individual source is allocated not the entire amount of radiation that would reach the regulatory limit, but only a portion, based on the reasonable assumption that other sources will exist, and that people's health will depend upon the cumulative risks that all of those sources create. Until releasing its proposed rule, EPA has consistently adhered to this internationally accepted apportionment principle. EPA adhered to, and relied upon, this guidance in the initial stages of developing the Yucca standard. EPA's final rule again adhered to this principle, setting the site-specific dose limit at 15% of the total allowable 100 millirem/year dose. EPA went on to explain that its 15 millirem/year standard "is 15% of the ICRP-recommended total dose limit. It falls within the range of standards used in other counties and the range recommended by NAS, and is also consistent with the individual-protection standards in 40 CFR part 191." 66 Fed. Reg. at 32089. In its responses to comments on Part 197, EPA relied directly on this apportionment principle in rejecting a suggested 70 millirem/year standard. EPA explained that "70 mrem from one source is too high a proportion of the annual 100 mrem recommended by the 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 insure that the sum, or total, of all included exposures is less than 1 mSv (100 mrem)." EPA, Response to Comments, 4-5 to 4-6 (2001). EPA then reiterated that ICRP recommends national authorities allocate "a fraction" of the 100 millirem total to establish an exposure limit for spent fuel and highlevel waste disposal facilities. Ibid. Yucca Mountain presents (and EPA has provided) no reason to abandon this concept. The proposed repository cannot be the sole source of local radiation, for, as EPA itself has noted, the area surrounding Yucca Mountain already has borne more than its fair share of the nuclear era's impacts. All these Nevada-specific exposures would occur in addition to the many other anthropogenic exposure sources. As EPA has noted, commercial nuclear power plants, university research and development, experimental reactors, government- controlled reactors, and foreign facilities, among other sources, all contribute radiation. See 66 Fed. Reg. at 32079. EPA has offered no basis to assume these other sources will cease to affect the Yucca Mountain area. Nevertheless, EPA's proposed 350-millirem (1000-millirem mean-equivalent) second-tier standard would completely abandon the principle of apportionment. EPA would allocate Yucca approximately 3.5 times—or over ten times, in mean-equivalent terms—that total dose standard to one site. EPA provides no coherent explanation for this shift. Instead, the proposed rule acknowledges that "in practice today, doses from any particular source of radiation are generally kept to a fraction of the 100 mrem overall limit, in recognition that a person may be exposed to more than one practice or source." 70 Fed. Reg. at 49040. But EPA then makes the remarkable claim that because the agency does not know what future sources will exist, it is appropriate to allocate all of the accepted 100 millirem/year total dose to one source. Id. at 49041. In multiple ways, this statement turns the principle of apportionment on its head. First, the principle always has been applied, in the past, to sites at which other future exposure sources were unknown and unknowable. It would require "immense speculation," for example, to guess what specific sources will be near the WIPP site, but EPA relied on the apportionment principle to establish the WIPP standard. See 58 Fed. Reg. at 66402. It would similarly require "immense speculation" to guess what specific sources will exist at Yucca Mountain over the next 10,000 years, yet in promulgating its original 10,000-year standard, EPA again applied the apportionment principle. 66 Fed. Reg. at 32089. The prerequisite for application of this principle has never been foreknowledge of particular future sources at the site in question; nuclear waste disposal systems are inherently long-lasting, and we never know exactly what other sources will exist. Indeed, that very lack of knowledge is a core reason for utilizing apportionment, not a reason to abandon the principle. Since EPA does not know what will happen in the future, but does know that other sources are possible—indeed, they are inevitable if we continue our current practices of using nuclear materials—it must make accommodations for those potential sources. EPA's approach, by contrast, is the equivalent of assuming that other sources will never affect the vicinity of Yucca Mountain—despite EPA's own statement that it would involve "immense speculation" to predict such future events. See 70 Fed. Reg. at 49041. In the guise of avoiding speculation, EPA proposes to make an unprecedented, absurdly optimistic, and totally speculative assumption. This rationale also ignores additional sources that already exist. EPA's blithe suggestion that Yucca Mountain will be the only source worth considering thus ignores present reality as well as the unpredictability of the future. Further sources also are a foreseeable possibility. Given its past and current uses, other sources of radioactive contamination may be installed at the Nevada Test Site. EPA supplies no other attempted justification for diverging from the NAS's recommended approach, its own past practice, and worldwide convention. Its abandonment of apportionment therefore is arbitrary, capricious, and inconsistent with the EnPA's mandate that EPA's rule be "based upon and consistent with" the NAS report's recommendations. (Comment 0226-9)

Response to Issue B:

EPA disagrees that the revised Part 197 standards are somehow inconsistent with the findings and recommendations of the NAS Report. The NAS specifically recommended that EPA promulgate its public health and safety standard applicable at the time "when greatest risk occurs, within the limits imposed by long-term stability of the geologic environment." NAS Report at 6-7 (see also, 55-56 and 67). EPA has done that. The individual-protection standard at 40 CFR 197.20(a)(2), consistent with the NAS's recommendation, applies at the time of peak dose after 10,000 years and within the period of geologic stability – which is defined to end at 1 million years after disposal. Regarding the principle of apportionment, Comment 0226-9 appears to attempt to argue that the NAS specifically recommended that EPA adopt and implement apportionment for the standard during the entire period of geologic stability at Yucca Mountain. We have searched diligently in an attempt to identify such a specific recommendation in the NAS Report and have been unsuccessful in doing so. At no point in its report does the NAS specifically recommend that EPA implement the principle of apportionment for the period of geologic stability (explicitly recognized as being on the order of 1 million years). While the NAS discussed apportionment, and noted how it has been implemented and considered in other geologic disposal contexts - for periods far shorter than the period of geologic stability at Yucca Mountain – it did not make a specific finding or recommendation that EPA should somehow attempt to implement this principle for a time period on the order of 1 million years. Further discussion of the issue of apportionment is presented in the preamble to today's final rule at Section III.A.

Section 24 Legality of the Standards

Issue C: Ground-water standards

1. In a cursory section of the proposed rule, EPA explains, without any legal or scientific justification, that the proposed rule would abruptly remove any groundwater protection standard at all once 10,000 years have elapsed. Moreover, EPA has announced in advance that it will *not even consider comments* regarding "any aspect of the groundwater protection standards." 70 Fed. Reg. at 49024. That rigid determination to terminate the groundwater protection standard without any public comment, which stems from a fundamental misunderstanding of the Court's ruling in *NEI*, is arbitrary and contrary to law. (Comment 0226-19)

2. Contrary to [EPA’s] premise, the Court's ruling does govern the separate groundwater standard. The groundwater protection standard is a component of Part 197, and it "incorporates a 10,000 year compliance period" and "requires DOE to show compliance for only 10,000 years." The court therefore expressly vacated this portion of the rule, and EPA's conclusion that the decision did not apply to the groundwater standard rests upon clear error. The reasoning underlying *NEI v. EPA* compels the same conclusion. As the Court held, EnPA requires EPA to avoid inconsistency with the NAS's recommendations in setting all standards. That requirement must extend to the groundwater standard, for the same sentence of § 801(a) that empowers EPA to set standards also requires consistency with the NAS's report. *See* NEI, 373 F.3d at 1315. EPA cannot invoke the half of that sentence that empowers it to set standards yet ignore the other half, which requires that those standards be based upon and consistent with the findings and recommendations of the NAS, and thus any standards it promulgated could not employ a 10,000-year compliance cutoff after the NAS expressly rejected that cutoff. The logic of the court's opinion therefore supports its literal meaning and indicates, contrary to EPA's current position, that the 10,000-year cutoff of the groundwater protection standard has been vacated. EPA therefore cannot re-adopt that cutoff, especially without allowing comment. (Comment 0226-20)

Response to Issue C:

EPA disagrees that it suffers from a “fundamental misunderstanding of” the D.C. Circuit’s decision with respect to the ground-water standard and our decision to maintain a 10,000-year compliance period therefor. Section 801 of the EnPA requires EPA to promulgate “public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of” at Yucca Mountain that are “based upon and consistent with the findings and recommendations of the NAS.” The NAS did not make any findings or recommendations pertaining to a possible ground-water standard at Yucca Mountain:

> “40 CFR 191 includes a provision to protect groundwater from contamination with radioactive materials that is separate from the 40 CFR 191 individual dose limits. These provisions have been added to 40 CFR

> 191 to bring it into conformity with the Safe Drinking Water Act, and have the goal of protecting groundwater as a resource. <u>We make no such recommendation, and have based our recommendations on those requirements necessary to limit risks to individuals.</u>"

NAS Report p. 121 (emphasis supplied). Thus, while it is doubtless true that "EnPA requires EPA to avoid inconsistency with the NAS's recommendations in setting" relevant standards; clearly this does not extend to those standards for which the NAS explicitly and specifically declined to issue a recommendation. Moreover, we strongly disagree that this conclusion could somehow be inconsistent with the D.C. Circuit's decision because the Court spoke directly to this issue: "Put another way, NAS made no 'finding' or 'recommendation' that EPA's regulation could fail to be 'based upon and consistent' with.' We thus agree with EPA that § 801 left it free to add a ground-water standard." NEI v. EPA, 373 F.3d 1251, 1282. It is but a trivial extension of logic and statutory interpretation that, if EPA is free to add a ground-water standard of its choosing – a standard for which the NAS made no recommendation whatsoever - it is free to apply that standard within a temporal timeframe divorced from that recommended by the NAS in the explicit context of the separate individual-protection standard. Finally, we note that EPA expressly intended the ground-water standard to be wholly severable from the individual-protection standard, and that vacature and remand of one was not, absent specific instruction from a reviewing court of competent jurisdiction, to affect the other. 66 FR 32129/3 – 32130/1.

Section 24 Legality of the Standards

Issue D: Uncertainty

1. In employing an uncertainty-based rationale directly at odds with the NAS's findings and recommendations, EPA has not only abrogated EnPA's mandate; it also has attempted to resurrect an approach already rejected by the Court. That attempt suggests that EPA does not realize, or is choosing not to acknowledge, that it is bound by a judicial decision. Uncertainty was a key rationale for the portion of 40 CFR Part 197 that the Court has already set aside. In attempting to justify its previous 10,000-year cutoff, EPA asserted, just as it asserts today, that "we have concerns regarding the uncertainties associated with such projections, and whether very long-term projections can be considered meaningful." 66 Fed. Reg. at 32096. It similarly stated that "[d]espite NAS's recommendation, we conclude that there is still considerable uncertainty as to whether current modeling capability allows development of computer models that will provide sufficiently meaningful and reliable projections over a time frame up to tens-of-thousands to hundreds-of-thousands of years." *Id.* at 32098. And it sought to cast a gloss of "policymaking" over those statements, asserting that "the selection of a compliance period for the individual-protection standard involves both technical and policy considerations." *Id.* EPA heavily relied on that "uncertainty" rationale in its arguments before the Court. It claimed that the 10,000-year cutoff was justified partly by "the large uncertainties inherent in attempting to project human exposures to releases from the repository for time periods over 10,000 years…." EPA Brief at 14, 19. And it provided a detailed discussion of these uncertainties, suggesting, in terms highly similar to those of the current proposed rule, that increasing

uncertainties made long-term compliance projections untenable. *Id.* at 44-45. At oral argument, EPA's counsel clearly repeated EPA's attempt to cast this uncertainty rationale as a key policy judgment, arguing, in
response to a question about the "policy aspects" of EPA's decision, that uncertainty was "one of the most significant" policy rationales for treating the post-10,000-year compliance assessment differently. Oral Argument transcript, *NEI v. EPA*, at 25. EPA's current argument—that uncertainty justifies a different post-10,000 year standard—thus has already been considered and rejected by the Court. The Court rejected EPA's 10,000-year cutoff and the uncertainty rationale upon which it purported to rest. 373 F.3d at 1270-73. Indeed, at oral argument, Judges Tatel and Edwards repeatedly indicated that they were well aware that EPA was trying to use uncertainty to justify its differing treatment of the post-10,000-year period and questioned EPA's discretion to employ that rationale. In a typical statement, Judge Tatel, responding to EPA's attempt to cast its uncertainty disagreement as a policy disagreement justifying its 10,000-year cutoff, said, "but that's the scientific judgment that Congress wanted the EPA to defer to." Transcript at 25. That transcript, the former rule, EPA's briefing, and the decision itself all indicate that EPA has already litigated its uncertainty rationale and lost. Accordingly, EPA is legally prohibited from resurrecting "uncertainty" as the core rationale for a permissive post-10,000-year standard.
(Comment 0226-38)

Response to Issue D:

First, we note that the proposed standard that formed the basis of the comment has been abandoned. The 1 millisievert peak dose individual-protection standard adopted in § 197.20(a)(2) of the final rule is fully protective of public health and safety and does not suffer the deficiencies of the number included in the proposed rule that were identified by many commenters. That said, however, it is nonetheless incorrect to assert or imply (1) that “uncertainty-based rationale [is] directly at odds with the NAS's findings and recommendations; (2) that “EPA has . . . abrogated EnPA's mandate;” and (3) that EPA “has attempted to resurrect an approach already rejected by the Court.” Acknowledgement of the basic factual concept that substantial uncertainty inheres to the results of a performance assessment conducted for a time frame of upwards of 1 million years is not “at odds with the NAS's findings and recommendations.” Further it is neither true that today’s standard “abrogate[s] EnPA's mandate,” nor that this is “an approach already rejected” by the D.C. Circuit.

First, and most importantly, the EnPA does not speak to the issue of whether the substantial uncertainties inherent in conducting a performance assessment for a period of up to 1 million years should be addressed in the required public health and safety standard. Rather, the EnPA rather straightforwardly requires that the required standard be “based upon and consistent” with the findings and recommendations of the NAS. Thus, for the Agency’s acknowledgement of these uncertainties in its individual-protection standard to be violative of the mandate of the EnPA, EPA’s standard must be inconsistent with a specific finding and/or recommendation of the NAS concerning application of these uncertainties in the development of the standard. This is not the case. Aside from specifically recommending that compliance be assessed out to the time of peak risk within the period of geologic stability, and rejecting the argument that increasing performance assessment uncertainty justified a compliance period significantly shorter than the time to peak risk, the NAS did not make specific findings or recommendations concerning how to address uncertainty. For example, the NAS noted:

> "Because there is a continuing increase in uncertainty about most of the parameters describing the repository system farther in the distant future, it might be expected that compliance of the repository in the near term could be assessed with more confidence. This is not necessarily true. Many of the uncertainties in parameters describing the geologic system are due not to temporal extrapolation but rather to difficulties in spatial interpolation of site characteristics. These spatial difficulties will be present at all times. Accordingly, even in the initial phase of the repository lifetime, a compliance decision must be based on a reasonable level of confidence in the predicted behavior rather than any absolute proof. Under some circumstances, use of a shorter period for analysis could in fact introduce additional uncertainties into the calculation. For example, uncertainties in waste canister lifetimes might have a more significant effect on assessing performance in the initial 10,000 years than in performance in the range of 100,000 years."

(NAS Report p.72). Further:

> "We believe that performance assessment using numerical models of physical and chemical processes and quantitative estimates of probabilities is the key approach to assessing compliance. However, the confidence that can be placed in such analyses is also a key part of the compliance issues. To some extent, this degree of confidence can be quantified, for example, by performing rigorous uncertainty analyses that propagate uncertainties in parameter values through the analysis to produce estimates of uncertainties in estimated risks. Uncertanties due to modeling approaches can also be assessed by comparing the results of assessments using various alternative models, or by comparing model results with data collected in experiments or in observations."

(NAS Report p. 73). Nowhere does NAS make a specific finding or recommendation that utilization of uncertainty analysis in such a manner as to adjust the numerical value of the standard to account for the significant uncertainties inherent in a performance assessment conducted for 1 million years is invalid, or should not be done. Indeed, on page 73 of its report, NAS specifically states that uncertainty analyses are important to produce estimates of uncertainties in estimated risks. It would seem to be beyond peradventure that it is appropriate to utilize the results of such analysis in determining the appropriate value of the standard. Thus, as stated above, if EPA's appropriate utilization of uncertainty analysis to inform the establishment of an appropriate individual-protection standard is not inconsistent with the findings and recommendations of the NAS, it cannot be violative of the EnPA's mandate. We also reject the suggestion in Comment 0226-38 that EPA's utilization of uncertainty analysis has "already been considered and rejected by the Court." The D.C. Circuit specifically addressed whether EPA's various rationales – including increasing uncertainty -- for limiting the regulatory compliance period to 10,000 years were sufficient and the Court found that they were not. Where NAS had spoken directly to a particular issue, EPA was obligated to promulgate standards that were based upon and consistent with the NAS findings and recommendations. That is beyond dispute. Where Comment 0226-38 fails is in its suggestion that the D.C. Circuit specifically spoke to whether the Agency could utilize uncertainty analysis in developing a standard that is to apply to the time of peak risk, within the period of geologic stability. The Court did not speak to that issue. Further, it cannot be ignored that, as quoted above, the NAS specifically discussed the utilization of uncertainty analysis in ascertaining the level of confidence that should be placed in performance assessment.

Section 24 Legality of the Standards

Issue E: Features, events, and processes

1. EPA may not exceed the authority Congress has delegated to it. Here, EPA's authority is limited; it may only set health and safety standards for Yucca Mountain. Yet, EPA's proposed rule does far more than just set a standard. In numerous ways, those extra components of EPA's proposed rule would usurp the NRC's Congressionally defined role of resolving adjudicatory facts and making a licensing decision. In addition to these usurpations of authority, EPA also proposes, without any Congressional authorization, to delegate part of its own rulemaking authority to the NRC. (Comment 0226-72)

2. EPA's FEP-setting process violates EnPA's mandate, and the core holding of the Court, for EPA's FEPs and the rationales EPA has employed to support them are inconsistent with NAS findings and recommendations. (Comment 0226-74)

3. In setting FEPs for certain physical parameters of the Yucca Mountain analysis, EPA proposes to use the rulemaking process to pre-determine adjudicative facts, and to do so in areas well outside its expertise. In so doing, EPA would exceed the limited authority Congress conferred upon it, both by exceeding its rulemaking function and by undertaking tasks that Congress delegated elsewhere. In the NWPA and EnPA, Congress specified a clear division of authority—one which built upon EPA's traditional role (incorporated in section 121 of the NWPA and the 1970 Reorganization Plan that established EPA). EPA's one and only duty is to promulgate, by rulemaking, a health-based standard "based upon and consistent with the NAS's findings and recommendations." EnPA § 801. DOE, not EPA, is to select a site and write an application for a license. The NRC, not EPA, is to judge, through an adjudicatory proceeding, whether that license application satisfies EPA's health-based standard, and whether the license should be granted. Like any administrative agency, EPA has no power beyond that delegated to it by law, and may not assume the functions delegated to its sister agencies. (Comment 0226-92)

4. The significance of Congress's division of authority is underscored by its concordance with the fundamental separation of powers that underlies our entire system of governance. Our Constitution itself has as its core principle the separation of powers between legislative, executive, and judicial entities; it does not contemplate the same entity

simultaneously functioning as advocate, rulemaker, and judge. Likewise, "the entire (Administrative Procedure) Act is based upon a dichotomy between rule making and adjudication." ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT (1947). In dividing authority among EPA, DOE, and the NRC, Congress utilized those core separation-of-powers principles, granting EPA only a limited rulemaking role, and EPA has no power to blur those distinctions. Indeed, the gravity of the Yucca Mountain decisions accentuates the importance of Congress's mandate; if government agencies are to decide that part of Nevada will be contaminated for a million years, that decision ought at the very least to be made through a process of checks and balances, and the agencies involved must respect the limits Congress placed upon their roles. EPA therefore is required, in promulgating this standard, to limit itself to the narrow and constrained rulemaking task Congress delegated to it. Yet many of the specific FEP determinations EPA's proposed rule would make are not properly within the scope of EPA's rulemaking task, and are certainly far outside its traditional expertise. The grant of rulemaking authority in the EnPA is based on the prior grant of rulemaking authority in the NWPA. Both statutes are based on the original grant of radiation standard setting authority in Reorganization Plan No. 3 of 1970. That grant (and therefore the grant in the EnPA) is expressly limited to the setting of standards defined as “limits on radiation exposures or levels, or concentrations or quantities of radioactive material” in the environment. The rest was reserved exclusively to NRC as the agency responsible for implementing the EPA standards through the licensing process. (Comment 0226-93)

5. EPA has used rulemaking to pre-set the highly technical assumptions that DOE’s modelers will make, and to pre-judge the resolution of site-specific licensing issues that are the exclusive province of NRC. Such things as specification of FEPs do not remotely qualify as the setting of limits on exposures, levels, or concentrations of radiation. Indeed, in the past, NRC has vigorously opposed EPA intrusions into its repository licensing functions very much like the ones EPA now proposes. *See* NRC letters to EPA and NRC memoranda found on NRC’s Licensing Support Network at NRC 000024406 and NRC 000024461. Scientific determinations such as this are more properly made in the NRC licensing review where there is the flexibility to account for more recent scientific advances and to adjust to specifics of the performance assessment actually proposed as the basis for licensing. EPA itself has no power, in its rulemaking process, to review DOE's current draft applications and preliminary modeling work and utilize that work to screen certain scenarios out of the site evaluation process. By constraining the modeling assumptions, EPA has gone far beyond its limited rule-writing role and instead has injected itself into NRC's licensing function. EPA's own past statements acknowledge that these determinations are not EPA's to make. In promulgating 40 CFR Part 197's standard, EPA did not purport to specify FEPs that DOE would or would not model. Instead, EPA noted that "[t]hese considerations and decisions properly belong to the implementing authority." 66 FR 32074, 32126 (July 13, 2001). EPA specifically explained that in the WIPP process, "where [EPA] had both the standard-setting and implementing authority," it had specified "requirements for modeling techniques and assumptions." *Id.* But it concluded that in the Yucca Mountain rulemaking, where such implementing authority did not repose in EPA, such "requirements go well beyond the simple statement of a compliance measure," and, with the exception of the FEP discussed below, it did not establish them. *Id.* Likewise, EPA

specifically noted that it declined "to specify that DOE must use a particular modeling approach to demonstrate compliance with the standards," and instead stated that "DOE (the organization responsible for developing the license application) and NRC (the authority responsible for the approval of the disposal facility) should make these decisions." *Id*. at 32127 (parentheses in original). (Comment 0226-94)

6. The proposed EPA rule includes various "findings" of adjudicatory fact—that is, findings of fact that are applicable only to Yucca Mountain and that should be the subject of NRC review of the DOE license application in the NRC licensing hearing. Those "findings" also are made without any significant factual inquiry on controversial and critical subjects over which EPA has no particular expertise. For example, EPA's entire "over-conservatism" and "uncertainty" theories rest on pre-determination of adjudicative facts. As Dr. Thorne points out in Appendix C, variations in uncertainty and conservatism with time are matters to be derived by detailed assessment modeling, which can only be done in consideration of an actual license application, and cannot be determined *a priori* by rule, as EPA presumes in its rule. EPA does not, and cannot, rely on universally applicable legislative facts to support this theory, for DOE's models will be specific to Yucca Mountain. Likewise, the source EPA cites for its over-conservatism rationale is specific to DOE's Yucca-Mountain models. *See* 70 FR 49021 (citing Cohen, Assumptions, Conservatisms, and Uncertainties in Yucca Mountain Performance Assessments (2005)). Accordingly, the inquiry about whether DOE's modeling efforts will be improperly conservative, improperly optimistic, or somewhere in between is a classic determination of adjudicative fact, and EPA has no power to extract that determination from the NRC's adjudicative process, prejudge its outcome, and use that prejudgment as a basis for its rule. EPA's proposed rule not only would involve *ultra vires* resolutions of adjudicative facts; it would resolve those facts before they are ripe for adjudication. The EPA findings are based on what is, in effect, an incomplete collection of information, some of which may be relied upon by DOE in its eventual license application, and some of which may not be. Because DOE has not yet submitted an application (and has in fact taken every conceivable measure to hide it from public view), all of its modeling is preliminary and subject to change. The final application will undoubtedly include numerous important changes from the information relied on in this rule, and when DOE actually submits an application the perceived flaws that led EPA to adopt particular positions on various FEPs and skew its standards may no longer exist. Moreover, none of that preliminary modeling has been the subject of a full review and concurrence by DOE, NRC or EPA, and the iteration relied upon by EPA already has apparently been superseded by another draft. EPA's adjudicatory decisions thus are premature as well as *ultra vires*. Each of these legal defects has the unlawful effect of depriving Nevada and other interested persons of their rights to an adjudicatory hearing on contested issues of adjudicatory fact under the Atomic Energy Act and NRC's Rules of Practice. To be sure, to a limited extent a Yucca specific rule must be based on findings of adjudicative fact, for example, a finding that the Yucca site is such that reasonable projections of peak dose can be made. But clearly Congress limited such adjudicative fact-finding to those facts essential for the promulgation of health-based standards, properly defined as limits on radiation exposures, levels or concentrations in the environment. Moreover, the adjudicative findings necessary for standard-setting were to be made by NAS. EPA’s findings of fact are well in excess of those necessary to accomplish

this limited rulemaking function and go well beyond, and in some respects are inconsistent with, the findings of NAS. Indeed, as pointed out above, EPA's rule is in danger of complete collapse when the proposed findings of fact in the DOE license and the NRC findings of adjudicatory fact in the licensing process turn out to be inconsistent with the very premises for the EPA rule. Such a collapse would be avoided if EPA limited its rule, and its underlying findings, to policy judgments about acceptable levels of risk based on NAS findings of fact about Yucca. (Comment 0226-96)

Response to Issue E:

The thrust of these comments is that EPA has either usurped authority not given, or - claimed to a lesser extent - abdicated authority that it does have, or made "findings" of adjudicatory facts. We categorically disagree with these comments. As stated in the NAS Report, and set forth in detail in the Agency's proposed rulemaking, delineation of critical features, events, and processes (FEPs) to be input into the performance assessment evaluated to adjudge compliance with the standards is an essential element of the standard-setting process. EPA is well within its statutory, regulatory, and technical authority and responsibilities to specify not only the critical FEPs to be considered, but, also, to specify how they are to be treated in performance assessment to ensure the most rigorous demonstration of projected repository performance. (We note that, notwithstanding assertions to the apparent contrary in Comment 0226-94, the NRC has not objected in this process to the Agency's decision to make such specifications in today's rule). The NAS stated:

> "Any standard to protect individuals and the public after the proposed repository is closed will require assessments of performance at times so far in the future that a direct demonstration of compliance is out of the question. The only way to evaluate the risks of adverse health effects and to compare them with the standard is to assess the estimated potential future behavior of the entire repository system and its potential effects on humans. This procedure, involving modeling of processes and events that might lead to releases and exposures, is called performance assessment."

NAS Report p. 8. In its later discussion of how probabilistic assessment of repository performance is to be conducted, NAS states that "It is important, therefore, that the "rules" for the compliance assessment be established in advance of the licensing process; that is, that the scenarios that might be excluded from the integrated risk analysis be identified." NAS Report at 73. From the outset of this process, EPA has undertaken, at great length, to identify such scenarios. In the 2005 proposed rulemaking, EPA explained that it is "important to emphasize certain key aspects of the performance assessment that will apply regardless of the time frame involved." 70 FR 49047/3. Further, "[t]he overall purpose of the performance assessment is to provide a reasonable test for compliance with those standards. A major part of providing that reasonable test is determining which features, events, and processes (FEPs) are to be included in the performance assessment performed by DOE." *Id.* EPA's rationales for specifying the inclusion and elimination of specific FEPs in the performance assessment are explained at 70 FR 49047 - 49060. Thus, in contrast to the commenter's assertion, not only is the specification of the identity and manner in which FEPs are to be applied in the compliance assessment well within EPA's statutory authority under the EnPA, but, EPA's extensive explanation of its scientific rationale for such decisions presents a sound, rational basis for those decisions.

Section 24 Legality of the Standards

Issue F: EPA's proposed standard violates the EnPA

1. EPA's intergenerational equity rationale, to the extent that it exists, fails for an important additional reason: EPA has never explained how a lax second-tier standard benefits anyone. While EPA's entire theory appears to be that providing future generations with the same protection we provide ourselves today would impose burdens upon present generations, EPA has not stated what those burdens are. Indeed, it has identified *no* possible trade-off that will result in any present harm if current levels of acceptable risk are sustained after 10,000 years. If EPA is implicitly suggesting that the benefit to this generation from the lax future standard is the present success of Yucca Mountain, it strays into impermissible territory, for EPA has no authority to pre-determine that the Yucca Mountain repository should be built regardless of health and safety threats. With the NWPA and EnPA, Congress gave EPA one duty—to set the health-based radiation standard for Yucca. It did not call upon EPA to evaluate whether the success of the nation's repository program at Yucca today can justify a weaker standard of care for future generations. EnPA section 801(a) (1) requires EPA to promulgate a "public health and safety standard for protection of the public from releases [from Yucca]." Section 801(a) (2) refers to this standard as "health-based." A "public health and safety" or "health based" standard must be based on a consideration of what is an acceptable level of risk; it may not be based on economic costs or a balancing of costs and benefits. *National Cottonseed Products Ass'n v. Brock*, 825 F.2d 482 (D.C. Cir. 1987) (citing *American Textile Manufacturers Ins't v. Donovan*, 452 U.S. 490 (1981)); *NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987); *Union of Concerned Scientists v. NRC*, 824 F.2d 108 (D.C. Cir. 1987).Moreover, Nevada disputes whether Yucca Mountain would actually provide any benefit to present generations. As Nevada has pointed out in detailed past comments, both the site itself and, potentially more importantly, the massive project of transporting 70,000 tons of nuclear waste across the country to the site pose enormous risks to present generations. *See* Nevada, *Comments on Department of Energy's Draft EIS*. Similarly, a lax second-tier standard provides significantly reduced protection to generations living within the 10,000-year period. If the repository is licensed on the *assumption* that peak dose will occur after 10,000 years, and that assumption proves wrong, the first-tier standard will provide no protection to the people who bear the brunt of the repository's impacts. Instead, those generations, whom EPA has never suggested should receive the same minimal protection it would accord to generations in the post- 10,000-year period, would be put at greater risk by EPA's decision to rationalize a lax second-tier standard on the theory that later harms are somehow more permissible. (Comment 0226-67)

2. In addition to usurping roles Congress delegated to other agencies, EPA's proposed rule would unlawfully delegate away EPA's own core responsibility for setting a standard.

Rather than following Congress's and the court's direction to set a standard applicable to peak dose, EPA proposes to set little more than a guideline, and to allow the NRC to consider a modeled projection of compliance with that guideline as little more than a "factor" in its ultimate compliance determination. By declining to promulgate a true standard, EPA impermissibly would delegate its discrete and limited rulemaking role to the NRC. (Comment 0226-102)

3. The NWPA and EnPA direct EPA to promulgate a binding standard. EnPA section 801(a) (1) states that EPA's "standards shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases" of radioactive material from the repository. *See NEI v. EPA*, 373 F.3d at 1262 (citing EnPA). The phrase "prescribe the maximum" clearly indicates Congress's demand for a binding limit, and does not allow for the possibility of approval of a repository predicted to produce higher doses. Likewise, Congress's use of the word "standard" indicates Congressional intent that the standard be an absolute limit; elsewhere in environmental regulation, where Congress has demanded that EPA "prescribe… standards," those standards are understood to provide limits that may not be exceeded. *See*, *e.g.*, 42 U.S.C. 7409 (providing for air quality standards, with which state air quality plans must demonstrate compliance); 42 U.S.C. § 9621 (requiring hazardous waste site cleanups to meet public health and safety standards). Finally, Congress's requirement that EPA promulgate its standards "by rule" indicates the binding nature of those standards; unlike policy statements or guidance documents, rules that implement Congress's statutory mandates by definition have coercive force. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (citing the 1947 Attorney General's manual); *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980). (Comment 0226-103)

4. Notwithstanding those Congressional directives, EPA proposes, in parts of its new rule, that its standard would not be binding unless the NRC decides to treat it that way, and that the NRC would have discretion to license a site even where the compliance evaluation projects a violation of the standard. EPA does suggest that under its new rule, "the post-10,000 year analyses are now proposed to be part of the 40 CFR part 197 standards with a quantitative limit imposed." 70 FR 49028. However, EPA of 'weight' that should be given to these very long-term assessments" as "an implementation decision that should be left to the NRC to determine, by balancing the inherent uncertainties in these projections against the projected dose levels." *Id.* (Comment 0226-104)

5. EPA suggests that compliance projections can "form a key *part* of the basis for a licensing decision," 70 FR 49029 (emphasis added). It argues that "we do not want to place more regulatory emphasis on peak dose projections than can be justified." 70 FR 49030. It suggests that "quantitative projections should be considered less for their strict numerical outcomes and more as one component in a qualitative evaluation of the overall safety case." *Id.* And it further states that NRC may consider a dose projection exceeding the dose standard not as a bar to licensing, but rather as only a "particularly important part of the 'full' record." 70 FR 49034. Finally, in a statement that ignores the NAS's conclusions about the manageability of scientific uncertainty, EPA suggests that NRC's "regulatory judgment must bridge the gap between what science can show and the unprecedented time frames involved ." 70 FR 49030. It is one thing to promulgate a dose standard and leave the implementation details (the selection of models, FEPs, and the like) to NRC. It is quite

another to set a "standard" and give NRC the discretion to grant a license that does not comply with it. (Comment 0226-105)

6. EPA also states: We anticipate that if these very long-range performance projections (beyond 10,000 years) indicate that repository performance would degrade dramatically under a wide range of conditions at some point in time, that this would become a concern in the licensing decision. If such a dramatic deterioration were projected to occur close to the regulatory time period it would be a more pressing concern for licensing decisions than if it were to occur many hundreds of thousands of years in the future. 70 FR 49028. This statement is problematic for several reasons. First, it indicates that EPA still construes the "compliance period" as 10,000 years in length, notwithstanding the clear recommendation of the NAS and holding of the Court. Second, by stating that significant deterioration after 10,000 years would be just a *concern*, it implies that such deterioration need not prevent licensing, even if it creates a violation of the standard. Those implications are wholly inconsistent with both Congress's requirement that EPA set a maximum dose standard and with the Court of Appeal's mandate that the standard, and thus the "regulatory time period," extend to peak dose. These statements all suggest that EPA is granting NRC discretion to decide whether EPA's standard really will be a mandatory standard, or whether it will just be a guideline. But Congress did not delegate such decision-making authority to NRC; it tasked EPA with setting, "by rule," a standard, and directed NRC to see that the standard was implemented. EPA may not sub-delegate its standard-setting authority by allowing NRC to choose whether or not it must comply with EPA's rule. EPA must clarify that the standard will be what Congress demanded: a binding limit on the projected peak dose from the repository. (Comment 0226-106)

7. EPA's new sub-delegation is particularly suspect because of its close resemblance to elements of the rule the court already set aside. In the original 40 CFR Part 197 standard, EPA required DOE to provide dose projections through peak dose, but allowed NRC discretion to decide how to factor those projections into its licensing. The Court expressly rejected this approach, finding it inconsistent with Congress's mandate that EPA set a standard applicable through peak dose. 373 F.3d at 1273. Yet EPA's new rule, by again suggesting that NRC has discretion to grant a license despite projected exceedances of the dose limit, is functionally identical to the rule the Court already rejected as failing to fulfill EPA's statutory mandate. Finally, EPA's direction to NRC regarding establishment of climate conditions and infiltration rates is no standard at all, but merely an unlawful intrusion into NRC's licensing process. (Comment 0226-107)

Response to Issue F:

Comment 0226-67 states that "a 'public health and safety' or 'health based' standard must be based on a consideration of what is an acceptable level of risk; it may not be based on economic costs or a balancing of costs and benefits." In support of this proposition, comment 0226-67 cites to a number of cases. The proposition stated by comment 0226-67 is wrong. Moreover, not one of the cases cited in the comment actually support the quoted proposition in any way. First, we note that, as a broad generalization, the statement that "a public health and safety or health-based standard . . . may not be based on economic costs or a balancing of costs and benefits," as a matter of administrative law, cannot be correct. As discussed below, there are numerous "public health and safety or health-based" standards that are authorized by a number of different statutory provisions. The factors and criteria governing promulgation of such standards is, typically, specific to the particular statute. The cases cited in the comment illustrate this point perfectly: *National Cottonseed Products Ass'n v. Brock*, 825 F.2d 482 [*NCPA*], is a challenge to an Occupational Safety and Health Administration regulation limiting cotton dust in the workplace. As permitted under § 6(a) of the Occupational Safety and Health Act [OSH Act], OSHA initially adopted a "national consensus standard" for cotton dust. *Id.* at 484. OSHA subsequently promulgated a more stringent standard for cotton dust under § 6(b) of the OSH Act. This later regulation was appealed and subsequently remanded to the agency for "reconsideration or further explanation of the standard's economic feasibility." *Id.* On remand, the agency reconsidered both the need for the regulations and their feasibility. Finding that (1) medical surveillance of workers exposed to cotton dust would alleviate the risk of material harm to such workers and (2) medical surveillance was technologically and economically feasible, OSHA issued orders requiring medical surveillance of workers exposed to cotton dust. Reviewing the medical surveillance standard, the D.C. Circuit (Judges Ruth Bader Ginsburg and Williams writing for the Court) held that OSHA's Section 6 standards must be both "technologically and economically feasible." *NCPA* at 487. Comment 0226-67's citation to *NCPA* notes that it cites *American Textile Manuf's Inst. v. Donovan*, 452 U.S. 490 (1981) [*ATMI*]. This case similarly does not support the comment's contention that, generally, public health and safety or health-based standards may not incorporate cost accounting or balancing of costs and benefits. ATMI concerned a challenge to an earlier OSHA § 6(b)(5) rule regulating cotton dust exposures in the workplace. In promulgating this standard, OSHA interpreted § 6(b)(5) to require adoption of the most stringent standard necessary to protect against material health impairment, and to allow such standard to be limited only by consideration of technological and economic feasibility. *Id.* at 503. Thus, the principal issue presented to the Court was "whether the [OSH Act] requires [OSHA], in promulgating a standard pursuant to Section 6(b)(5) of the Act to determine that the costs of the standard bear a reasonable relationship to its benefits." *Id.* at 507. The Court found that "cost-benefit analysis by OSHA is not required by the statute because feasibility analysis is." *Id.* at 509. Thus, while the *ATMI* decision holds that standards promulgated under Section 6 of the OSH Act do not require cost benefit analysis, OSHA, nonetheless, must determine whether such standards are technologically and economically feasible. Moreover, there is nothing in the ATMI decision that supports a conclusion that, generally, public health and safety standards or health-based standards "may not be based economic costs or a balancing of costs and benefits." This broad, generally applicable statement simply finds no support in the pages of the ATMI decision (or any other case). Indeed, to the contrary, footnotes 29 and 30 conclusively demonstrate that any such determination is statute-specific: "Petitioners argue that without cost-benefit balancing, the issuance of a single standard might result in a 'serious misallocatio[n] of the finite resources that are available for the protection of worker safety and health,' given the other health hazards in the workplace. . . . <u>This argument is more properly addressed to other provisions of the Act which may authorize OSHA to explore costs and benefits for deciding between issuance of several standards regulating different varieties of health and safety hazards</u>, e.g., § 6(g) of the Act, . . . or for promulgating other types of standards not issued under § 6(b)(5)." *Id.*, note 29 (citations omitted) (emphasis supplied). Succeeding textual discussion and footnote 30 (citing numerous statutory provisions), conclusively demonstrate that there are a myriad of instances where Congress has specifically mandated cost-benefit analysis be applied in the development of public health and safety standards. The other cases cited in comment 0226-67 (*NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987) and *Union of Concerned Scientists v. NRC*, 824 F.2d 108 (D.C. Cir. 1987)) also, curiously, provide no support for the proposition for which they are cited.

As for other comments, to the extent that language in the preamble of the NPRM may be interpreted as limiting the regulatory effect of the peak dose standard promulgated at 40 CFR 197.20(a)(2) such an interpretation was unintended. DOE must demonstrate by appropriate means that, inter alia, the repository will meet the standards set forth at 40 CFR 197.20 before NRC may grant a license for that facility.

Section 24 Legality of the Standards

Issue G: Miscellaneous comments

1. In its proposed rule, 70 FR 49014, EPA purports to rely upon and apply a "Reasonable Expectation" standard in evaluating repository compliance, emphatically urging *NRC* to employ it as well in its *implementation* of dose and time-of-compliance standards and calling Reasonable Expectation not just an optional gauge of safety but "a critical element in implementing our standards." *Id.* at 49020. EPA thus seeks to base its rule on some special notion of "reasonable expectation" that distinguishes it from the traditional standard of reasonable assurance. It is impossible to understand what effect "reasonable expectation" had on EPA's proposal, because EPA does not explain how reasonable expectation is different from reasonable assurance. However, in the context of EPA's present rulemaking, "Reasonable Expectation" cannot mean anything significantly different from the meaning previously ascribed to it in Court by both EPA and NRC, when it was agreed that reasonable expectation and reasonable assurance meant the same thing in repository licensing. EPA cannot proceed as if the agreed judicial resolution of this issue had never happened. In Court, Nevada's challenge to use of a "Reasonable Expectation" standard was rendered moot by those agencies' agreement that it was an equivalent standard to the well-known and commonly construed "Reasonable Assurance" standard of safety that peppers all of NRC case law. The court went on to note that, during oral argument, NRC counsel confirmed that the two standards are "substantively identical." *Id.* The court noted Nevada's satisfaction with NRC's concession that Reasonable Assurance and Reasonable Expectation are identical standards. (Comment 0226-108)

2. EPA's proposed rule violates the Information Quality Act, 44 U.S.C. § 3516 note (Title V, Treasury and General Government Appropriations Act for Fiscal Year 2001, § 515), and OMB's regulations promulgated there under, 67 FR 8452 (Feb. 22, 2002). This is because the Cohen Report, which forms EPA's critical scientific basis for the rule, is clearly a "Highly Influential Scientific Assessment" or, at the least, an "Influential Scientific Assessment," that requires under the IQA an adequate peer review, yet no such review was

ever conducted. This failure is significant for, as OMB has pointed out, "when an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened." *Id.* Given the plethora of technical errors and obvious biases in the Cohen Report, which emerged not as a peer reviewed scientific study but an unabashed advocacy piece, this omission was legally and scientifically fatal. (Comment 0226-116)

3. All of the above criticisms of EPA's proposed rule highlight what at bottom appears to be a palpable and, indeed, shameless effort to make a nuclear waste repository fit at Yucca Mountain, no matter what. In their own terms, those criticisms raise discrete legal issues that independently call into serious question the validity of the rule as proposed. At the same time, those distinct issues manifest agency action that is profoundly at odds with fundamental norms of the structure of dual sovereignty set out in the Constitution. (Comment 0226-119)

4. Key here is the fact that the Constitution does not create a unified national government, but a federation of sovereign states whose existence preceded the Union. The attributes of sovereignty possessed by the States are "fundamental postulates implicit in the constitutional design." *Alden v. Maine*, 527 U.S. 706, 728-29 (1999). Indeed, the sovereignty of the States is a "separate and distinct structural principle" that "inheres in the system of federalism established by the Constitution." *Id.* at 730. This principle has been elaborated upon and applied in a variety of contexts by the Supreme Court. *See* Robert J. Cynkar, *Dumping on Federalism*, 75 U. COLO. L. REV. 1261, 1278-99 (2004). This constitutional status of the States means that they are entitled to equal dignity and respect as sovereigns. Though the Supremacy Clause mandates that federal power appropriately exercised governs over competing laws or policies of the States, viewed through the Constitution's prism of federalism, the appropriate -- that is, the constitutional - exercise of federal authority requires such federal power to be exercised on the basis of generally applicable, rational, facially neutral criteria. Federal power does not extend so far as to allow the imposition of arbitrary burdens on particular States, or on any State. By straining to make the repository fit at Yucca, EPA has abandoned any pretense of a rational basis for its rule and of equal treatment for Nevada from among other possible sites, thereby infringing Nevada's constitutionally protected rights as a sovereign. Even the federal government's prerogatives under the Property Clause do not override competing constitutional principles, or allow the federalist structure of the Constitution to be so twisted, as to allow this proposed rule to pass constitutional muster. Further analysis of this constitutional issue with respect to Yucca is contained in an attached law review article, Robert J. Cynkar, *Dumping on Federalism*, University of Colorado Law Review, Vol. 75, No. 4 (Fall 2004), which is attached as Appendix F. (Comment 0226-120)

5. The Nuclear Waste Policy Act (NWPA) states that "… the cost of such disposal should be the responsibility of the generators and owners of such waste and spent fuel." By defining a much less stringent radiological standard after 10,000 years (350 millirem based on the median value of the predictions) could require that future generations incur additional costs to take remedial action to retrofit the repository to meet standards (15

millirem based on the expected value of predictions) that we consider reasonable with today's understanding of radiological hazards. Thus the action proposed by the EPA is in violation of the NWPA. (Comment 0263-3)

6. The NWPA states that "… to ensure that such waste and spent fuel do not adversely affect the public health and safety and the environment for this or future generations." By defining a significantly larger radiological standard after 10,000 years compared to the standard before that time, EPA demonstrate that they do not intend to provide the same protection to all generations. If the post 10,000 years standard is protective of future generations then why not apply this higher dose level and less stringent standard to all times (and to all existing nuclear facilities)? This duplicity of standards puts EPA in violation of the NWPA. (Comment 0263-4)

7. This rule would also weaken substantially the intent of the NWPA by allowing a "barrier" definition to include engineered barriers that only "decrease the mobility of radionuclides" or "substantially delays the movement of water or radionuclides." Whereas, the NWPA defines an "engineered barrier" to be a manmade component that is designed to "prevent the release of radionuclides." Thus, the language in the proposed rule again appears to work in cooperation with the theme of delayed release, and doesn't stand alone as a regulation. Being that the purpose of the standard is to protect the public and the first measure of protection is isolation of the waste by not allowing it into the accessible biosphere. Citizen Alert recommends that the barrier definition in the NWPA be retained. (Comment 0268-5)

8. Citizen Alert does not agree with the EPA's preamble opinion that the agency need only accept comments that are related to the 10,000 year compliance period. The Court of Appeals vacated the core of the standard, and thus all aspects of the standard are subject to revision. It is the EPA that decided to revise the standard despite the court allowed option to merely extend the existing standard through the period of peak dose. As such the EPA has opened the door to any comments regarding any aspect of the standard. Indeed, the proposed standard contains numerous constraints on how it is to be applied. For example: "For performance assessments conducted to show compliance with §§ 197.25(b) and 197.30, DOE's performance assessments shall exclude unlikely features, events, or processes, or sequences of events and processes." - 40 CFR 197, 49064 Federal Register / Vol. 70, No. 161. Such directives according to EPA's own interpretation of the court ruling would also be outside of the scope of revision to 40 CFR 197. The EPA doesn't seem to even remember what was written in its own preamble, and appears to be selecting portions of the rule for revision, but not allowing the public the same discretion. (Comment 0268-8)

9. In addition, material currently stored at plant sites and elsewhere pose no hazard, so incompletion of Yucca Mountain should not be considered a barrier to building new nuclear power plants. Any laws or rules stating otherwise are without substantive basis. (Comment 0269-2)

10. EPA has declared that it will not consider public comment on many aspects of the proposed regulation, which EPA discusses in its rulemaking, despite the fact that this

decision is integral to the overall radiation standard. Not only is this more shoddy science, but also it is under administrative procedure requirements; EPA must accept and respond to all comments on its proposed rule. (Comments 0293-5 and 0302-17)

11. PSR asserts that the newly proposed EPA radiation standards are extremely dangerous, unethical and illegal…Unfortunately, the EPA has developed rules that are weaker than its original standards and propose a dramatic reversal of international and U.S. public health standards for radiation protection. (Comment 0301-2)

12. EPA's proposed regulation is not based upon and consistent with the NAS recommendations regarding specifying the standard at peak risks, within the limits imposed by the long-term stability of the geologic environment. (Comment 0311.1-2)

13. The proposed standard is not in conformity with Executive Order 13045 for the protection of children because it fails to account for the disproportionate risk from radiation for exposures early in life. (Comment 0314.1-7)

14. The revised standard for the Yucca Mtn. Project is inconsistent with federal law (also international law). (Comment 0336-1)

15. The Department agrees with EPA that it is appropriate to revise only those portions of the regulations in 40 CFR Part 197 that were vacated by the Court's decision. The aspects of the rule that were not vacated are supported by a comprehensive record that includes both technical and policy considerations, including extensive public comment. There is no basis to revisit EPA regulations that were based on that record and that were not vacated by the Court's decision. (Comment 0352-1)

16. The EPA has proposed a standard that does not address the fundamental direction of the court. The NAS found that there is no scientific basis for a 10,000 year limit or any other time period for compliance. The NAS also found that in the face of uncertainty, the standard should be more protective rather than less. (Comments 0353-9 and 0361-9)

17. Last year, the U.S. Court of Appeals vacated your previous standard due to its inconsistency with federal law. I believe that this revised proposal is also inconsistent with the law and is an insult to Nevadans. (Comment 0354-1)

Response to Issue G:

Reasonable expectation is defined at 40 CFR 197.14. EPA disagrees the final rule raises Constitutional issues. To the extent that there are any Constitutional issues relevant to the Yucca Mountain regulatory scheme, these have been addressed by the D.C. Circuit in its opinion in *NEI v. EPA*. It is not clear what Commenter 0268-8 means by the "core of the standard." The D.C. Circuit opinion in NEI v. EPA vacated EPA's earlier limitation of the Part 197 individual-protection standard to 10,000 years. 373 F.3d at 1315. The scope of this rulemaking is to address that specific~~ally~~ issue and other matters directly related to it. EPA has no obligation under the APA to address or respond to comments outside the scope of this rulemaking. In response to Comment 0328-4, the Nuclear Waste Policy Act does include the definition of engineered barriers as described by the commenter. However, there are several issues that must be described for a complete answer to this comment. First, the phrase included in the definition of engineered barriers "preventing the release of radionuclides" is not specific with regard to time frames. It should be apparent that no artificially-made barrier will be permanently impermeable. That is an unrealistic assumption. Even concrete has (albeit very low) permeability. In fact, even natural materials used for containment have permeability. For example, clay liners used for containment of liquid or solid waste have permeabilities (hydraulic conductivities) on the order of 10^{-7} cm/sec. Secondly, § 801 (a) of the EnPA, which gave authority to EPA to promulgate generally applicable standards for the Yucca Mountain site, directed EPA "…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." Using this directive, it is clear that Congress also realized that the engineered barriers of a geologic repository would not remain impermeable forever. All other comments compiled above have been addressed in other sections of this document, or in the preamble to today's Final Rule.

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Section 25 Out-Of-The-Scope of the Rulemaking or Non-Comment

1. We are alarmed that the EPA is separately considering issuing overall radiation guidance from all sources (not just for the proposed Yucca Mountain repository) that would allow exposure to doses an order of magnitude higher than it has long considered protective of the public. The proposed guidance would reverse EPA's entire history and position on public protection from radiation. (Comment 0003-5)

2. There is a low-tech solution to the problem of radioactive waste storage at Yucca Mountain. Radioactive waste could be placed in stainless steel barrels, which are lined with a cage of reinforcement rods several inches from the walls and floor of the barrels. Radioactive material would be placed in the center, and would be surrounded by concrete near the sides and ends of the barrels. (Comment 0088-1)

3. EPA in coordination with CDC should begin a large scale education program for physicians and the general public into the dangers of routine medical exposure and the need to understand and limit those exposures, while also recognizing the health benefits and tradeoffs involved. (Comment 0091-4)

4. EPA also needs to work with NRC to immediately change the NRC standards to correspond to the 0.14 millirem per year general standard. Radiation workers should not be allowed to be exposed to more than 100 times the exposure of the general populace - i.e. 14 millirem per year average. (Comment 0091-5)

5. EPA should also work with NASA to reduce the exposure to astronauts which is exceptionally high. (Comment 0091-6)

6. Nevada is crying foul solely to stop construction of Yucca. Shall we allow one state out of fifty to drive public policy on this issue? While the wheels of motion are stopped by lawyers (making over $500 per hour each) to ponder time frames of 10,000 years plus, the other forty-nine states in the union are concerned about the next ten to twenty years of public health and safety. Many, many metric tons of spent nuclear fuel are haphazardly distributed across the continental US in thin metal containers directly exposed to the environment. These containers are much, much more likely to serve as a threat to the health and safety of the general public in the very near future. In this case, the ends must justify the means. A repository needs to be constructed NOW to minimize current risk. (Comment 0095-2)

7. The adopted rule should include the requirement that the disposal of all nuclear waste, currently existing and proposed to be created, shall be subject to the disposal standards protecting individuals and human intrusions equivalent to this one million year Yucca Mountain standard. The rule ought to require of nuclear weapons development and the permitting of nuclear energy facilities a demonstration of approved permits and the secured funds necessary to be able to dispose of planned waste in compliance with these proposed rules. The NRC should prioritize the licensing for DOE to construct the Yucca Mountain

repository to reduce the serious threat to the public, environment, and national security of having the current degraded and temporary waste disposal facilities. (Comment 0104-2)

8. I worked on researching dry cask storage containers in use in Wisconsin for many years and have real concerns that Alloy 22 and the design of your waste package and drip shields will work as expected. This is not a perfect world. (Comment 0105-1)

9. If more nuclear plants are built, Yucca Mt. won't hold the waste. Where will it go? Energy conservancy and renewable energy sources are ready. What is the EPA doing about that? (Comment 0105-3)

10. The real protection that EPA should be focusing on is retrievability over hundreds or even a thousand years to protect the public in the event mistakes have been made or the waste becomes valuable in the future. (Comment 0110-2)

11. Radioactive waste should never be buried underground, but should be kept above ground and constantly monitored and maintained in dry cask storage casks on concrete pads. Only in this way, can we really know that the waste is safe….You certainly have given me no good reason to accept 350 mrem p/yr at all. Predicting when the casks will fail is impossible. So this dose standard is meaningless for casks underground. Put them aboveground where we can actually monitor and know the doses over time. (Comment 0113-2)

12. How can you predict a "central tendency" and throw out doses from possible terrorism and sabotage. Certainly anything is possible, but we now know terrorists can get into places we never expected they could. Why couldn't they attack Yucca Mt.? I think it is very wrong to put all this dangerous waste in one place. Each state should take care of its own waste above ground – after all they reaped the power. Where is the human justification to expose people in transport accidents or possible terrorist attacks in transport? High doses are possible there over all the years transport will be necessary, especially if new plants are built in addition. (Comment 0113-10)

13. Costs could be enormous if something goes wrong in the repository after much of the waste is underground especially. What are your emergency plan and dose predictions for different scenarios? It's as if you expect nothing to happen after 10,000 years that could cause exposures beyond 350 mrem/yr. You've just thrown out all the high numbers and used the median. Things like Katrina in New Orleans recently do happen. To stick your head in the sand and not be prepared for them is wrong. (Comment 0113-12)

14. Yucca Mt. was supposed to depend on the site for protection, but now you are depending on the engineered container. I'd really like to see if the final cask design is even ready at this point. Is it? How has it been tested? Certainly not underground. Certainly not for long-term testing. How you can even attempt to predict peak doses from cask failure at this time in cask, drip shield, and pallet design is beyond me. (Comment 0113-14)

15. Admit clearly that it is impossible to give an acceptable standard after 10,000 years and don't specify one at all. (Comment 0113-15)

16. I do not believe that the simplification of storage... the pelletizing, the "canisters" and the concept of burying it underground away from high population centers had been logically considered. Nuclear material can never be considered waste. It must be re-cycled and re- used. Rather than flog this dead horse, revisit the potential of these materials. Only the utilization of these materials until they pass their half-lives and beyond, re-using and recirculating the materials for either power or medical application is a reasonable solution to our long term storage issues. (Comment 0115-1)

17. Please protect our country and its roads from the nationwide voyage that the waste would require to arrive at the mountain for storage, and the continuing reliance on nuclear energy that this decision would imply. (Comment 0118-2)

18. Please vote no to nuclear storage at Yucca Mountain. (Comment 0118-3)

19. I write to protest the intended use of Yucca Mountain for nuclear waste storage. We are custodians, NOT owners, ONLY custodians of the Earth. We will answer, whether on this Earth or before the Most High Himself, for our betrayal of His trust. (Comment 0123-1)

20. Transporting the nuclear waste across many states will certainly present a hazard to the health of the citizens of those states that is just as great as the dangers of a terrorist attack and would present a target for terrorists as well. (Comment 0125-2)

21. I must protest the relaxation of the mercury standards that are being put forth by the Bush Administration. (Comment 0125-3)

22. Make No Mistake! The aim of nuclear power, is to make spent fuel (nuclear waste) from which atom bombs are fabricated. Even easier, dirty bombs, and make electric rate payers absorb the high cost. Weapons are made what ever they tell you. That is why 40 sovereign countries have nuclear power. It is steam from the heat that makes electricity. We can make electricity from many non-toxic sources. Ocean wave technology, wind, solar, geothermal, etc, can be put in place of nuclear power which is not (clean) power and produces Co2 in the fuel cycle. Nuclear power has already polluted the planet! (Comment 0129-1)

23. Burial merely defers the pain. We must stop producing nuclear waste, store that which we've already created in a safe but accessible manner and dedicate a huge amount of resources into safer production and disposal (transmutation?) of the waste. (Comment – 134-3)

24. The time is long past for you to solve this problem. Do not foist off on unborn generations our own generation's failings. (Comment 0143-2)

25. I know you probably will not be able to use Yucca Mt, for nuclear waste storage if you have to abide by an acceptable cancer rate, but then maybe you should consider making acceptable the current storage areas for these wastes, and waiting until a suitable storage mechanism is developed. And you could start by quitting making this waste. (Comment 0154-2)

26. Please dissolve your Administration and send the proceeds directly to the energy companies who have coopted your activities. In this way, the stench of your croneyism will reach up into the Heavens faster and provide a meaningful reaction, and faster, too!! (Comment 0155-1)

27. I have come to the realization that yucca mountain is here to stay and there is nothing that nevadians can do about this. I do have a suggestion though--if you insist that we must store nuclear waste from other states there at the site then you should compensate nevadians for living in a toxic state. My suggestion to you is that we receive free water rights as long as we are living here, and the government should send each member of each family a monthly check to compensate them for the trouble they have to go through(medically and otherwise). There should be one stipulation—that they had to have lived in Nevada for at least 10 years prior to yucca mountain opening in order to start receiving any kind of compensation from the government. (Comment 0156-1)

28. The way they are going to bring the wastes by rail could be dangerous for all of us. (Comment 0162-2)

29. The nuclear industry is financially supported by tax money and governmental policy. It must be a moral decision that our money will go into alternative energy research and not in the furtherance of an industry that has no safe cradle to grave process. (Comment 0169-2)

30. Why, in 1987, was a site, the only site, chosen for a nuclear waste repository, after others were politically eliminated, that has active seismic occurrences and has a volcanic prehistory? (Comment 0173-4)

31. After the tragic events of September 11, 2001 there should have been a reconsideration of transportation of nuclear waste nationwide by rail, truck or barge. Terrorism, a worst case scenario is being ignored… (Comment 0173-6)

32. Nevadans should never forget that we were promised in 2000 by President Bush, sound science as the deciding factor in deciding if Yucca Mountain is safe and secure. In 2004 he, during his campaign, promised that the courts would decide. Instead we seem to be proceeding to a federal administration or congressional legislative, political decision. This is undemocratic and un-American. (Comment 0173-7)

33. EPA has adopted a framework for its long-term safety requirements for Yucca Mountain that could reasonably be applied, in the future, to the disposal of other persistently and permanently hazardous materials, in particular for shallow disposal where long-term uncertainties are very large. (Comment 0174-2)

34. It is a tragedy that this EPA hearing process limits discussion to safety standards only, when there is no safe standard that can be imposed upon this futile attempt to hide our greatest mistake. (Comment 0176-1)

35. It is a tragedy that our government has spent and continues to spend billions of dollars at Yucca Mountain digging a hole in the Earth in a vain attempt to bury the greatest mistake of the curious, precocious human family--the unleashing of the power of the atom. It is a tragedy that those same billions of dollars were not spent on developing clean, alternative energy sources or on reprocessing and neutralizing the deadly materials. It is a heartrending tragedy that we cling to our stockpile of nuclear weapons for safety, even continue research, and develop additional weapons that threaten the safety of every living thing. Don't point to nuclear medicine as justification for our greatest mistake. I am well aware that these are sweeping generalizations with no scientific referents. Nevertheless I raise the question as to the wisdom of our priorities and wonder just how much of our wealth is being directed to safe, life-enhancing scientific research in comparison to our investment in the Yucca Mountain Project and overall nuclear folly. Who is pondering the ramifications of this sweeping query? (Comment 0176-2)

36. The basic challenge is to develop a regulation that (1) results in licensing of Yucca Mountain if it is a good site and disqualification of the site if it is a poor one, (2) addresses the many and complex uncertainties in assessing performance over very long time frames, and (3) incorporates a fairly clear decision rule that all stakeholders can understand. The last two points, especially, seem to me to require a delicate balancing act. In general, a standard must be implementable. (Comment 0186-5)

37. Science fiction author Robert A. Heinlein, a former naval engineer, recommended this alternative: vitrify these high-level wastes, and then build replicas of the Great Pyramid of Cheops in Dead Sea bottoms in the Great Basin desert. These basins do not drain into any rivers or water supplies used by or usable by humans, and the vitrified wastes are not released from the vitrified blocks at a rate faster than weathering from natural uranium ores, which nature is equipped to handle. (Comment 0190-3)

38. Why is E.P.A. continuing to ask the public for their opinions when you cannot validate the radiation exposure standards set for Yucca Mountain because they are in flux? Even after 20 years and 8 to 12 billion $$$$ spent on the project there is no lynch-pin component. After 20 years a canister not only has not been selected but none can be tested with high level waste in it. All Laboratory tests have failed because pf my bugs and colloids. When will there be a plan for the mine? (Comment 0198-5)

39. Where will you get staff to monitor or work on this project? All scientific projects are in the same boat. Close up the YM Project and get back to your original and valuable projects which your agency was designed to do. Protect the public and we the "PEOPLE" wi11 appreciate your stopping this PORK PROJECT. (Comment 0198-7)

40. In a time of across the board rising energy costs why is this country sticking to outdated and DIRTY energy sources, instead of running full speed toward CLEAN renewable sources? (Comment 0199-1)

41. One of the issue which I had, I make the issue of risk assessment and complex natures. It brought to the attention of NRC and EPA no action has been done. You are required by federal regulation, federal acts, federal regulation, the curative [cumulative?] impact and the curative [cumulative] effects. And this will be -- probably will go to the Court. (Comment 0209.1-3)

42. Time and money would be better spent on research to figure out what to do with the spent fuel rather than bury it in Nevada. (Comment 0209.4-2)

43. A little background. I was injured working on the Yucca Mountain Project. The subcontractor that I was working for was Manpower of Southern Nevada. Manpower was a subcontractor to Bechtel SAIC, now known as CIC. So we've got the U.S. Department of Energy; the subcontractor is Bechtel; the subcontractor to them is Manpower of Southern Nevada. And the insurance company that is handling my workers compensation case, which is a subcontractor to Manpower is Nevada CompFirst. Now, my concern was who has responsibility for the fact that I was injured by the Yucca Mountain Project? The EPA must include health and safety standards for all persons who may be injured by the YMP including YMP workers. Lastly, it is my understanding that three specific agencies have some jurisdiction regarding YMP: The EPA, the DOE, the NRC. None of these agencies have standards which require YMP subcontractors to comply with existing and future laws – including county, city, state, and federal laws -- or face the loss of the YMP contract. This lack of standardized, zero tolerance for subcontractor law breaking in performing YMP contracts is inappropriate. The EPA must include standards which require that all YMP subcontractors found to be in violation of codes, statutes, and laws will have their contract with the YMP terminated. To avoid passing the buck for such a standard from agency to agency, all agencies -- including EPA, NRC, and DOE -- must have the same standard. (Comment 0209.8-1)

44. And I remind you that we still have no plan for transporting this deadly waste through our communities for thousands of miles. The safety of the American people along the transportation route is in jeopardy due to this moving hazard that too easily can become a moving target. (Comment 0209.15-2)

45. It's great to talk about just this piece of land that you can put it into, but how the heck are you going to get it there? That's going to effect a lot of people. And I know that you say, Well, we're not looking at that. Well, you might as well -- and if you're walking around with blinders, you better take those blinders off because that stuff may come by your house tomorrow. And then you can scream and yell just like the way I am. Then you will have a concern. But then that concern can be very easily remedied by you just moving away from that route.

That is a problem that my people have. My people, just like me, have that problem. Not just my tribe but many tribes across the country. Many tribes across the country that you will impact when you do these shipments to this wasteland. (Comment 0209.17-1)

46. I know that they speak to us because when I walk around out in the middle of the desert, which you say there's nothing out there, well, there is. There's a lot of life. I walk around in the middle of winter, and I see Bluebirds that walk along with me. I see a lot of other animals that walk along with me. I speak to the rabbits when they're out there. I speak to the rattlesnake when he's out there hissing at me. And I talk to him. He doesn't bother me because I was taught to talk to them. We spoke with each other.

These things are the things that I have to protect, and these things that I fight to protect. And I fight all of the government all the time. I fight this project because this project is not good for the animals that can't speak because you can't listen to them because they don't speak to you.

It's a wasteland to you because you do not know what's out there. You probably haven't even gotten out of your car to see what that land can give to you. You probably haven't even seen what the beauty of that land is. You probably haven't even got out of your car to see that little tiny plant, that little tiny flower with purples and yellows and whites and oranges and reds.

You've never seen those, that's why it's nothing to you. You do not hold those things as anything. Those things are in your way of what you want to do. What's in your way of what you want to do is actually me because those plants that are out there, they are a part of me. (Comment 0209.17-2)

47. I advocate leaving the waste at the power plants, where no travel is necessary, and invest in waste-processing technologies used by other nations to recycle nuclear rods. (Comment 0210.1-1)

48. I'm here on personal business that is related to atomic energy. I cannot divulge what it is, but I can tell you that, in the future, there is going to be a day…that we will be able to denature radioactivity and put it back in the ore state. For I have seen it in my mind's eye. And in that ore state, you will be able to store it in aluminum-clad paper sacks. If you drop it on the floor and bust it apart, in its denatured condition, you'll be able to take a dust pan and a broom, sweep it up, and put it in a sack. (Comment 0211.5-1)

49. And I want to tell you, when they dropped the atomic bomb on Hiroshima and Nagasaki in 1945, I was a 16-year-old. I remember that like it was yesterday. From that day down to today, 60 years later, I have yet to recall any incident in the newspapers or on television of any major nuclear accident where people got killed by the hundreds and thousands. It is not there. I'm telling you I have the utmost confidence in our energy commission…they have done a wonderful job in the last 60 years. And I highly commend you for it. (Comment 0211.5-2)

50. From the time I had my heart attack, I asked my internal medicine specialist, cardiologist, why I was in the hospital at that time. Didn't know. But he took a blood sample and realized that my metabolism was way up there. Well, what can we do about

your metabolism? So he suggested that we bring the level of the thyroid condition down since it regulates metabolism. So he gave me an Iodine 131 radioactive pill at the time rather than undergoing surgery. So I had the Iodine 131 pill to, basically, disintegrate my thyroid in 1980. And I've been taking Synthroid ever since. Since then I haven't had any further heart attacks, but I've been injected probably a dozen times with a technician for stress testing. So, again, nuclear science has an advantage to improving the life, enhancing the quality of life. And medicine is certainly one area which we see that in day-to-day activities. (Comment 0211.7-1)

51. [A]bout three weeks ago, a Nobel Laureate, presented a paper in Vienna, Austria. And he presented it concerning energy and waste. And the main emphasis was the fact was that if we, in the U.S., continue at a 20 percent nuclear generation of electricity, as we -- as we are now from the mix of fossil fuel, hydro, solar, et cetera, for the next century, we will need nine repositories. So we should consider Yucca Mountain as a prototype, basically, for the future repositories. Unless, as this gentleman indicated, we get into an accelerated decay phenomenon, which hopefully our scientists are working on in Argonne and in our national laboratories. (Comment 0211.7-3)

52. So the important thing here is that we have several options. The once-through concept that we are exercising now and at the same energy generation rate, we will need nine repositories within this century, over the next 95 years. Or if we went to a processing mode, as the French are doing, and as we did at Hanford, and we generated 57 million gallons of sludge and high-level waste, which will eventually be vitrified and go into Yucca Mountain as the 10 percent of high-level waste. So I leave you with that thought in mind. But nuclear energy or nuclear science is a -- is a great field, and it's just evolving. And so let's not stop it at Yucca Mountain, let's complete the nuclear fuel cycle. (Comment 0211.7-4)

53. Now, I want to talk to the average layman and laywoman and tell them that we have always been afraid of things that we don't know. Maybe Yucca Mountain didn't use the nuclear reactors for a good purpose before. But I'm going to give you the benefit of the doubt. Nuclear reactors can be used for electricity, which we are going to need in the next years. Like the people before me, they say France is using them. Iran says they are using it. Korea supposedly is using it for good uses. So nuclear power can be used for electricity and other good things. (Comment 0211.9-1)

54. When the gentleman who was working in the nuclear industry a moment ago said, in all likelihood, if Yucca Mountain is approved, we'll need many, many repositories within this century. What does that really mean? Doesn't this law and your certification and recommendation really give the green light to the manifestation of many, many, more nuclear reactors being built in America? Many, many, more repositories and all of the potential impacts -- granted, some positive in terms of the energy that it produces -- but more importantly, in relation to what we're discussing today, devastatingly negative consequences? (Comment 0211.10-2)

55. Remember, the scope of this also includes the transportation. I think that's very important because the standards, when they talk to human intrusion, are not limited to

human intrusion at Yucca Mountain. Anywhere along the transportation routes near the major metropolises of this country, human intrusion can underline the safety of those containers and cause a devastation unlike anything we've ever experienced. And, again, you at EPA are charged with that responsibility to ensure our safety. So please consider those factors as well. (Comment 0211.10-3)

56. And in your rule, you write about realism versus conservative assumptions when dealing with uncertainties. Well, the water patterns out there aren't terribly uncertain. And you have an excellent chance to see realistic records of this. And I can even send you the pictures if you'd like. People out there take them and send them to me. And I took some myself. (Comment 0211.11-2)

57. But remember the Bush Administration has asked that there be a shortened time for resumption of testing. It used to be three years, now it's 18 months. And I'm not sure what their plans are, but there's been talk about resumption of testing for new nuclear weapons. And I think you need to check through -- or Mr. Johnson, the head of the EPA, needs to check with his counterpart in the Cabinet about what their -- what their plans are so that there may be, in fact, cumulative doses. And would Yucca Mountain put the skids on resumed nuclear testing, or would that somehow make an impact on Yucca Mountain? (Comment 0211.11-4)

58. I just want to add that I live in Pahrump, which is not far from Yucca Mountain. And I've been in Amargosa quite often. And I have no – I haven't seen anything that is unusual. I drink the water. And I'm back in Pahrump, and I'm not so far from Yucca Mountain. I'm actually very close. (Comment 0211.12-1)

59. Further, as the new period of compliance has been introduced and the DOE has no estimate of performance over the new compliance period, the Energy Secretary must inform the President that Yucca Mountain cannot be considered suitable for a high level radioactive waste repository, i.e., the site recommendation must be rescinded. (Comment 0263-2)

60. Nuclear waste management options have been studied for years and there is no known solution better than geologic repositories. The DOE Yucca Mountain Final Environmental Impact Statement evaluated the no action alternative to Yucca Mountain and that was continued storage at existing sites. That alternative was either costly (trillions of dollars) or clearly environmentally unacceptable with multiple gross violations of accepted environmental standards. (Comment 0264-4)

61. [Competing releases of radionuclides and heavy metals from containers] have not been discussed in the Final Environmental Impact Statement at all. The health risks posed by the potential release of a fraction of this amount of heavy metals along with radionuclides must be further addressed. Recently new proposed Department of Energy canister design would double the thickness of the canister from 1" to 2" this will double the amount of heavy metals to be deposited at YMP about 300,000 to 400,00 tons. This raises several serious environmental concerns such as what is the caring capacity of the zeolite and the potential

groundwater contamination with heavy metals such as (Cr and Ni). This must be addressed to estimate potential hazards to humans. The YMP Performance Assessment did not consider competing effects of radionuclides and heavy metals why? Competitive effects are assumed to be negligible. Can the DOE provide appropriate rage scale scientific data to prove to justify their assumptions? (Comment 0270-1)

62. The authors also believe that the proposed level high nuclear waste repository at Yucca Mountain that will ultimately become a hazardous waste site (RECRA or CERCLA) due to the canisters corrosion and the large amounts of toxic heavy metals in Alloy C-22 canisters. These materials potentially could migrate into the biosphere and thus be hazardous wastes subject to the Resource and Conservation Recovery Act (RCRA) of 1976. The USEPA should have taken into consideration and accounted for all physical and chemical the poetical mechanisms for interactions of heavy metals and radionuclides in the environment in setting the new radiation standards at YMP for 100,000 years or more; as well as considering the converting of actinides (239Pu, 237Np) into lead. (Comment 0270-2)

63. Upon closure the YMP site will become a superfund site which will be subject to CERCLA because of substantial threat of release … "of any pollutant or contaminate which may present an imminent and substantial danger to public health or welfare" as defined in (42 U.S.C. § 9604). (Comment 0270-3)

64. Ultimately, the proposed high level nuclear waste repository is likely to become a mixed waste site due to the mixing of radionuclides and heavy metals from canister corrosion. This raises several legal issues including why the USDOE in the FEIS did not address this issue at all as a potential health hazard. Second, why the USEPA did approved the FEIS since there is a lack of adequate scientific data and no large scale scientific information is available to verify laboratory data. Next, why the proposed EPA standard is for YMP is solely based on background radiation standards? If it is determined that YMP is a Mixed Waste Site…dilution is prohibited as treatment for both listed and characteristic…Why did the EPA allow the DOE to use 3000 acre foot for dilution of radioactive waste at YMP when this is prohibited under current LDR regulations? What scientific proof does the USEPA have that will not become a mixed waste site? The burden of proof is on the DOE to show that the groundwater near YMP is not going to become contaminated with metals originated at YMP. So far DOE has failed to do so. Why the EPA did not incorporated the latest reports in the literature showing interaction between metals and ionizing radiation. Furthermore, why did the EPA also ignore metals genomic instability of titanium, nickel, chromium VI and depleted uranium? (Comment 0270-4)

65. What, if any, public health systems are going to be put in place in the event of contamination caused accidentally, deliberately or by unseen disaster, today or 430,000 years from now, i.e., assistance, insurance, emergency medical availability and/or immediate disaster response. What would happen if our government waited four days to respond to a massive nuclear disaster as FEMA did in New Orleans? How would citizens reach help or afford it? (Comment 0272-1)

66. Thermo alcove temperature and fluid dynamic control which incurs condensation and removal of said radioactive fluids and drum containers storage will require duron glass acid waste pipe and containment facility to valve fill and contain for transport under emergency vicarious movement and it's reaction security. (Comment 0288-1)

67. While A4NR is greatly concerned by the recently licensed "temporary" radioactive waste facility on our seismically active coastal bluffs, it is our position that sending it to an unsecure and unsafe site by means of inadequate transportation routes are not the answer. (Comment 0294-7)

68. EPA should take into consideration also the potential synergistic interactions and deleterious effects between and among radiation and the host of other contaminants that are released into the biosystem -- as they affect one another and human recipients . They are insufficiently studied and not accounted for in standards-setting . They are deemed hazardous individually; their combined additional adverse effects on human well-being must be understood and taken into consideration. (Comment 0331-6)

69. I am writing in opposition to your proposal to reduce reporting requirements for industries that release toxic chemicals. (Comment 0334-1)

70. with respect to the specific questions posed by EPA on elements of the proposed standard (*e.g.*, median vs. mean; treatment of features, events, and processes; Reasonably Maximally Exposed Individual) Duke endorses the comments provided by NEI on the behalf of the nuclear industry. (Comment 340-3)

71. If EPA retains numerical criteria of any magnitude for the post 10,000 year period, EPA should further address the uncertainty aspects of using such a value in NRC adjudicatory regulatory proceedings. (Comment 351-3)

72. At the public meeting in Las Vegas, EPA provided some material to explain to the public the relationship of 350 millirems in relation to a chest x-ray, average dose from household radon, and other benchmarks. According to the EPA the least exposure is one (1) millirem per year, for people living near nuclear power plants. For years in Nevada we've been told that we have to accept the repository because it will be "safe" and that we have to assume the risk for the rest of the country because the waste isn't safe at nuclear power plants and communities are threatened. The chart provided by EPA indicates to us that one of the safest places to be is next to a nuclear power plant, which begs the question as to why it is necessary to transport this deadly waste to Nevada and expose current and future Nevadans to risks that are greater than those assumed by the rest of the country. (Comments 0353-7 and 0361-7)

73. Since 1970 the U.S. has not been able to meet its own demand for oil. In fact, no nation can continue much longer to meet its demand on its oil. Remaining oil needs to be conserved for its chemical usage, or else the plastic industry and many other industries will soon be ended. Nuclear-hydrogen needs to be developed ASAP. But before this can happen our 300-year solution for SNF needs to be operating. In the mid-1980s the congress

created the office of the "Nuclear Waste Negotiators." David Leroy, current National Academy of Science Chairman was the first negotiator, under President Bush Sr., next was Idaho Congressman Richard Stallings, now one of our board advisors. He was the second Negotiator, under President Clinton. Two proposals resulted, one from Goshute Indian Chief Leon Bear, for the PFS site in Tooele County, and a second for my Pigeon Spur site in Box Elder County. (Comment 0356.1-1)

74. For twenty years the Congress has attempted to get alleviation of SNF for our nation's 103 operating nuclear utilities. Uranium is mined in the central hub of the west. Solutions for the fuel's remnant (SNF) have logically been sought near the fuel source. For twenty years Utah has fought all of Congress's proposed solutions. Unfortunately Utah's arguments have been all political by a few politicians seeking public attention to obtain office. (Comment 0356.1-2)

75. Nearly 40 states have SNF stored with their nuclear power utilities who need an SNF solution just to continue getting their power. They all need nuclear-hydrogen and the truth about SNF is that SNF has harmed no one. SNF is 97% potential fuel that will be used eventually to power our nation. (Comment 0356.1-4)

76. EPA Director Mike Leavitt was wrong for not endorsing and helping nuclear energy. This is reflected in the new White House Report on Energy for the 21st Century. Fuel for end-of-oil, slowing global warming, economics of trade, sharing oil with the rest of the world, and even world peace are at stake if the U.S. does not quickly develop nuclear-hydrogen, which development waits for the SNF disposal solution held in Utah. (Comment 0356.1-5)

77. Intermediate storage of SNF "aging storage" is required. The only potential solution the Congress now has is Yucca Mountain, and the Congress is not going to change the 1982 law and put both intermediate storage and permanent geological disposal in Nevada. The Congress must make its present options work, including the PFS project in Tooele County and aging storage and SNF reprocessing according to the 300-year SNF disposal solution. (Comment 0356.1-6)

78. INL, Argonne, and DOE chemists now agree 5 9s (99.999%) separation of the transuranics in SNF from the fission wastes is possible. This is a "new source" for new fuel. Then in 300-years the 30-year half life cesium and strontium (hot stuff) will decay 1,000 fold and fission wastes will qualify for low level Class-C. So in 300 years no high level wastes remain and the SNF is disposed of. Our protective design for near surface, still convective air-cooled, storage eliminates the heat-unloading requirement for Yucca Mountain. Only a small fraction of the original SNF would ever need to go to Yucca so its usefulness would be greatly extended. We need to get the 300-year storage of SNF being done ASAP to pave the way for the building of 2400 new nuclear power plants for manufacturing hydrogen and U.S. growth. (Comment 0356.1-7)

79. What is the "worst case release" for the facility? (Comment 0367.1-1)

80. What was the background in Carlsbad prior to WIPP and what they are now? (With WIPP in operation?) (Comment 0367.1-9)

81. DOE must provide credible science evidence that it can be met such that Yucca does not create unacceptable doses. (Comment 0367.1-18)

82. Doorman at the Waldorf Astoria gets a higher dose than rad worker from granite. (Comment 0367.1-24)

83. What is acceptable incidence of disease/sickness from lead, asbestos? (Comment 0367.2-4)

84. Why aren't workers treated as members of the public? (Comment 0367.2-7)

85. Why can't we have a rule that any subs in violation of standards lose their contract? (Comment 0367.2-8)

86. The safest item on the list is living next to a nuclear power plant, so why are we moving waste from there? (Comment 0367.2-9)

87. The Shoshone do not want to accept money to agree to accept nuclear waste on their traditional lands. Waste should be buried at the location where it originated. (Comment 0367.2-10)

88. It's clear that the public comments don't matter, since the NRC is already writing their standards based on EPA's "proposed" standards. (Comment 0367.2-12)

89. Sound science and protecting public health are not synonymous with Bush administration. (Comment 0367.2-14)

90. Nevada says no. This similar to tobacco industry, who said tobacco was safe. (Comment 0367.2-15)

91. It is not fair that Utah got rid of its plans for nuclear waste, but NV can't. (Comment 0367.2-17)

92. The land needs to be kept as clean and healthy as possible – you can't fix it if it's damaged. (Comment 0367.2-20)

93. Many people who will be injured by the Yucca Mountain Project will not be able to fight for their rights. (Comment 0367.2-21)

94. Workers or subcontractors on the project should be protected like the public. (Comment 0367.2-22)

95. If subcontractors violate codes of conduct they should automatically lose their contracts. (Comment 0367.2-23)

96. I'm very glad that the EPA has embraced the idea of limiting the peak dose from a high-level waste repository. That's very important. (Comment 0368.3-1)

Response to Section 25:

EPA appreciates the public concern about these issues. They are, however, not a part of this specific rulemaking. As we noted in the preamble to the proposed standards (70 FR 49022), we are considering comments only on the standards that were affected by the July 2004 ruling of the U.S. Court of Appeals for the District of Columbia Circuit.