



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 4, 2000

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: Dennis K. Rathbun, Director
Office of Congressional Affairs

SUBJECT: EPA RESPONSES TO QUESTIONS FOR RECORD OF JUNE 23,
2000, HOUSE COMMERCE HEARING ON YUCCA MOUNTAIN

The House Commerce Committee's Subcommittee on Energy and Power has released the Environmental Protection Agency's (EPA) responses to follow-up questions for the record of the June 23, 2000, hearing on the status of the Department of Energy's program to develop a high-level radioactive waste repository at Yucca Mountain, NV. A copy of the responses is attached. NRC provided its responses to follow-up questions on August 28, 2000.

Attachment:
As stated

cc: OEDO
OGC
OGC (Cyr)
NMSS
RES
NRR
OPA
SECY
OIG
ACNW
OCIO
OCFO
OCAA

Contact: Tom Combs, 415-1776



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 18 2000

OFFICE OF
AIR AND RADIATION

The Honorable Joe Barton
Chairman
Subcommittee on Energy and Power
Committee on Commerce
U. S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed for insertion into the hearing record are the U.S. Environmental Protection Agency's (EPA) responses to follow-up questions submitted by Members of the Subcommittee from the June 23, 2000, hearing on the status of the Department of Energy's program to develop a permanent geologic repository at Yucca Mountain, Nevada, for spent nuclear fuel and high-level radioactive waste before the Subcommittee on Energy and Power. I hope this information will be useful to you and Members of the Subcommittee.

Thank you for providing EPA the opportunity to testify on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen D. Page", is written over a large, faint circular stamp or watermark.

Stephen D. Page, Director
Office of Radiation and Indoor Air

Enclosure



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**EPA Responses to Follow-up Questions
from June 26, 2000 Hearing on Yucca Mountain
Subcommittee on Energy and Power**

- 1. EPA has already proposed an individual protection standard to protect human health. Is a separate groundwater standard also necessary to protect human health, or is the purpose of the groundwater standard to protect groundwater as a resource?**

The purpose of the ground water standard is to protect groundwater as a resource. Ground water is one of our nation's most precious resources because of its many uses. This is especially true in the vicinity of Yucca Mountain, where ground water is currently used as drinking water, as a resource to support a diverse agricultural economy, and as an ecological habitat supporting sensitive ecosystems. The Agency is protecting ground water at Yucca Mountain to protect the significant ground water resource in the vicinity of Yucca Mountain.

- 2. The Department of Energy, the Nuclear Regulatory Commission, and the National Academy's Board on Radioactive Waste Management have each stated that they do not support a separate groundwater protection standard for the Yucca Mountain repository. How does the EPA justify a separate groundwater standard in light of the criticisms from these other technical experts?**

Our differences with DOE, NRC and NAS, regarding ground water protection, are based on policy, not science. The NAS has even commented that, under the Energy Policy Act, EPA has the authority to set a separate ground water standard as a matter of policy. EPA's proposal (64 FR 46976, August 27, 1999) included separate ground water protection standards to protect the significant ground water resources around Yucca Mountain. We proposed these ground water protection standards to be consistent with EPA's mission and long-standing Agency policy, as discussed further in response to questions 5 and 13 below.

- 3. Apparently, EPA's proposed 4 mrem ground water standard is derived from the Maximum Contaminant Levels established under the Safe Drinking Water Act. To quote the Board on Radioactive Waste Management, EPA is basing this ground water standard "on a 25-year old regulation which in turn is based on 40-year old dosimetry."**

(a) Please explain how EPA has used the best available science when it has relied on an old standard based on even older science.

We based our MCLs on the best scientific knowledge regarding the relationship between radiation exposure and risk that existed in 1975 when we developed the MCLs. Scientific

understanding has evolved since 1975. We are working to update the existing MCLs based on a number of factors, including the current understanding of the risk of developing a fatal cancer from exposure to radiation; pertinent risk management factors (such as information about treatment technologies and analytical methods); and applicable statutory requirements.

(b) Where is EPA in the process of updating the Safe Drinking Water MCLs for radionuclides? Will those updates be incorporated into the final rule for Yucca Mountain? If not, why not?

EPA is planning to update the MCLs for radionuclides. It is unlikely that the MCLs will be revised at the time EPA issues a final Yucca Mountain standard. If EPA's final standard for Yucca Mountain contains a ground water protection standard, the standard will incorporate the MCLs that are in effect at the time. If the MCLs are revised after the standard is finalized, EPA could amend the final rule to include the updated MCLs.

(c) Does the EPA intend to issue a final rule for Yucca Mountain incorporating a groundwater protection standard that it acknowledges is based on old science? If so, what is the reason for such a decision?

EPA is in the process of finalizing the standards for Yucca Mountain and therefore cannot speak to the specifics of the final rule. However, if EPA finalizes a standard for ground water protection, EPA will fully explain the rationale for this decision. EPA has received comments that are concerned with the science behind the SDWA MCLs, therefore EPA will be fully responding to these comments in the Response to Comments document that will accompany the final rule.

4. What is the scientific basis for the old Safe Drinking Water MCLs? Please provide the Committee with the technical foundation that supports the selection of the original 4 millirem standard.

The MCL was set at a *uniform dose* of 4 mrem to the whole body or the critical organ for any nuclide or combination of nuclides. This necessarily resulted in a range of health *risks* because a combination of nuclides resulting in 4 mrem dose does not produce the same effects on all parts of the body. It depends on the nuclides involved. Two nuclides at 4 mrem dose do not produce the same effects. This is not arbitrary or capricious, it is a function of radiobiology.

Different ingested nuclides emit radiation of various energies, and produce doses to nearby tissues, are transported to various locations in the body or are excreted, decay to other elements, and the process results in various risks of cancer in the body depending on the tissue affected. Had EPA regulated on the basis of uniform risk, it would mean there will be a different picoCuries, and doses to different organs. Uniform picoCurie concentrations means different doses and different risks. Concentration, dose, and risk are

not simply interchangeable. The practical expression of the 4 mrem dose limit selected was in concentration (picoCurie) units that are measurable in the water. Each beta/photon emitter had an associated picoCurie concentration associated with 4 mrem.

How the current standard is arrived at is less important now, twenty five years later, than the fact that the standard is currently providing a level of protection which legally must be maintained, or increased with the aid of better science.

5. **DOE commented last fall that the EPA is not properly applying the Maximum Contaminant Levels (MCLs) from the Safe Drinking Water Act, which were designed to apply at the tap and after treatment. Instead, EPA seems to be proposing that this 4 millirem standard apply at the groundwater source, in the aquifer. Please explain EPA's rationale for applying the MCLs from the Safe Drinking Water Act to water in the aquifer, before treatment. Is this a policy decision or a science-based decision?**

EPA first published a ground water protection strategy in 1984 and it advised protecting ground water according to its use, value and vulnerability. Although this was a valuable first step, more specific guidance was needed. In 1991, EPA developed a more comprehensive ground water protection strategy ("Protecting the Nation's Ground Water: EPA's Strategy for the 1990s," 21Z-1020, July 1991) to guide Agency programs where contamination of ground water is of concern. Among other things, this strategy presents a clear statement of policy, emphasizes pollution prevention, and clearly identifies Federal and State roles. This strategy was developed based on significant input from State and local governments, other Federal agencies, environmentalists, industry, and public interest groups, among others. The resulting Strategy has guided the course of EPA and State efforts with a clear priority on preventing ground water contamination.

A significant inventory of long-lived radioactive materials may be disposed in a deep geologic repository directly over aquifers presently supplying ground water resources to populations in the vicinity of Yucca Mountain. Part D (Agency Policy on EPA's Use of Quality Standards in Ground-Water Prevention and Remediation Activities) of the Agency's strategy referenced above clearly indicates that in the case of pollution prevention, allowing contamination of the ground water that is a source of drinking water to equal or exceed the appropriate MCLs would be a failure of prevention. Should this situation occur, future generations will have to decide whether to forego use of the ground water resource or to expend resources to clean up contaminated ground water. This would violate one of the primary principles in radioactive waste management, accepted nationally and internationally, that radioactive waste disposal should place no undue burdens upon future generations. (See, for example, Principle 4: Protection of Future Generations in the IAEA's "The Principles of Radioactive Waste Management, Safety Series No. 111-F", 1995).

6. (a) Has EPA evaluated the background level of radioactivity at the Yucca Mountain site?

Yes, the Agency has examined available information on the background levels of radioactivity in ground waters downgradient of the repository site and in ambient air quality information around the site, and we have examined data concerning radiation exposures around the Nevada Test Site. We are also aware of estimates of background radiation levels for the general population around the Nevada Test Site (see below).

(b) How does the 15 millirem all-pathways individual protection standard compare to the background level of radioactivity at the Yucca Mountain site?

The 15 mrem/yr individual protection limit is not tied to ambient background levels, but rather to a consideration of minimizing additional exposures above background levels from these "practices". Potential doses from a waste repository cannot be considered as part of the ambient background, but rather an exposure from the "practice" of waste disposal. The international consensus on radiation protection, as reflected by the positions of national and international expert groups (see the NAS Report, pg. 40), is that exposures to members of the public from all "practices" should be limited to 100 mrem/yr, with any specific practice expected to contribute only a portion of the recommended limit. Radiation exposure limits both in the United States and abroad share that fundamental approach. The 15 mrem/yr standard is consistent with the NAS recommended risk level for the repository (see the preamble to the proposed rule), and is consistent with other Agency applications for waste disposal. This 15 mrem/yr standard is also particularly appropriate for residents around the Test Site since they could also be exposed to radiation from the past and present activities at the site (such as radionuclides entering ground waters from the hundreds of underground nuclear detonations at the site and eventually migrating off the Test Site and into ground waters outside the site). Table 8-55 of DOE's Draft Environmental Impact Statement lists sources of radiation exposure from activities on the Nevada Test Site, including waste disposal operations such as the Greater Confinement Disposal facility.

(c) How does the proposed 4 millirem ground water protection standard compare to the background level of radioactivity at the Yucca Mountain site?

As discussed above, the 4 mrem limit applies to man-made radionuclides only and does not include natural beta/photon emitters, and therefore has no relation to background levels of naturally occurring beta/photon emitters in ground waters at Yucca Mountain.

(d) How do the 15 all-pathways and 4 millirem ground water standards compare to background radiation levels throughout Nevada?

See previous responses.

(e) How do the proposed standards compare to the national average, and to levels in populated areas such as Denver, CO?

Once again, the Yucca Mountain radiation protection standards are not tied to background levels, but rather to the principle of determining the acceptable exposure levels above background from “practices” that result in radiation exposures, i.e., to the widely accepted 100 mrem/yr limit for the sum of all “practices”. This approach of minimizing exposures from any and all “practices” is a cornerstone of all radiation protection standards accepted nationally and internationally.

7. Does the rest of the country, from public drinking water systems to hazardous waste disposal sites to mine sites, meet this 4 mrem ground water standard? In other words, is this standard applied uniformly for all facilities in all parts of the country?

It should be clarified at the outset that the standards are set for drinking water under the authority of the SDWA. Their application in cleanup situations is a result of CERCLA. Section 121(d) of CERCLA requires the attainment of the maximum contamination level goals (MCLGs) and drinking water standards (e.g., MCLs) under SDWA when relevant and appropriate. The National Contingency Plan (NCP) (40 CFR 300.430(e)(2)(I)(B)) clarifies that MCLs or non-zero MCLGs established under SDWA will typically be considered relevant and appropriate cleanup levels for ground waters that are a current or potential source of drinking water. In addition states, rely on the Underground Injection Control (UIC) program and Comprehensive State Ground Water Protection Program to protect ground water.

8. There is apparently some flexibility in the “point of compliance” where the groundwater standard must be met. EPA has proposed four possible points of compliance in the draft rule: 5 kilometers from the repository, 18 km, 20 km, and 30 km.

(a) What is the significance of these different compliance points?

(b) What is the population center at each of these proposed distances from the repository site?

EPA has proposed four different compliance points for public comment. EPA chose these alternatives to provide a range of possible options for consideration in light of various site-specific factors such as: (i) geologic conditions; (ii) hydrologic conditions; (iii) historical record of water use; (iv) likelihood of future drilling for water or other resources; (v) depth to groundwater; (vi) soil conditions; (vii) presence of existing communities; and (viii) patterns of water use of existing communities in the greater Amargosa Valley area.

It should be noted that in the proposal, EPA proposed two conceptually different types of points of compliance for the groundwater standard. EPA solicited comments on two alternatives based upon a "controlled area" approach that contemplate specific geographic areas that would have specifically designated boundaries on all sides. These were Alternative 1 (a controlled area 5 km from the repository footprint in all directions) and Alternative 4 (a controlled area that combines 5 km from the repository to the north and west, but allows a larger unspecified area within the existing Nevada Test Site to the east and south, not to exceed the southwest corner of the Nevada Test Site 18km from the repository in the direction of Lathrop Wells). This location is significant because it represents the farthest southern boundary of federally controlled land in the direction of the predicted repository releases. EPA also solicited comments on two alternatives based upon a modified approach that would require compliance at a specific geographic location, instead of along all boundaries of a designated controlled area. These were Alternative 2 (a point 20 km from the repository at the northern edge of Lathrop Wells) and Alternative 3 (a point to be chosen by DOE within a geographic area 30 km from the repository in the vicinity of Lathrop Wells).

The current population at each of these locations for the alternatives proposed by EPA is as follows. At 5 kilometers from the repository, there is currently no population center. The repository and much of the surrounding area is restricted federal land and people currently do not reside there. Under the so-called 18 km alternative, EPA has likewise proposed a controlled area that would not include any current population center because the area would encompass land that is presently federal land with restricted access.

The 20 km and 30 km alternatives proposed by EPA would use a specific geographic point as the place at which DOE will demonstrate compliance with the groundwater standard in the licensing process. The 20 km point of compliance would be at the northern edge of Lathrop Wells which has a current population of approximately 10-15 permanent residents. This population center is a community that has grown up around businesses located at the crossing of two major roads. Local government projections indicate that the population in this area of Lathrop Wells may expand to approximately 150 people in the relatively near future. The 30 km point of compliance would be in the middle of an area with a current population of approximately 1200 permanent residents. This population is not located in a densely inhabited population center, but rather spread across a larger, less densely populated, area more typical of rural residential communities.

9. **The proposed individual protection standard of 15 millirem apparently translates to an annual cancer risk of 7 in 1 million, which falls within the risk range recommended by the National Academy.**

- (a) **What is the annual risk of fatal cancer that is associated with the 4 millirem groundwater standard?**

In 1976 EPA's "reasonable estimate" of the fatal cancer risk associated with lifetime ingestion of drinking water at the beta/photon MCL of 4 mrem/year was about 1 per million per year (see page 132, Appendix B, "National Interim Primary Drinking Water Regulations," EPA-570/9-76-003). This estimate was based on the 1972 National Academy of Sciences report which presented two different risk projection models and a range of individual fatal cancer risks, from 0.4 to 2 per million per year. EPA stated that the risks would be proportionately smaller for ingestion of water containing lesser amounts of radioactivity or for partial body irradiation.

EPA now estimates the fatal cancer risk at the MCL to be about 2 per million per year, based on its current risk models.

(b) Is that risk the same for all radionuclides? Please explain fully.

No, the risk is not the same for all radionuclides because the beta/photon MCL is based on a dose limit, not a uniform risk limit. Specifically, the MCL limits the *critical organ dose* from ingested beta/photon emitters to 4 mrem/y. For many radionuclides, this type of dose limit leads to non-uniform, partial body irradiation and variable cancer risks.

For partial body irradiation, which is not uncommon for ingested radionuclides since the radioactivity may be largely concentrated in a particular organ or group of organs, the estimated risk is somewhat less than for total body exposure where all the organs are irradiated. [p. 132]

For example, I-129 concentrates predominately in one organ, the thyroid gland, whereas tritium (H-3) distributes fairly uniformly throughout the body. In the case of I-129, the thyroid gland is the designated critical organ, and the derived activity concentration corresponding to the 4 mrem/y limit is 1 pCi/L (see Table IV-2A in EPA-570/9-76-003). For H-3, the total body is the critical organ, and the derived activity concentration at the MCL is 20,000 pCi/L. The table below presents EPA's current estimates of the individual lifetime excess fatal and total cancer risks associated with ingestion of these I-129 and H-3 activity concentrations, assuming a drinking water intake rate of 2 liter/day, 365 d/y, for 70 y, and using radionuclide-specific mortality and morbidity coefficients from Federal Guidance Report No. 13 (EPA 402-R-99-001, September 1999).

Table of EPA estimates of the annual and lifetime fatal cancer risks associated with ingestion of I-129 and H-3 at activity concentrations corresponding to the 4 mrem/y beta/photon MCL.

Isotope	MCL (pCi/L)	Lifetime Excess Fatal Cancer Risk	Lifetime Excess Total Cancer Risk
I-129	1	8×10^{-7}	8×10^{-6}
H-3	20,000	4×10^{-5}	5×10^{-5}

10. I understand that one of the first radionuclides that could be released from the repository would be iodine-129. What is the health risk associated with a 4 millirem dose from iodine-129.

See response to question 9(b).

11. You mentioned that these same ground water standards were applied at the Waste Isolation Pilot Plant (WIPP) in New Mexico. Please explain the relevance of applying a drinking water standard to WIPP, given that the water in the vicinity of those salt deposits is not potable.

EPA developed a generic standard for the management and disposal of high-level and transuranic radioactive waste (40 CFR part 191), which include separate ground water protection provisions. These standards apply to any and all deep geologic disposal facilities, except Yucca Mountain. EPA was directed by the WIPP Land Withdrawal Act to certify, by informal rulemaking, whether the WIPP will comply with the waste disposal regulations at 40 CFR Part 191.

12. Mr. Page mentioned in his written testimony that EPA is protecting the ground water resource as a matter of policy. In fact, he referenced a formal Agency policy of protecting ground water which dates back to 1990. Did EPA follow the notice-and-comment rulemaking procedures under the Administrative Procedures Act when it adopted this policy? Does this policy have any legal-binding effect?

In 1984, the EPA issued a ground water protection strategy. Later in the decade, EPA established a ground water task force to address comprehensive protection of the ground water resource. Extensive input was provided by state and local governments, other Federal agencies, environmentalists, industry and public interest groups in developing the published policy report ("Protecting the Nation's Ground Water: EPA's Strategy for the 1990s"). EPA did not use APA, notice-and-comment rulemaking to develop this policy. This policy led to development of Comprehensive State Ground Water Protection Programs.

13. In the 1991 document, "Protecting the Nation's Ground Water: EPA's Strategy for the 1990s," EPA states that it "*will also consider the use, value, and vulnerability of the resource, as well as social and economic values.*" Which of these factors did EPA consider before proposing to apply the 1976 Safe Drinking Water Act MCLs to Yucca Mountain, and where is that consideration to be found in the record for the rulemaking?

EPA's 1991 ground water protection strategy ("Protecting the Nation's Ground Water:

EPA's Strategy for the 1990s,") advises consideration of the use, value, vulnerability of the resource, as well as social and economic values. Part D of the Strategy, for example, advises the use of the Maximum Contaminant Levels under the Safe Drinking Water Act as "reference points" for water resource protection efforts when the ground water in question is a potential source of drinking water.

14. **How is the separate groundwater standard consistent with the direction of the 1992 Energy Policy Act that the Yucca Mountain standards prescribing the maximum annual effective dose to individual members of the public "*shall be the only such standards applicable to the Yucca Mountain site?*"**

Section §801(a) of the EnPA directs EPA to promulgate "public health and safety standards for the protection of the public from releases from radioactive materials stored or disposed of in the Yucca Mountain site." The provision includes two express instructions to the Agency: (i) that the standards "shall prescribe the maximum annual effective dose equivalent to individual members of the public" from the waste in the repository; and (ii) that the standards shall be "based upon and consistent with" the findings and recommendations of the NAS.

EPA interprets this provision as authority to develop the standards that the Agency, in its technical and policy judgment, considers necessary and appropriate to protect the public and ground water resources from exposure to the waste in the repository. EPA believes that it has promulgated standards that comply with the two requirements of the statute. EPA's proposed individual protection standard does include a [maximum annual effective dose equivalent] to individuals. EPA's proposed regulations are also based upon and consistent with the NAS findings and recommendations.

15. **The Conference Report accompanying the 1992 Act read as follows: "*The Conferees did not intend for the National Academy of Sciences, in making its recommendations, to establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards.*" The national Academy was not intended to usurp EPA's rulemaking authority. On the other hand, the direction to EPA is very clear in the 1992 law – the EPA Administrator is to set generally applicable standards for the Yucca Mountain site "based on and consistent with the findings and recommendations of the National Academy of Sciences."**

- (a) **That does not say, as Mr. Page suggested in written testimony, that "EPA was to consider technical recommendations from the National Academy of Sciences." The law says "based upon and consistent with." Yet, at least in part, EPA's proposed standard is not based on and consistent with the National Academy's recommendations. How does EPA justify deviating**

from the legislative mandate of the 1992 Act?

EPA does not believe that the language of Section 801(a)(2) mandates that EPA promulgate a standard that effectively codifies, unchanged, the recommendations of the National Academy of Sciences panel. Rather, EPA believes that the actual intent of Congress was explicitly set forth in the Conference Report that accompanied the Energy Policy Act. In that report, the Conference Committee stated quite clearly that the role of the NAS panel was to provide "expert scientific guidance," but that Section 801 is not intended to limit EPA's discretion in the exercise of its regulatory authority:

"The Conferees do not intend for the National Academy of Sciences, in making its recommendations, to establish specific standards for protection of the public but rather to provide expert scientific guidance on the issues involved in establishing those standards. Under the provisions of section 801, the authority and responsibility to establish the standards, pursuant to rulemaking, would remain with the Administrator, as is the case under existing law. The provisions of section 801 are not intended to limit the Administrator's discretion in the exercise of his authority related to public health and safety issues." (H.R. Rep. No. 1018, 102nd Cong., 2d Sess. 391 (1992)).

Moreover, EPA's interpretation of the EnPA as not limiting the Agency's regulatory authority in this rulemaking is consistent with the views EPA expressed to Congress during deliberations over the legislation. The Chairman of the Senate Subcommittee on Nuclear Regulation requested EPA's views of the bill reported out of conference. The Deputy Administrator of EPA indicated that the NAS Report would provide helpful input. The Deputy Administrator pointed to the language, cited above, stating the intent of the conferees not to limit our rulemaking discretion, and assured Congress that any standards for radioactive materials that we ultimately issue would be the subject of public comment and involvement. (138 Cong. Rec. S33,955 (daily ed. October 8, 1992)).

EPA's interpretation also is consistent with the role that both NAS and Congress understood NAS would fulfill. During the Congressional deliberations over the legislation, NAS informed Congress that while it would conduct the study, it would not assume a standard-setting role because that is properly the responsibility of government officials. (138 Cong. Rec. S33,953 (October 8, 1992)). Therefore, EPA does not believe that its proposal deviated in any respect from the legislative mandate of the EnPA.

- (b) The National Academy did not define specific standards that EPA must follow, but it did recommend certain methodologies and risk levels that are based on sound science. EPA has chosen to deviate from those National Academy recommendations. That now places a greater burden on EPA to convince the Congress and the public that EPA does, in fact, have a sound scientific basis for the standards it**

proposed. What does EPA intend to do between now and the time it plans to issue a final rule that will demonstrate that there is a sound scientific basis for EPA's proposed radiation standards?

Firstly, EPA's proposed standard is mostly consistent with the NAS recommendations or the intent of the recommendations. For example, although the NAS recommended a risk based standard, EPA's dose based standard of 15 mrem falls within the NAS recommended risk range. The NAS also stated that EPA's RMEI is broadly consistent with their recommendations and that we followed their recommendations on human intrusion very closely.

As a matter of routine procedure in Agency rulemakings, a number of supporting documents are prepared to accompany a final rule which will document the information and rationales for the Agency's decisions. There are four major supporting documents as described below.

- A lengthy preamble is published in the Federal Register along with the final rule regulatory language, i.e., the standard itself. The preamble explains the reasons for the Agency's decisions on the form and content of the rule itself. The preamble discusses the technical, scientific and policy considerations that were used in making decisions and the most salient points raised in the public comment.
- A Background Information Document (BID) is also being prepared. The BID serves as a resource to document much of the factual information we used in developing the standard. The BID is effectively a technical reference focused around the substantive information used to address rulemaking issues.
- The Response to Comments Document (RCD) contains detailed responses to all the comments we received during the public review period for the proposed standard. This document is a major resource for in-depth discussion of specific issues involved in the final standard.
- The Economic Impact Analysis (EIA), which will present our analysis of the economic impact of the rulemaking on the repository program.
- In addition to these four major sources for explanation of the rule's form and content, we have established a public docket for the rulemaking (EPA Air Docket # A-95-12) which contains copies of other documents used in developing the rule, including such items as studies to address specific regulatory issues (such as comparisons of potential dose receptor alternatives for the site). These reports and publications in the docket are also referenced in the four major support documents described above and the docket serves as a reference library for the rulemaking.

In developing the standards we gave very serious consideration to the recommendations of the NAS, and where we chose not to adopt specific aspects of their recommendations (as given in the NAS report, "Technical Bases for the Yucca Mountain Standards") we are developing discussions of the rationales we used in making these decisions for presentation in the rule preamble and the RCD. As the NAS recognized in its

recommendations, many of the decisions necessary in this rulemaking involve both scientific and policy questions and considerations. The NAS Report also stated in many places that the Agency might elect not to follow the panel's recommendations exactly because of policy considerations or other reasons. The documents we are preparing will present the total explanation of the scientific and policy considerations that will determine the form and content of the final rule.

16. The National Academy recommended that EPA adopt a risk based standard for the protection of individuals, yet EPA proposed a dose based standard. While the 1992 Act directed EPA to "*prescribe the maximum annual effective dose equivalent to individual members of the public,*" that statutory language could be interpreted merely to dictate the final form of the standard, and certainly does not prevent EPA from using risk, as the National Academy recommended, to derive a final dose equivalent.

(a) Is EPA, in fact, using a risk level to determine the final dose?

(b) If so, why doesn't EPA follow the recommendation of the National Academy and present the standard in terms of risk with a derived value of dose? Please explain fully.

Yes, EPA did use the level of risk of fatal cancer from exposure to radiation in order to select the appropriate dose for the individual protection standard. Moreover, EPA did select a risk level within the range recommended by NAS and translated that into the corresponding dose. In accordance with the statute, EPA expressed the individual protection standard in terms of maximum annual effective dose.

17. Mr. Page's testimony at page 3 refers to technical discussions regarding environmental protection standards for Yucca Mountain held between EPA and NAS, DOE, NRC, OMB and OSTP during the period between 1995 and 1999. Please list the date and substance of each technical or policy discussion held between EPA and these other entities and identify all participants in those discussions.

Date	Participants	Subject
6/22/98	EPA: Larry Weinstock, Frank Marcinowski OSTP: Art Bienenstock, Beverly Hartline, Fran Sharples, Martin Offutt, Gerald Kiernan, Elaine Podovani DOE: Lake Barrett, Alan Brownstein NRC: Malcolm Knapp, Michael Bell OMB: John Pfeiffer	Draft Standard

6/29/98	<p>EPA: Larry Weinstock, Frank Marcinowski, Al Colli, Ken Czyscinski</p> <p>OSTP: Art Bienenstock, Beverly Hartline, Martin Offutt, Elaine Podovani</p> <p>DOE: Lake Barrett, Alan Brownstein, Abraham Van Luik</p> <p>NRC: John Greeves, Michael Bell, Tim McCartin</p> <p>LANL: Bruce Robinson</p>	Ground water, modeling, reasonable expectation
7/14/98	<p>EPA: Larry Weinstock, Frank Marcinowski, Al Colli, Ken Czyscinski, Brian Littleton</p> <p>DOE: Alan Brownstein, Steve Brocum, Abraham Van Luik, Wendy Dixon</p> <p>NRC: Michael Bell, Tim McCartin, Keith McConnell</p> <p>USGS: Dwight Hoxie</p> <p>DOE Contractors</p>	Ground water, individual protection
7/28/98	<p>EPA: Larry Weinstock, Frank Marcinowski, Al Colli</p> <p>OSTP: Art Bienenstock, Beverly Hartline, Fran Sharples, Martin Offutt, Gerald Kiernan, Elaine Podovani</p> <p>DOE: Lake Barrett, Alan Brownstein, Steve Brocum</p> <p>NRC: Malcolm Knapp, Michael Bell, Tim McCartin</p>	NAS recommendations on risk range, critical group, compliance period, human intrusion
9/25/98	<p>EPA: Larry Weinstock, Frank Marcinowski, Al Colli, Ken Czyscinski, Bill Diamond, Phil Metzger</p> <p>OSTP: Art Bienenstock, Beverly Hartline, Fran Sharples, Martin Offutt, Gerald Kiernan, Elaine Podovani</p> <p>DOE: Lake Barrett, Alan Brownstein, Steve Brocum</p> <p>NRC: Carl Paperiello, Michael Bell, Tim McCartin</p>	Ground water standard, reasonably maximally exposed individual
10/1/98	<p>EPA: Frank Marcinowski, Al Colli, Ken Czyscinski, Ray Clark, Wendy Melgin, Phil Berger</p> <p>OSTP: Beverly Hartline</p> <p>DOE: Alan Brownstein, Steve Brocum, William Boyle</p> <p>NRC: Malcolm Knapp, John Greeves, Michael Bell, Tim McCartin</p> <p>USGS: Ray Wallace, Claudia Faunt</p> <p>EPA Contractors</p> <p>DOE Contractors</p>	Ground water flow and modeling

10/23/98	EPA: Larry Weinstock, Frank Marcinowski, Al Colli, Ken Czyscinski, Ray Clark, Wendy Melgin, Phil Berger OSTP: Beverly Hartline DOE: Lake Barrett, Alan Brownstein, Steve Brocum NRC: Carl Paperiello, Tim McCartin EPA Contractors DOE Contractors	Ground water modeling
11/2/98	EPA: Larry Weinstock, Frank Marcinowski, Al Colli, Mike Bandrowski OSTP: Art Bienenstock, Beverly Hartline, Fran Sharples, Martin Offutt, Bruce MacDonald DOE: Lake Barrett, Alan Brownstein NRC: Carl Paperiello, Tim McCartin, Mike Bell	Ground water withdrawal amounts and modeling
12/21/98	EPA: Bob Perciasepe, Steve Page, Larry Weinstock, Frank Marcinowski DOE: Lake Barrett, Alan Brownstein	Overview of DOE radioactive waste management program
1/15/99	EPA: Larry Weinstock, Frank Marcinowski, Geoffrey Wilcox, Ken Czyscinski, Jim Taft, Mike Bandrowski DOE: Alan Brownstein, Steve Brocum EPA Contractors DOE Contractors	Draft standard
1/22/99	EPA: Larry Weinstock, Frank Marcinowski, Ken Czyscinski, DOE: Alan Brownstein, Steve Brocum, Nancy Slater DOE Contractors	Draft standard
5/11/99	EPA: Larry Weinstock, Frank Marcinowski, Ken Czyscinski, Ray Clark DOE: Alan Brownstein, Steve Brocum DOE Contractors	Yucca Mountain design alternatives presented by DOE
5/20/99	EPA OMB Council of Economic Advisors OSTP	Preproposal draft standard

18. Please list the date and substance of each technical or policy discussion regarding EPA's Yucca Mountain standards between EPA and NAS, DOE, NRC, OMB and OSTP held after August 27, 1999. Please identify all participants in those discussions.

Date	Participants	Subject
12/17/99	EPA: Frank Marcinowski, Mary Kruger, Ray Clark, Ken Czyscinski, Elliot Foutes, Geoffrey Wilcox, Sharon White OMB: Erik Godwin	Economic Impact Analysis
1/21/00	EPA: Frank Marcinowski, Mary Kruger, Ray Clark, Ken Czyscinski, Elliot Foutes OMB: Art Fraas, Erik Godwin DOE: Lake Barrett, Alan Brownstein	Economic Impact Analysis
5/11/00	EPA: Bob Perciasepe, Frank Marcinowski, Mary Kruger OSTP: Art Bienenstock, Pat Gallagher	OSTP comments on proposal
5/18/00	EPA: Bob Perciasepe, Frank Marcinowski, Mary Kruger NRC: Dick Meserve, Carl Paperiello	NRC comments on proposal
6/27/00	EPA: Bob Perciasepe, Steve Page, Frank Marcinowski DOE: Ernie Moniz, Ivan Itkin, M.L. Wagner, Alan Brownstein	DOE comments on proposal

19. Please cite each peer-reviewed scientific study that was considered by EPA in its decision to include a separate groundwater protection standard based on Safe Drinking Water Act maximum contaminant levels. Please explain how each scientific study supports EPA's proposed groundwater standard.

EPA did not base its decision to include a separate ground water standard on any specific scientific studies. As discussed in response to question 2 above, EPA included ground water protection standards in its proposal, and is considering such standards for inclusion in the final rule, primarily for consistency with Agency policy.

20. Please cite each international standard for nuclear waste disposal which includes a separate groundwater protection standard. Please describe how the maximum contaminant levels in each international standard compare to those proposed by EPA for the Yucca Mountain repository.

In the international arena, protection of the environment is an emerging issue. International standards typically contain the more traditional dose limit to human beings but more recent standards include provisions to address environmental protection. In 1995, the International Atomic Energy Agency, through a consensus of its member States (including the United States), issued "The Principles of Radioactive Waste Management" (Safety Series No. 111-F). Principle 2: Protection of the environment states that "Radioactive waste shall be managed in such a way as to provide an acceptable level of protection of the environment....Radioactive waste disposal may have adverse effects on

the future availability or utilization of natural resources, for example, land, forests, surface waters, ground waters and raw materials, over extended periods of time. Radioactive waste management, therefore, should be conducted in such a way as to limit, to the extent practicable, these effects." More recently, Sweden's proposed regulations for the final management of spent nuclear fuel or nuclear waste contain a separate section devoted to environmental protection. In this case, the concern is to limit the harmful effects to ecosystems and the resources that support them, among which, ground water is a primary sustaining resource. While different international organizations and countries may take alternative approaches to protecting the environment, the common goal is to maintain the integrity of those resources, such as ground water, supporting both human and non-human ecosystems.

- 21. Is there any statutory requirement to promulgate a final rule on the Yucca Mountain environmental protection standards this summer? Please explain why EPA plans to promulgate a final rule this summer when EPA will not have completed updating the 1976 maximum contaminant levels used in the groundwater protection standard.**

There is no statutory mandate to promulgate a final rule on the Yucca Mountain environmental protection standards in the summer of 2000. Actually, Section 801(a)(1) of the EnPA mandates that EPA promulgate public health and safety standards for protection of the public from releases from radioactive materials disposed in the repository at the Yucca Mountain site "not later than 1 year after the Administrator receives the findings and recommendations" of the NAS. The reason we had planned to finalize our standards during the summer of 2000 is that it seemed like a reasonable time frame to complete our analyses of public comments, undergo the interagency review process, and make appropriate revisions to the final rule and supporting documents.

- 22. Will the update to the 1976 MCLs reconsider and/or change the MCL for each of the radioisotopes covered by the proposed Yucca Mountain environmental protection standard? Please list the radioisotopes for which the MCLs will remain unchanged. For any radioisotope-specific MCL that is not being changes, is this because there has been no additional relevant scientific study on that radioisotope? If there has been relevant scientific study since 1976 on any radioisotope for which the MCL id not being updated, please provide the cite and conclusions of each study regarding the risks of exposure to the radioisotope in question. How does the conclusion of each study support the decision not to update the relevant MCL?**

See responses to questions 3(a) and 3(b).

- 23. Please cite each peer-reviewed study that supports EPA's ongoing efforts to update the MCLs for radioisotopes. For each study cited, please explain how the study was used by EPA and to which specific MCLs the study applies.**

Please see the Notice of Data Availability and the technical support document accompanying it. In addition for man-made beta/photon emitters, the FGR-13 cited above is the source of revised information.

24. Please explain how the scientific basis for establishing MCLs changed between ICRP Publication 2 and ICRP Publication 30, between ICRP Publication 30 and ICRP Publication 60, and between ICRP Publication 60 and ICRP Publication 72. Which of these publications will be relied upon after the MCLs are updated (as described in Mr. Page's testimony at page 12)? Will the same ICRP methodology be applied to all radioisotopes MCLs? If not, please explain on a radioisotope by radioisotope basis which ICRP methodology will be applied in setting each MCL. Please explain how and why the updates in the ICRP methodology either were or were not applied in setting each MCL.

40 CFR §141.16, *Maximum contaminant levels for beta particle and photon radioactivity from man-made radionuclides in community water system*, stipulates:

(b) Except for the radionuclides listed in Table A [tritium and Sr-90], the concentration of man-made radionuclides causing 4 mrem total body or organ dose equivalents shall be calculated on the basis of a liter per day drinking water intake using the 168 hour data listed in "Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure," NBS Handbook 69 as amended August 1963, U.S. Department of Commerce. If two or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 millirem/year.

NBS Handbook 69 contains dose conversion factors taken from ICRP Publication 2. Appendix B of EPA-570/9-76-003 provides guidance for using the NBS Handbook 69/ICRP Publication 2 dose factors to derive radionuclide-specific activity concentrations (in picoCuries per liter, pCi/L) yielding an annual dose of 4 millirem. Tables IV-2A and IV-2B of the appendix list the derived activity concentrations.

On July 18, 1991, EPA proposed a revised MCL for beta particle and photon emitters (56 FR 33050). Appendix B of the proposed rule included a look-up table of radionuclide-specific activity concentrations (in pCi/L) corresponding to an annual effective dose equivalent of 4 millirem, the proposed revised MCL. To derive this table, EPA used its RADRISK computer code which incorporated dose conversion factors from ICRP Publication 30.

EPA's current radiation risk assessment methodology is based on ICRP Publication 60 and ICRP Publication 72. This methodology applies state-of-the-art methods and models

that take into account age and gender dependence of intake, metabolism, dosimetry, radiogenic risk, and competing causes of death in estimating the risks to health from internal or external exposure to radionuclides. EPA has incorporated these methods and models in its calculations of radionuclide-specific cancer mortality and morbidity risk coefficients. EPA uses these risk coefficients, which are provided in Federal Guidance Report No. 13 (EPA 402-R-99-001), to estimate the fatal and total cancer risks associated with radionuclide MCLs.

On April 21, 2000, EPA published a Notice of Data Availability (NODA) to inform the public and the regulated community of new information concerning radionuclides in drinking water and to solicit comments on possible risk management decisions on MCL revisions (65 FR 21576). The Agency is under a court agreement to publish final regulations by November 2000. Since this process is ongoing—EPA is currently responding to comments received on the NODA and is finalizing decisions on the regulations—ORIA cannot comment at this time on radionuclide MCL revisions or on what ICRP publication or publications will be used to establish the MCLs.

25. For each radionuclide which EPA proposes to regulate via a specific MCL under a separate groundwater protection standard, please provide the following specific information:

- (a) What level of cancer risk does this MCL equate to?
- (b) On what scientific analysis does EPA base this determination of the risk level?
- (c) Does such analysis represent the latest available science?
- (d) What is EPA's basis for concluding that the selected MCL represents an appropriate risk level for Yucca Mountain groundwater?
- (e) Is this risk level consistent with the risk level recommended by the National Academy of Sciences and incorporated in the 15 millirem all-pathways standard? If not consistent, what is EPA's justification for the varying risk levels?
- (f) How does the risk level specified for this radioisotope compare to the risk levels represented with the proposed MCLs for other radioisotopes?

(a) The following tables present EPA's estimates of lifetime excess fatal and total cancer risks associated with the current radionuclide MCLs:

Fatal Cancer Risks

Statistic	Maximum Contaminant Level		
	Ra-226/Ra-228	Gross Alpha	Beta/Photon
Average	1×10^{-4}	2×10^{-5}	4×10^{-5}

Total Cancer Risks

Statistic	Maximum Contaminant Level		
	Ra-226/Ra-228	Gross Alpha	Beta/Photon
Average	2×10^{-4}	3×10^{-5}	6×10^{-5}

(b) EPA uses its current radiation risk assessment methodology to estimate the fatal and total cancer risks associated with radionuclide MCLs. Specifically, EPA calculates these risks using the cancer mortality and morbidity risk coefficients provided in Federal Guidance Report No. 13 (EPA 402-R-99-001), assuming a 2 L/d drinking water intake rate, 365 d/y, for 70 y.

(c) Yes. EPA's radiogenic risk methodology applies state-of-the-art methods and models from ICRP Publications 60 and 72. These methods and models take into account age and gender dependence of intake, metabolism, dosimetry, radiogenic risk, and competing causes of death in estimating the risks to health from internal or external exposure to radionuclides.

(d) EPA incorporated the existing MCLs in its proposed Yucca Mountain standards (64 FR 46976, August 27, 1999). This proposal acknowledged that the MCLs might change in the final rule but that, for the radionuclides of concern at Yucca Mountain, the concentration values for those MCLs are not likely to change significantly. (See 64 FR 47000.) Should the MCLs applied to Yucca Mountain be equal to or similar to those of the existing MCLs (40 CFR 141.15 and 141.16), the risk level associated with the existing 4 millirem/yr beta particle and photon radioactivity MCL results in concentration limits with risks that fall within the Agency's lifetime risk range goal of 10^{-6} to 10^{-4} . (See 65 FR 21581, April 21, 2000.) This risk range has guided numerous Agency actions, including the establishment of the MCLs, and provides consistency among a wide variety of programs with differing legislative mandates.

(e) As noted in our proposed rule (at 64 FR 46985, August 27, 1999), the range of annual risk of fatal cancer suggested by NAS was 1 chance in 100,000 to 1 chance in 1,000,000. This corresponds to a range of 20 to 2 millirem/year. The 4 millirem/year MCL for man-made beta and photon emitting radionuclides falls at the lower end of this range and is therefore consistent with the NAS suggested risk range.

(f) As indicated by both the Viability Assessment (Figure 4-12) and the Draft Environmental Impact Statement (DEIS) for Yucca Mountain (Tables 8-42, 8-46, and 8-50), the primary radionuclides of concern during a 10,000 year regulatory period are carbon-14 (C-14), technetium-99 (Tc-99), and iodine-129 (I-129). These are all beta emitting radionuclides that fall under the 4 millirem/year MCL limitation. When this level

was derived in 1976, the cancer risk associated with whole body irradiation (as is the case for C-14 and Tc-99) at 4 millirem/year equated to a lifetime cancer risk of 5.6×10^{-5} , assuming a 70-year lifetime. A recent re-evaluation, using EPA's Federal Guidance Report 13, of the risk associated with each of the 1976 MCL concentration levels corresponding to the 4 millirem/year limit indicates that the risk associated with each of these radionuclide concentration limits falls within the Agency's lifetime risk range goal of 10^{-6} to 10^{-4} . (See 65 FR 21581, April 21, 2000.)

- 26. Are there radioisotopes which EPA does not propose to regulate under the ground water protection standard? What is the scientific basis for making such a determination?**

At this time, EPA is not planning to regulate potassium-40, or lead-210. These were not listed with separate limits in the original rule and EPA did not propose to regulate them in its 1991 proposal. K-40 is naturally occurring as a part of all potassium in the environment and in the human body and accounts for a large part of the radiation dose to the body. The amount of potassium in the body is controlled by homeostatic mechanisms. A large amount of potassium-40 would be needed to change the ratio of nonradioactive to radioactive potassium. EPA must determine a limit from other than natural sources which would provide an unacceptable incremental increase in risk above the natural exposure before regulating. Lead-210 is naturally occurring and EPA placed it in the unregulated contaminant monitoring rule for further study to determine if regulatory limits would result in significant risk reduction.

- 27. Please explain fully the impact of the issuance of the Notice of Data Availability (NODA) will have on the proposed Yucca Mountain environmental protection standards.**

The NODA updates information relevant to the Agency's review of the radionuclide MCLs established under the SDWA. The NODA itself will have no impact on the proposed Yucca Mountain standard. However, should the Agency issue revised radionuclide MCLs, different from those referenced in the proposed Yucca Mountain standard, we could amend the final Yucca Mountain standard to reflect those revised MCLs.

- 28. Mr. Page's testimony indicates that, once EPA's internal review process is completed for the final rule on Yucca Mountain, EPA will begin an interagency review process administered by the Office of Management and Budget, in which the DOE and NRC will participate. Please describe the process that EPA will use to resolve any differences that might remain at the end of this interagency review process.**

The Agency is required by Executive Order to submit its final rulemaking to OMB for review and approval. It is OMB's decision as to which agencies it wants to have participate in that process. However, it is reasonable to assume that DOE and NRC will participate since they were involved in the process preceding the proposed rule. During the "interagency review process," it is OMB's role to facilitate discussions among the participants and to decide what is acceptable for inclusion in the final rule. The Agency will be a full and willing participant in those discussions.

29. **Mr. Page's testimony states that EPA staff has traveled to local communities to hold public hearings and meetings to discuss the proposed standards? Please list the date and substance of each such public hearing or meeting.**

Following is a list of public meetings and hearings, in chronological order.

Date	Location	Substance
9/20/1995	Amargosa Valley, NV	Public meeting on EPA's role and process for setting environmental standards for the proposed Yucca Mountain repository, and to receive comments on the NAS Report. Format: EPA presentation, public testimony, question and answer. (Docket A-95-12, II.E.1)
9/21/1995	Las Vegas, NV	Public meeting on EPA's role and process for setting environmental standards for the proposed Yucca Mountain repository, and to receive comments on the NAS Report. Format: EPA presentation, public testimony, question and answer. (Docket A-95-12, II.E.1)
10/19/1999	Las Vegas, NV	Meeting with Las Vegas Mayor's Office. Discussion of need for separate ground water protection standard, EPA's rulemaking process; plans to submit written comments. (Docket A-95-12, II.E.18)
10/20/1999	Las Vegas, NV	Meeting with Nevada Legislative Counsel Bureau. Discussion of differences in the dose standard proposed by EPA and NRC; the need for a separate ground water standard; alternatives for disposal; EPA rulemaking process. (Docket A-95-12, II.E.17)

10/20/1999	Las Vegas, NV	Meeting with Nevada Governor's office. Meeting with State Legislature. Discussion of need for stringent standard, point of compliance, regulatory time frame, definition of disposal and engineered barriers. (Docket A-95-12, II.E.19)
10/13/1999	Washington D.C.	Public Hearing. Testifiers presented oral testimony regarding EPA's proposed radiation protection standards for Yucca Mountain. (Docket A-95-12, I (Docket A-95-12, IV.F.1)
10/19/1999	Amargosa Valley, NV	Public Hearing. Testifiers presented oral testimony regarding EPA's proposed radiation protection standards for Yucca Mountain. (Docket A-95-12, IV.F.2)
10/20-10/21/1999	Las Vegas, NV	Public Hearing. Testifiers presented oral testimony regarding EPA's proposed radiation protection standards for Yucca Mountain. (Docket A-95-12, IV.F.3)
10/28/1999	San Francisco, NV	Public meeting with Nevada Indian tribes. Discussion of EPA's role and proposed standard, and concerns of the tribal representatives in attendance. (Docket A-95-12, IV.E.1)
11/22/1999	Reno, NV	Workshop session on EPA's proposed standard at the Inter-Tribal Council of Nevada Annual Convention. (Docket A-95-12, IV.E.3)

30. Mr. Page testified that *"EPA's proposed Yucca Mountain standards are based on and consistent with the recommendations of the NAS. Where our proposed rule departed from a strict reading of the NAS report, we made a special effort to explain our reasoning."* Where EPA departed from the recommendations of the NAS with respect to a separate groundwater standard, is EPA contending that a "special effort to explain [its] reasoning" is sufficient to comply with the requirements of the Energy Policy Act of 1992? Please explain fully how EPA believes it is satisfying both the intent and the letter of the Energy Policy Act.

As discussed above in response to question 15, the legislative history of the Energy Policy Act of 1992, including specific testimony by the National Academy of Sciences on the legislation that was to become the Energy Policy Act of 1992, made abundantly clear that the role of the NAS was not to dictate the standard. Nor is it the role of EPA, under that

Act, to simply codify unchanged, unexamined, and unrevised the recommendations of the NAS. In its comments on the proposed rule, the NAS stated: "The Board recognizes EPA has the authority under the Energy Policy Act to establish separate ground-water limits as a matter of policy, but if it does so it should explicitly state the policy decisions embedded in the proposed standard and ask the public to comment on those decisions." NAS Comments at 11 (Docket No. IV-D-31). Thus, NAS made no recommendation concerning a separate groundwater standard, so EPA's proposal of such a standard could not be inconsistent with an NAS recommendation. Further, in commenting on EPA's proposed standard, NAS stated that EPA (1) clearly has authority under the EnPA to establish such a standard to protect a valuable resource, but (2) should clearly state that it is doing so as a matter of policy. If EPA promulgates a final rule containing a separate groundwater standard, the Agency will clearly articulate its rationale for doing so - whether, as the NAS recommended, this is clearly a decision based solely on a very important policy of protecting a valuable resource, or if the Agency determines that there are technical as well as policy reasons for doing so.

31. Mr. Page's testimony at page 6 states that *"The annual risk associated with EPA's proposed 15 millirem standard and 4 millirem standard for groundwater fall within this [NAS-recommended] annual risk range."* If 15 millirem to an individual from all sources is acceptable, why is it not acceptable for more than 4/15ths of that exposure to be attributable to groundwater?

See Response to Question 50.

32. Mr. Page's testimony at page 7 states that *"EPA has proposed the groundwater standard as an implementation of policy which we plan to articulate more clearly in the final rule."* Given that this policy has not been sufficiently clearly articulated in the proposed rule on Yucca Mountain standards, does EPA plan to reissue the proposed rule to allow legally sufficient opportunity for notice and comment under the Administrative Procedure Act?

The legal obligations that an administrative agency must satisfy when conducting informal rulemaking pursuant to Section 4 of the Administrative Procedure Act (APA) do not include articulation of potential policy decisions or technical determinations in a notice of proposed rulemaking in form and substance requisite for promulgation as a final rule. Section 4 of the APA (5 U.S.C. § 553) requires, except in certain circumstances not relevant here, publication in the *Federal Register* of a "[g]eneral notice of proposed rulemaking". Such notice must include (1) a statement of the time, place, and nature of public rulemaking proceedings; (2) a reference to the legal authority under which the rule is proposed; and (3) either the terms and substance of the proposed rule or a description of the subject and issues involved. The specificity with which issues must be set forth in a notice of proposed rulemaking to meet the requirements of the APA has been elucidated by reviewing courts: "The test of adequacy of a Notice of Proposed Rulemaking

("NPRM") is whether it 'fairly apprise[d] interested parties of all significant subjects and issues involved.'" *Heckler v. St. James Hosp.*, 579 F. Supp. 757, 763 (N.D. Ill. 1984) (quoting *American Iron and Steel Inst. v. EPA*, 568 F.2d 284, 291 (3rd Cir. 1977)), *aff'd*, 760 F.2d 1460 (7th Cir. 1985); *see also*, *Rybachek v. U.S. EPA*, 904 F.2d 1276, 1287 (9th Cir. 1990) ("The EPA's failure to propose in advance the actual wording of the BMPs does not make the BMPs invalid. The EPA need not 'publish in advance every precise proposal which it may ultimately adopt as a rule.' *California Citizens Band Ass'n v. United States*, 375 F.2d 43, 48 (9th Cir), *cert. denied*, 389 U.S. 844 (1967). Instead, the EPA is only required to publish in this context the 'terms or substance of the proposed rule or a description of the subjects and issues involved.' 5 U.S.C. § 553(b)(3) (1988));" *accord*, *Spartan Radiocasting Co. v. F.C.C.*, 619 F.2d 314, 321 (4th Cir. 1980). EPA's proposed rule for public health and safety standards for protection of the public from releases from radioactive materials disposed in the Yucca Mountain repository discusses all of the issues and subjects relevant to this rulemaking in detail. EPA has more than met its obligations under the APA to fairly apprise interested parties of all significant subjects and issues involved.

- 33. Please list the dates, locations, and substance of all other applications of this EPA ground water policy.**

This policy has been applied in numerous superfund sites where ground water is contaminated or threatened. The record of decision for each site is publically available and explains how CERCLA mandate to clean up to drinking water standards applies in that particular situation.

- 34. Does EPA contend that ground water at Yucca Mountain site needs to be protected to ensure that the ground water does not interfere with the attainment of the surface water quality standards? Please explain your answer fully.**

That consideration has not been voiced with respect to Yucca Mountain deliberations. Ground water not surface water has been the focus of concern.

- 35. Mr. Page's testimony at page 8 states that EPA believes ground water is a resource needing special protection and, as such, proposed a level of protection for ground water at Yucca Mountain at the same level as the MCLs for radionuclides established under the Safe Drinking Water Act. What is the statutory basis providing EPA with authority to designate ground water as a resource requiring special protection? Has such a designation been subject to notice and comment by the public? Is so, please provide citation to the relevant Federal Register notice(s), the identity of the commenters, and the substance of their comments.**

A number of Federal statutes provide EPA with the authority to prevent and control sources of ground water contamination, for example, the Safe Drinking Water Act

(SDWA), the Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response Compensation and Liability Act (CERCLA). During the early 1980's EPA recognized that these authorities were fragmented among many different statutes. As a result, in 1984, EPA issued a ground water protection strategy to articulate both the problem and EPA's role in a national ground water protection program.

In 1989 a ground water task force was established to address comprehensive protection of the ground water resource. EPA did not use notice and comment rulemaking to develop this policy, however, significant input was provided by state and local governments, other Federal agencies, environmentalists, industry, and public interest groups in developing the published policy report ("Protecting the Nation's Ground Water: EPA's Strategy for the 1990s"). This strategy has guided the course of EPA and State efforts with a clear priority on preventing ground water contamination.

- 36. Please define "reasonably expected drinking water supplies" as used in Mr. Page's testimony at page 8.**

This is not a technical or legal term. Mr. Page used this terminology to refer to groundwater resources that are probable sources of drinking water, now or in the future. In the case of groundwater in the vicinity of Yucca Mountain, EPA believes that the aquifer is of a size and character sufficient to support a significant population both currently and in the future.

In addition, the groundwater resources in the vicinity of Yucca Mountain are a potential source of water for more distant communities. Although the growing communities in the Las Vegas metropolitan area may not extend to the vicinity of Yucca Mountain in the near future, it is possible that those communities may seek to tap the aquifer as a resource to support those communities.

- 37. To the extent that EPA's proposed groundwater protection standard is designed to protect individual groundwater users, when is the groundwater at issue likely to be used by individuals. Please explain full [sic] in your answer and provide any documents related to this determination of future groundwater use in the Yucca Mountain vicinity.**

The ground water downgradient from Yucca Mountain is currently being used to support a population of approximately 1500 residents of the Town of Amargosa Valley, Nevada. In addition, it is being used to support agricultural activities, e.g., several hundreds of acres of alfalfa and the largest dairy farm in the State of Nevada. The same source of ground water also supports the businesses in Amargosa Valley.

Given that the ground water is being used now, there is no reason to believe that it will not be used in the future. This is not documented because it would be the same for any existing ground water supply which is currently being used and did not appear in danger of being totally drained in the foreseeable future -- there is no indication that the ground water supply for Amargosa Valley is in danger of being mined to "extinction." As to setting the standards using the assumption that the ground water will be used in the future, on page 122 of its report to EPA, NAS stated:

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

In concert with this recommendation, we have proposed using the current technology and living patterns, the so-called "fixed biosphere," for Yucca Mountain. The NAS recommended this approach to avoid unlimited speculation regarding factors which were not directly related to the performance of the disposal system. Since we agree with that approach and since the ground water is being used today, we have proposed that it will be used in the future in a similar manner.

38. **Mr. Page's testimony at page 8 contains the following statement: "We frequently require compliance with the MCLs in our regulations." Please list each regulation in which EPA has required compliance with radionuclide MCLs in protecting ground water and explain the basis for including the MCLs. Also list every instance where EPA has not required compliance with these MCLs and explain the basis for not including the MCLs.**

See response to question 7.

39. **In August 1999, EPA released a report entitled "Evaluation of the Potential Economic Impacts of 40 CFR Part 197: Environmental Radiation Standards for Yucca Mountain, Nevada." This report provided a largely qualitative analysis of the potential economic impacts of the proposed rule. Does EPA intend to produce a more thorough and quantitative economic analysis prior to the issuance of the final rule? Does EPA believe it has complied with the APA notice and comment requirements if it does not release a quantitative economic analysis prior to issuance of the final rule? Please explain fully the basis for your answer.**

The EIA shows, that, based on the current repository design, DOE will meet our proposed standard. We do not believe it is our role to examine the performance and costs of other

repository designs. To the extent that there is any obligation under the APA to provide the opportunity for comment on the economic impact document produced in conjunction with this rule, for the reasons set forth above in response to question 32, EPA believes that it has fully complied with all applicable notice and comment requirements of that Act. Moreover, EPA does indeed intend to produce a more thorough economic impact of the proposed rule. This EIA will accompany the final rulemaking as it makes its way through the review process.

40. **In the August 1999 economic evaluation, EPA proposes a worst case scenario wherein the Yucca Mountain Site is disqualified and DOE must spend another \$2 billion to identify and characterize an alternative site. Why did EPA not evaluate a true worst case in which the proposed standard invalidates any repository in the U.S., requiring a continuation of on-site storage at reactors around the country? Please provide and documentation relating to the evaluation of the worst case scenario as described in the August 1999 report, as well as any other alternative worst case scenarios which were not included in the at report.**

A scenario in which EPA's proposed standard "invalidates any repository in the U.S." is not valid. EPA was not in possession of any information at the time of the original EIA (or now, for that matter) that suggested that the true worst case for the proposed standard would be the invalidation of any repository site and the continuation of storage. Instead, it seemed more prudent and reasonable, then and now, to assume that if the Yucca Mountain facility were to be found unacceptable that it would be relocated and the characterization costs experienced up until that time, reincurred at the relocated site.

The impact of EPA's rulemaking is premised on the rationale the DOE has provided for its own design changes and upon its own performance assessments. These performance assessments have suggested a degree of containment such that the possibility of relocation would seem to be remote.

41. **In his testimony, Mr. Page referred to DOE's 1998 Viability Assessment in support of EPA's contention that the costs of complying with EPA's proposed radiation standards would not be significant. Please provide references to those portions of the Viability Assessment used by EPA in support of this contention. Specifically, identify those portions of the Viability Assessment which address the subject of compliance with a separate groundwater protection standard.**

EPA has examined DOE's results of detailed performance assessments for the Yucca Mountain site in two documents, the "Viability Assessment of a Repository at Yucca Mountain", (DOE/RW-0508, vol. 3, 1998, abbreviated here as the DOE/VA), and the "Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High-Level Radioactive Waste at Yucca Mountain, Nye County,

Nevada", (DOE/EIS-0250D, 1999, abbreviated here as the DEIS). Information in both these documents is relevant to fully answering this question about Mr. Page's statements.

The performance analyses presented in the VA and DEIS documents are closely related. In the Viability Assessment, the basic framing, underlying assumptions and analytical approaches to the repository assessments are presented along with total system results, i.e., all-pathways total dose estimates to a down gradient receptor - a farmer, at 20 km from the repository, with characteristics similar to the receptor proposed by the Agency in the proposed rule (the reasonably maximally exposed individual or RMEI). These results are what we used for comparison with our proposed individual protection standard (15 mrem/yr). Volume 3 of the DOE/VA documents, presents the results of these analyses, and from an inspection of the information it can be seen that for the 10,000 year period the mean dose is 0.1 mrem/yr and the median dose is 0.02 mrem/yr - well below the 15 mrem/yr individual protection standard. This is a total all-pathways dose, not a drinking water dose alone, which would be significantly lower. EPA has carefully examined the framing of the base case performance scenario and the assumptions described in the DOE/VA assessments and EPA believes that these analyses are in fact very conservative. Assumptions were made that are very unrealistic for the sake of simplifying the analyses, and which are in fact highly conservative, i.e., they act to significantly overestimate projected releases. The results given in the DOE/VA documents should be considered "worst case" situations rather than expected case behavior.

The DEIS presents additional variations on the VA analyses, along with results for radionuclide concentrations in ground waters at various distances from the repository. These radionuclide concentrations in ground water can be compared directly with MCL limits for specific radionuclides as an indication of compliance with our ground water standards. The framing and assumptions for the DEIS assessments are essentially the same as used in the DOE/VA. In Chapter 5 of the DEIS, results are tabulated for radionuclide concentrations in ground waters downgradient from the repository at distances of 5, 20, 30 and 80 km. DOE's assessments show that the radionuclides reaching these distances during the regulatory time period (10,000 years) are technetium-99 (Tc), iodine-129 (I) and a small percentage of carbon-14 (C). From inspection of tables 5-7, 5-11 and 5-15 in the DEIS, it can be seen that the MCL concentration limits (in picoCuries per liter (pCi/l)) for Tc (MCL for Tc = 900 pCi/l), I (MCL for I = 1 pCi/l) and C-14 (MCL for C-14 = 2000 pCi/l) are not exceeded at any distance. These results indicate that the repository system as modeled (remembering that the assessments are very conservative, i.e., they over estimate releases) can meet the ground water standards. These data from DOE's own assessments, coupled with DOE's move to a more durable waste package, are the reasons for Mr. Page's statements that we have not seen evidence that the repository design planned for the Yucca Mountain site cannot meet the standards in the proposed rule.

42. **Mr. Page's testimony at page 13 states that EPA is still considering options and alternatives for the final Yucca Mountain standards. Please provide a description of all options and alternatives that are still under consideration, as well as those options and alternatives that were previously considered but subsequently dropped. Please identify the EPA individual who is responsible for deciding the disposition of these past and current options and alternatives.**

EPA's proposal included options and alternatives on many aspects of the standards. Some of these alternatives were offered in the rule language itself, while others were discussed in the preamble, with EPA's preferred alternative included in the rule language. EPA offered alternatives, and requested public comment, on:

- EPA described four alternatives for identifying the RMEI:
 1. Subsistence (low technology) farmer
 2. Commercial farmer
 3. Rural-residential individual
 4. Community domestic use of an underground source of drinking water
- EPA described three broad subarea alternatives for the location of the RMEI:
 1. Including the area between Yucca Mountain and the Town of Amargosa Valley
 2. Including the northern part of the Town of Amargosa Valley
 3. Including the remainder of the Town of Amargosa Valley
- EPA described two alternatives for the period of regulatory compliance with the individual-protection standard (the RMEI):
 1. A specified time period of 10,000 years during which compliance must be demonstrated
 2. A compliance period that extends to the time of peak dose to the RMEI
- EPA described two alternatives for the period of regulatory compliance with the human-intrusion standard:
 1. A specified time period of 10,000 years during which compliance must be demonstrated
 2. A compliance period that extends to the earliest time of possible intrusion (if less than 10,000 years, analyses covering longer time periods must be placed in the Environmental Impact Statement for Yucca Mountain)
- EPA described four alternatives for the representative volume of ground water:
 1. 4,000 acre-feet/year, corresponding to the perennial yield of the aquifer
 2. 1,285 acre-feet/year, corresponding to an average alfalfa farm
 3. 120 acre-feet/year, corresponding to a community of 150 people
 4. 10 acre-feet/year, corresponding to domestic use for a family of four

- EPA described four alternatives for the point of compliance for ground water:
 1. A controlled area extending no more than 5 km from the repository in any direction
 2. A point roughly 20 km from the repository
 3. A point roughly 30 km from the repository
 4. A controlled area that may include the Nevada Test site
- EPA described two alternatives for the period of regulatory compliance with the ground-water standard:
 1. A specified time period of 10,000 years during which compliance must be demonstrated
 2. A compliance period that extends to the time of peak concentration
- EPA also explicitly requested public comment on other aspects of the proposal and encouraged commenters to provide information to support approaches other than those proposed by EPA. The significant issues EPA asked for public comment on include:
 1. Whether EPA's proposed 15 mrem/year individual-protection standard is appropriate
 2. Whether EPA should use the critical group approach instead of the RMEI
 3. Whether EPA should include qualitative assurance requirements in its rule
 4. Whether EPA should specify an all-pathways standard with no separate ground water protection
 5. Whether EPA should issue guidelines for DOE's elicitation of expert opinion

EPA received a significant amount of public comment on these and other issues, and is considering those comments, and the latest information available from DOE and NRC, in developing the final standards. While EPA made its preferred positions clear in its proposal, it would be accurate to say that, until the rule is final, none of these alternatives has been definitively eliminated. The EPA Administrator will make the final decisions.

- 43. Given that the National Academy of Sciences has taken the position that a risk-based standard would promote consistency between the Yucca Mountain standards and standards applied to other hazards, such as toxic chemicals, please explain EPA's basis for not using a risk-based standard in the proposed rule.**

See response to question 16.

- 44. EPA proposes to require the repository performance beyond 10,000 years to be examined to see if "dramatic changes" could be anticipated. Please define "dramatic changes" in this context and state the statutory basis for proposing such a requirement. Please quantify the benefit to the public from this aspect of the proposed standard.**

The rationale for making repository performance projections for periods beyond the 10,000-year regulatory compliance period is to provide a more comprehensive picture of anticipated behavior of the waste containment and isolation performance over the range of natural conditions that can be expected at the site consistent with the recommendations of the NAS. The 10,000-year time frame is fully consistent with the generic disposal regulations, the WIPP certification rulemaking, and NRC licensing criteria. The assumption behind deep geologic disposal is that the combination of engineered and natural barriers will contain radionuclides in the repository proper for long periods of time, and limit any eventual releases to small amounts of radionuclides that reach the environment. Over time periods of thousands to tens of thousands of years it is expected that a gradual degradation of the repository engineered barrier system (EBS) will occur from the effects of the site conditions on the EBS integrity, e.g., even extremely small quantities of ground water contacting waste packages would eventually result in sufficient corrosion to breach the waste container. The intent of the post-10,000 year performance projections is to examine how the repository system is expected to perform as the EBS system degrades as a function of changes in conditions at the site over the long term (beyond 10,000 years). By examining repository performance over very long time frames, the analyses can assess the effects of natural processes and events whose effects may not become manifest until time periods after the 10,000 year regulatory period. This context "dramatic changes" would imply large increases in repository releases.

The 10,000 year upper limit is fundamentally a policy decision that balances two considerations: the uncertainty in long-term performance projections and the degree of confidence necessary to conclude the licensing process. It is generally recognized that uncertainties in projecting the performance increase with time; however, this should not be interpreted to mean that a performance projection for year 10,000 is reliable, but the result for year 10,001 is completely unreliable for regulatory decisions. Projecting performance beyond 10,000 years offers a more comprehensive picture of the site's anticipated performance for decision making. As discussed in the preamble to the proposed rule, the 10,000 year regulatory period: has precedence in previous rulemakings and applications for radioactive as well as hazardous wastes; is a reasonable compromise between scientific uncertainties and licensing processes; and represents a consensus on this issue as seen by the occurrence of the 10,000 year regulatory performance period in the many radioactive waste disposal programs abroad. The NAS commented on our proposed treatment of performance calculations, saying "there may be little practical difference between the TYMS report's recommendations and the proposed EPA standards", but also suggesting that we be more specific about how the post-10,000 year calculations are to be treated in licensing or pass the task to the NRC. We will address this aspect in the final rule.

45. **What is the risk level associated with the EPA's MCL for arsenic? How does this risk level compare with the risk levels associated with the radionuclides MCLs proposed**

for Yucca Mountain? How does the arsenic risk level compare to the risk level associated with the proposed 15 mrem all-pathways standard? What is the scientific basis for the EPA's arsenic MCL?

For Arsenic, at the proposed MCL of 5 parts per billion (ppb), the risk for the 90th percentile person is 6×10^{-5} to 1.1×10^{-4} for community water consumption, or 7×10^{-5} to 1.2×10^{-4} for total water consumption (Tables X-2A & B of the arsenic proposal). The National Research Council (NRC) noted that the current MCL of 50 ppb could have a risk of 1 to 1.5×10^{-3} , using one of their risk analyses.

As stated earlier, the risk for beta/photon emitters at a 4 mrem dose varies between about 10^{-4} to 10^{-6} . The range of risk at the MCL for the different alpha emitting nuclides at the alpha MCL or the uranium proposed MCL is also in that range. The risk of a 15 mrem all-pathways is approximately 6×10^{-4} . This could be internal or external radiation.

EPA derived U.S. population risks from arsenic exposure from four risk estimates derived by the NRC of the National Academy of Sciences. Estimated risk reductions for bladder cancer at different MCL options were input into a Monte Carlo model of population risks to arsenic exposure. EPA's risk characterization is fully discussed in the June 22, 2000 FR proposed rule (65 FR 38888).

- 46. Please identify all assumptions made by EPA regarding the lifestyle of the hypothetical Reasonably Maximally Exposed Individual (RMEI) considered in EPA's 15 millirem all-pathways radiation standard, including the amount of groundwater such an individual consumes per day. Please identify all lifestyle assumptions made in deriving each of the radionuclide MCLs in the proposed groundwater standard. Please explain fully the rationale for any differences in these two sets of lifestyle assumptions.**

In order to calculate all-pathway dose estimates for repository releases from Yucca Mountain, assumptions about the characteristics of the exposed individuals must be made because variations in these characteristics significantly affect the calculated dose, e.g., the amount of contaminated drinking water consumed or the kinds and amounts of consumed food produced with the contaminated water. For the Reasonably Maximally Exposed Individual (RMEI) proposed in the draft standard, we made the following assumptions.

- The RMEI should have a lifestyle patterned after current residents living downgradient from the repository - we proposed a "rural-residential" RMEI which is consistent with the current population at the nearest location to the repository where there are currently people in residence (the Lathrop Wells area mentioned in §197.21a).

- In order for the RMEI to be reasonably maximally exposed, at least one or more of the parameters that strongly control dose must be assumed to be at a high value - we chose to set drinking water consumption to 2 liters per day - a high-end value but not unrealistically high for someone living in an arid location. We also consider the location to be a high-end value.
- We assumed that the remainder of the RMEI's intake of food would be consistent with the eating habits of the general population in the area -as determined by surveys of that population (see §197.21 of the proposed standard).
- We assumed that the RMEI would also have a lifestyle representative of people currently living in the Town of Amargosa Valley- this would include growing some portion of the RMEI's own food, including grazing of livestock.

We believe the exact specifics, or ranges of variation, for some of these food consumption and lifestyle characteristics to be used in actual dose assessments are implementation details to be decided between the DOE and the NRC, as long as they are consistent with the general assumptions given above. We have only made general assumptions about the characteristics of the RMEI (except for the 2 l/day drinking water assumption), because we believe that the DOE and the NRC should have the flexibility to assess reasonable variations in RMEI characteristics so that the dose estimates are more representative of potential exposures and not artificially and unrealistically constrained to rigid limits.

The drinking water consumption rate assumed in the development of the 4 mrem/yr MCL limit for beta/photon emitters was 2 liters/day (EPA-570/9-76-003, National Interim Primary Drinking Water Regulations), which is the same drinking water intake level assumed in the description of the RMEI characteristics for the individual protection standard in §197.20 of the Yucca Mountain standard.

- 47. Given the abundance of criticism EPA has recently received for failing to incorporate sound science into its regulatory decision-making, how can EPA persist in disregarding the recommendations of the National Academy of Sciences, the Department of Energy, the Nuclear Regulatory Commission, and others, in setting standards for Yucca Mountain?**

With respect to the recommendations of the National Academy of Sciences, as contained in the National Research Council report "Technical Bases for Yucca Mountain Standards," EPA is consistent with the major recommendations, except for regulatory time frame, the form of the standard, and ground water protection, as discussed in the November 26, 1999 comments from NAS on EPA's proposed Yucca Mountain standards. With respect to regulatory time frame, NAS is recommending an unprecedented position. With respect to the form of the standard, while the NAS advocated risk, EPA chose a dose standard based on a risk level in order to be consistent with the language in the

Energy Policy Act. This risk level is consistent with the NAS recommended range of risk.

As discussed in response to question 2 above, the inclusion of separate ground water protection standards in our proposal (64 FR 46976, August 27, 1999) was primarily a policy decision to protect the significant ground water resources around Yucca Mountain. Such standards would provide consistency with other Agency programs to protect ground water and would assure that the geologic disposal of spent nuclear fuel, high-level and transuranic waste anywhere in this country would meet comparable standards. At the same time, EPA is sensitive to the technical issues associated with establishing such standards and has taken comment on scientific issues related to assuring such standards can be implemented.

- 48. EPA has publically acknowledged that its current MCLs are based on obsolete methods. Why does EPA feel constrained to rely on dosimetry modeling that is 40 years out-of-date and that results in standards that provide levels of protection that vary significantly and arbitrarily?**

See response to question 3(a).

- 49. Why does EPA continue to mislead the public by portraying its proposed groundwater limits for Yucca Mountain as a single numerical limit (i.e., 4 millirem per year) when, in fact, implementation of its proposed standards would prescribe risk levels that vary over several orders of magnitude depending on the radioisotope?**

EPA is not misleading the public. The 4 millirem per year is the regulatory limit that applies to man-made beta and photon emitting radionuclides. While the risk associated with that dose limit does vary depending on the radionuclide, the risks are consistent with the Agency's acceptable risk range of 10^{-4} to 10^{-6} for regulating such contaminants.

- 50. Can EPA explain what policy basis it uses to justify providing different levels of protection for different radioisotopes that vary arbitrarily over such a wide range?**

It must be noted that the levels of protection developed for different radioisotopes has evolved over decades under a wide variety of Congressional mandates. For example, under the Atomic Energy Act, EPA has established radiation standards that typically consider the cost and effectiveness of different treatment options (e.g., 40 CFR Part 190). The Clean Air Act (section 112) requires a different approach for public health protection. EPA first determined "acceptable risk" that considers all health information. A second step follows in which the actual standard is set below the acceptable risk level while providing "an ample margin of safety". The Safe Drinking Water Act requires a different two-step process. First, the Maximum Contaminant Level Goals (MCLGs) must be established

based only on the available health effects information. For radiation, which is a carcinogen, the MCLG is zero. The second step is to define Maximum Contamination Levels (MCLs), which are enforceable, at levels as close as practicable to the MCLGs, taking into account health-effects information, feasibility of treatment, and costs of removing contaminants from drinking water. Given these different regulatory frameworks, the protection levels associated with a given radionuclide may indeed vary. While this may be the case, EPA traditionally has endeavored to limit lifetime risks to individuals from a wide variety of pollutants to a range of 10^{-6} to 10^{-4} . While the risk associated with that dose limit does vary depending on the radionuclide, the risks are consistent with the Agency's acceptable risk range of 10^{-4} to 10^{-6} for regulating such contaminants.

51. **Why has EPA elected to abandon the critical group concept recommended by the National Academy of Sciences, an approach widely accepted by state and other government regulators, as well as by regulatory authorities in the United Kingdom, Sweden, Switzerland, and Canada?**

Although NAS recommended using a CG approach to achieve a group that is "homogeneous in risk", they recognized that a non-CG approach could accomplish the same purpose. In its report, NAS stated "[i]t is essential that the scenario that is ultimately selected be consistent with the critical-group concept that we have advanced" (NAS Report p. 10, emphasis added). We chose to use an approach involving limiting exposure to a defined "reasonably maximally exposed individual", the RMEI. The NAS recognized that EPA did not "abandon" the recommended approach, stating that the RMEI approach is "broadly consistent with the TYMS report's recommendations" (NAS comments on proposed 40 CFR part 197). In fact, there are significant similarities between the CG and RMEI approaches, including the overall goal of evaluating potential doses to more highly-exposed segments of the population. EPA prefers an approach to exposure assessment consistent with EPA programs, that is, the RMEI.

52. **Does EPA have any current scientific evidence showing that water with radioactivity levels corresponding to a dose above 4 millirem per year, but less than EPA's proposed all-pathway limit of 15 millirem per year, is in any way harmful to human health or the environment?**

Due to the limitations of epidemiologic studies, it has been—and probably will always be—impossible to directly demonstrate any harmful effects of radiation at dose levels corresponding to small percentage increments above natural background. Nevertheless there is an extensive body of laboratory data, supported by strong theoretical arguments, indicating that the probability of inducing "stochastic effects" such as cancer is, at low doses, proportional to dose with no threshold. In particular, there is strong evidence that even a single track of ionizing radiation can cause permanent damage to the cell's DNA. The assumption of low dose linearity for radiation protection purposes has been repeatedly

endorsed by distinguished panels organized nationally and internationally by such bodies as the National Academy of Sciences (NAS), the National Council on Radiation Protection and Measurements (NCRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiation Protection (ICRP), and the National Radiation Protection Board of the United Kingdom (NRPB), and is implicitly utilized by nearly every government agency involved in radiation protection worldwide.

Our knowledge of the mechanisms of induction of effects by low dose radiation is incomplete. Further research may help to illuminate these mechanisms and allow us to project low dose effects with more confidence, but at this point, the general consensus of experts is that the linear no-threshold assumption is the only prudent basis for assessing the deleterious effects of low dose radiation.

- 53. Does EPA know of any community that has spent resources to “clean up” groundwater that is naturally radioactive at levels below 15 millirem, but above 4 millirem, to achieve the 4 millirem limit?**

The “4 millirem limit” does not apply to naturally occurring radionuclides; it applies to man-made beta and photon emitting radionuclides. The technical support document for the Agency’s Notice of Data Availability regarding radionuclides in drinking water (65 FR 21576, April 21, 2000) provides information on the number of public water systems exceeding each of the applicable MCLs. From 1976 through 1998, only ten of the 10,159 public water systems reporting levels exceeding the MCLs did so because they exceeded the beta-photon limit of 4 millirem/yr. By far, most exceedences of the MCLs are related to naturally occurring radionuclides such as Ra-226, Ra-228 and other alpha-emitting radionuclides. (See Table II-2, “Radionuclides Notice of Data Availability Technical Support Document,” Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, March 2000.)

- 54. Please describe in detail the methodology used to obtain the 4 mrem ground water standard and identify opportunities for public input as well as peer review prior to finalization of the standard.**

The methodology used to derive the picoCurie levels for man-made nuclides which correspond to 4 mrem is detailed in National Bureau of Standards Handbook-69, incorporated by reference into the standard. It did not use effective dose equivalent factors. The 1976 rule had a maximum risk in mind. It targeted one excess death in a million persons per year as the ceiling of risk. A dose of 4 mrem was selected as the closest approximation to that risk. 4 mrem to the whole body was then calculated to actually result in a risk of 0.8 deaths per million persons per year, just below the upper limit of 1.0 deaths envisioned. That risk was 5.6×10^{-5} , and pertained to the whole body dosers. Risks for organ-specific nuclides was lower. For each nuclide, a picoCurie limit

was established corresponding to the 4 mrem dose. Federal Guidance Report-13 now allows us to check the level of protection afforded to see if the rule provides adequate safeguards to public health or not. The beta/photon emitters fall in round numbers between 10^{-4} and a 10^{-6} risk.

The standard was proposed in December 24, 1975 and after public comment, promulgated July 9, 1976. Our Notice of Data Availability, which supplements the 1991 proposal, was published in the Federal Register on April 21, 2000, and we are responding to comments received. The Federal Guidance Report-13 was peer reviewed and published as interim in January, 1998 and as final in September, 1999.