UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 2, 1999

Mr. Stephen D. Page, Director
Office of Radiation and Indoor Air
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Mr. Page:

This letter provides the comments of the U.S. Nuclear Regulatory Commission (NRC) staff on the Notice of Proposed Rulemaking, "Environmental Radiation Protection Standards for Yucca Mountain, Nevada" (64 FR 46976) at proposed 40 CFR Part 197. As the Agency responsible for licensing a possible repository at Yucca Mountain, Nevada, the NRC is concerned that the standards exhibit a sound scientific and technical basis and that the need for the standards adopted be fully justified on health and safety grounds. The NRC staff disagrees with the need for, and health and safety basis of, some of the requirements in the proposed standards. In addition, the NRC staff is concerned that EPA has not provided any analysis of the costs and benefits of its approach to regulating radioactive waste disposed at Yucca Mountain. The staff's objections to the proposed standards are given below and in the enclosure to this letter.

1. The NRC staff objects to the inclusion of separate ground-water protection requirements for the proposed repository at Yucca Mountain because these requirements would result in non-uniform risk levels, they misapply the Maximum Contaminant Levels for radionuclides, and they far exceed what is needed for protection of public health and safety.

Although Maximum Contaminant Levels (MCLs) may have been considered reasonable standards during their development in 1975, current understanding of the risk posed to individual organs by radiation exposure demonstrates that the MCLs for individual radionuclides provide a level of protection that varies significantly. For example, consider the annual risk of developing a fatal cancer from drinking water that contains Neptunium-237 (Np-237) and Iodine-129 (I-129) at their respective MCL. The risk of developing a fatal cancer from ingestion of Np-237 at its MCL is 30 chances in 1,000,000 (3×10^{-5}), while the risk from ingestion of I-129 at its MCL is 0.07 chance in 1,000,000 (7×10^{-8}). More than a four-hundred fold difference exists between the risk levels prescribed for these two radionuclides. Therefore, this simple comparison shows an application of MCLs that results in non-uniform risk levels which are likely to lead to greater confusion about the level of risk which is acceptable and attainable, rather than confidence that the health and safety of the public are being protected. It is our understanding that there are no EPA efforts currently underway to modify the MCLs to ensure a uniform risk level.

The EPA does not demonstrate a need for such an overly conservative, separate groundwater limit to protect public health and safety. The all-pathway dose limit, by definition, ensures that risks from all radionuclides and all exposure pathways, including the groundwater pathway, are acceptable and protective. All radionuclides and all exposure pathways will have to be acceptably evaluated at Yucca Mountain, and will have to meet an individual protection standard that is fully protective of public health and

safety and the environment. Therefore, the proposed standard should not contain separate ground-water protection requirements because they are unnecessary for protection of public health and safety and because they lead to inconsistent and unreconcilable results as described above, which we believe will cause confusion and diminish rather than enhance public confidence that adequately protective limits have been established.

Certain MCLs maintain a risk level so small that the individual, all-pathway dose limit is meaningless. EPA has proposed an annual, individual dose limit of 0.15 mSv (15 mrem) which is equivalent to an annual risk of developing a fatal cancer of 9 chances in 1,000,000 (9×10^{-6}).[1] The MCL for I-129 (annual risk of 0.07 chance in 1,000,000) is more than 100 times below the risk of the individual dose limit. Consequently, the groundwater protection criteria become the de facto standards instead of the individual protection limit called for by the Energy Policy Act of 1992 (EnPA - Public Law 102-486).

The EPA's current proposal is a continuation of EPA's practice of using the MCLs without appropriate justification. Specifically, EPA would have NRC require that groundwater in the vicinity of Yucca Mountain meet EPA's MCL, originally established to implement the Safe Drinking Water Act (SDWA). The MCLs were based on an analysis of treating contaminated water in public drinking water systems subject to the SDWA and not on an analysis of technology and costs of remediating groundwater at actual sites. In this rule, EPA proposes to apply the same MCLs to groundwater supplies before treatment rather than "at the tap" after treatment. Therefore, in the absence of an appropriate and comprehensive cost-benefit analysis, EPA should not require the expenditure of potentially significant amounts of taxpayer money to prevent potential contamination of groundwater that may require treatment prior to use anyway. Instead, EPA's standards should permit a decision to spend much smaller sums for water treatment in the event that such contamination should occur. Finally, EPA's application of MCLs at DOE's Waste Isolation Pilot Plant (WIPP) site in New Mexico should not be considered a precedent for the Yucca Mountain site since the WIPP site is located in a salt formation and lacks potable groundwater making the application of MCLs irrelevant.

Furthermore, the NRC staff is troubled by the discussion of ground-water protection that suggests additional options that are not representative of ground-water conditions at Yucca Mountain and further increase the conservatism in applying these unnecessary separate requirements. The preamble to the standard requests comment on alternative dilution volumes that are extremely small (e.g. 10 and 120 acre-feet). These dilution volumes are not reflective of the resource to be protected (the EPA states the representative volumetric flow is 4000 acre-ft/year for the sub-basin in which the proposed repository is located). The standard also requests comment on alternative locations for determining compliance (e.g., 5 kilometers) that are similarly not reflective of the resource. As explained in connection with the compliance location for the individual protection (e.g., 20 kilometers), cautious and reasonable assumptions for

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[1] This value was calculated by EPA's use of NCRP Report No. 126 risk value of 6×10^{-2} health effects per Sievert (Sv) [6×10^{-4} health effects per rem] and the NAS recommendations for an annual risk limit.

lifestyles and the practicality of obtaining water provide no basis for identifying the 5 kilometer location for protection of ground water.

Is there a better approach? Yes. An individual, all-pathway dose limit of 0.25 mSv (25 mrem) total effective dose equivalent (TEDE) properly accounts for the radiation sensitivity of individual organs, and ensures the risks from all radionuclides and all exposure pathways are acceptable and protective.

2. The NRC staff objects to those portions of the proposed standard that address technical matters of compliance determination and implementation - matters which Congress has assigned to the NRC, not to the EPA.

In the proposed rule, there are many requirements where the EPA has inappropriately assumed the Commission's responsibility. For example, the EPA introduces a new term, "reasonable expectation," in place of the Commission's term, "reasonable assurance." Confidence that the U.S. Department of Energy (DOE) has or has not demonstrated compliance with the EPA's standards is the essence of NRC's licensing process, and is the Commission's responsibility. The NRC has effectively used "reasonable assurance" in licensing a variety of atomic energy activities. The reasonable assurance standard is derived from the finding the Commission is required to make under the Atomic Energy Act that the licensed activity provides "adequate protection" to the health and safety of the public; the standard has been approved by the Supreme Court. Power Reactor Development Co. v. Electrical Union, 367 U.S. 396, 407 (1961). This standard, in addition to being commonly used and accepted in the Commission's licensing activities, allows the flexibility necessary for the Commission to make judgmental distinctions with respect to quantitative data which may have large uncertainties. The NRC staff has incorporated this concept of reasonable assurance in its development of implementing regulations for Yucca Mountain (Proposed 10 CFR Part 63).

A second example is the EPA's requirement that the dose should be calculated to the "reasonably maximally exposed individual" (RMEI). The RMEI is the EPA's proposal of a technical criterion for determining whether the standard will achieve its purpose of protecting the individuals most likely to receive doses from any releases from the repository. The RMEI is untested in NRC's licensing process, and involves a matter of implementation within the NRC's statutory responsibilities. The NRC staff, consistent with the National Academy of Science (NAS) recommendations and international practice, intends to use the "average member of the critical group" approach to determine the population that should be the focus in implementation of the individual protection standard. The EPA should conform to the recommendations of the NAS and international practice by adopting the use of the "average member of the critical group." [Comments on other examples of the EPA's intrusion into implementation matters are provided in the Enclosure to this letter.]

3. The NRC staff objects to the imposition of a 0.15 mSv (15 mrem) per year individual dose limit from all pathways, because this lower dose limit will unnecessarily increase the conservatism of the dose assessment.

An annual all-pathways individual dose limit of 0.25 mSv (25 mrem) is fully protective of public health and safety and is a suitable standard for a potential repository at Yucca Mountain. The 0.25 mSv/year (25 mrem/year) limit represents a small fraction of the national and international public dose limit of 1 mSv/year (100 mrem/year) and provides a level of radiation protection that is consistent with our and EPA's regulations for related activities (e.g., low-level, high-level, and transuranic waste management, storage, and disposal; spent fuel storage and disposal). Although the EPA rule proposes a lower limit of 0.15 mSv (15 mrem), and the difference between 0.15 and 0.25 mSv (15 and 25 mrem) is small, the lower value is not necessary for protection of public health and safety and would provide little, if any, reduction in health risk when compared with 0.25 mSv (25 mrem). It is also important to consider that the average American receives approximately 3 mSv/yr (300 mrem/yr) from natural background radiation. In addition to the lack of public health and safety benefit, there are regulatory concerns associated with lowering the dose limit to 0.15 mSv (15 mrem). Specifically, as the dose limit becomes smaller, limitations in the DOE's models used for estimating performance, and the associated uncertainties in supporting analyses, become more pronounced. Further, a 0.15 mSv (15 mrem) dose limit is likely to cause unnecessary confusion for the public and cause the NRC to expend resources without a commensurate increase in public health and safety.

In addition to the above objections to provisions proposed in 40 CFR Part 197, the NRC staff also provides responses to the EPA's solicitation for input on specific questions annotated in Section IV of the "Supplementary Information" text. These responses are provided in the enclosure to this letter.

In summary, the NRC staff believes there are fundamental flaws in the proposed rule which EPA should reconsider before finalizing the rule. Moreover, many of the requirements in the proposed rule will, if included in the final rule, add significant cost and burden to the DOE license application process and significantly increase the complexity of the NRC's licensing process without a commensurate, if any, increase in the protection of public health and safety and the environment. The NRC staff will attend the EPA-sponsored public meetings on the proposed Yucca Mountain Standard and may provide further comments, if warranted.

Sincerely,

William D. Travers
Executive Director
for Operations

Enclosure: Additional Comments

cc: See attached list

Letter to S. Page from W. Travers dated: November 2, 1999

cc: R. Loux, State of Nevada
S. Frishman, State of Nevada
L. Barrett, DOE/Wash, DC
A. Brownstein, DOE/Wash, DC
S. Hanauer, DOE/Wash, DC
C. Einberg, DOE/Wash, DC
D. Shelor, DOE/Wash, DC
N. Slater, DOE/Wash, DC
R. Dyer, YMPO
S. Brocoum, YMPO
R. Clark, YMPO
A. Gil, YMPO
G. Dials, M&O
J. Bailey, M&O
D. Wilkins, M&O
M. Voegele, M&O
S. Echols, M&O
B. Price, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
D. Bechtel, Clark County, NV
E. von Tiesenhousen, Clark County, NV
J. Regan, Churchill County, NV
T. Cain, Esmeralda County, NV
L. Fiorenzi, Eureka County, NV
A. Remus, Inyo County, CA
T. Manzini, Lander County, NV
E. Culverwell, Lincoln County, NV
J. Wallis, Mineral County, NV
L. Bradshaw, Nye County, NV
M. Murphy, Nye County, NV
J. McKnight, Nye County, NV
N. Stellavato, Nye County, NV
D. Kolkman, White Pine County, NV
D. Weigel, GAO
W. Barnard, NWTRB
R. Holden, NCAI
A. Mitre, NIEC
R. Arnold, Pahrump County, NV
J. Lyznicky, AMA
R. Clark, EPA
F. Marcinowski, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI
J. Kessler, EPRI
G. McKnight, Pahrump, NV
R. Wallace, USGS
R. Craig, USGS
W. Booth, Engineering Svcs, LTD
S. Trubatch, Winston & Strawn

COMMENTS ON PROPOSED U.S. ENVIRONMENTAL PROTECTION AGENCY STANDARDS FOR YUCCA MOUNTAIN (40 CFR PART 197)

Unwarranted Specification of Implementation Criteria:

The U.S. Nuclear Regulatory Commission (NRC) staff objects to those portions of the proposed standard that address technical matters of compliance determination and implementation -- matters assigned to NRC's jurisdiction and responsibility. The NRC staff offers the following comments on specific portions of the standard that prescribe implementation and/or solicit comment on implementation:

A) Use of Reasonable Expectation

The U.S. Environmental Protection Agency (EPA) proposes to "establish minimum requirements for implementation" by requiring the NRC to use reasonable expectation as a basis for determining compliance. The NRC staff objects to the EPA's intrusion into an area of implementation related to making a license determination. The NRC has the sole licensing responsibility to determine compliance of the U.S. Department of Energy's (DOE's) license application with pertinent regulations and standards. The EPA has no authority to define how the NRC should make its licensing decision and should remove language that presumes to prescribe matters of NRC implementation.

Furthermore, the EPA incorrectly portrays how the NRC makes its licensing decisions. The EPA wrongly asserts that use of "reasonable assurance" as a basis for judging compliance would force the NRC to focus on extreme values (i.e., "tails of distributions") for representing the performance of a Yucca Mountain repository. This is not correct for the proposed repository at Yucca Mountain. Over the last several years, the Commission has clearly articulated how performance analyses are to be conducted to assist the NRC's goal of protecting health and safety. The Commission's Final Policy Statement on the "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (FRN Volume 60, Number 158, August 16, 1995) stated that use of probabilistic risk assessment (PRA), which includes performance assessment for waste management systems, should: 1) reduce unnecessary conservatism; and 2) be as realistic as practicable when supporting regulatory decisions. In particular, the NRC's proposed implementing regulation for disposal of high-level waste at Yucca Mountain (10 CFR Part 63) propounds a comparison of the average or mean dose with the individual dose limit to determine compliance. The NRC's draft Branch Technical Position on Performance Assessment for Low-Level Waste Disposal Facilities (FRN May 29, 1997, Volume 62, Number 103) also uses an average dose as the basis for comparison with the dose limit. The NRC has made it clear that it does not focus on extreme values but rather is evaluating expected doses. The EPA should remove language that incorrectly portrays the NRC's use of reasonable assurance.

B) Specification of the Reasonably Maximally Exposed Individual (RMEI)

The EPA proposes that the RMEI be used for making dose estimates and also prescribes the approach to be used for determining the diet, and specifies the water intake volume of the

RMEI. The EPA should not require use of the RMEI, but instead endorse use of the more widely-accepted critical group (CG) concept, consistent with the National Academy of Sciences (NAS) recommendations (see also the NRC staff response to the EPA's question #3). Specification of attributes or characteristics of the RMEI or how these attributes or characteristics are to be determined should not be prescribed in the standards, but left to the NRC's implementing regulation (see also NRC staff responses to EPA's questions #4, 5, and 6).

C) Specification of the Stylized Calculation for Human Intrusion

Prescription of the stylized calculation for evaluating human intrusion should not be part of the EPA standards. Specification of the stylized calculation more appropriately belongs in the NRC's implementing regulations (see also the NRC staff response to the EPA's question #10). Additionally, the standards include an alternative for evaluating human intrusion beyond 10,000 years in the event an intrusion is not likely in the initial 10,000 years. The EPA should prescribe only the standard that is to be met and should not stipulate implementation details for what constitutes compliance with the standard.

D) Request for Comment on Inclusion of Assurance Requirements

It is unnecessary for the EPA to establish additional qualitative "assurance requirements" to "add confidence that the Yucca Mountain disposal system will achieve the level of protection proposed in the quantitative standards." The degree of confidence that the NRC must have, in assessing whether the DOE's compliance demonstration satisfies applicable requirements, including the EPA disposal standards, is inherently an implementation matter for the NRC licensing requirements and licensing process to determine. Further NRC staff response to this specific request is provided later in this document.

E) Request for Comment on Inclusion of Requirements for Use of Expert Opinion

It is unnecessary for the EPA to set guidelines for the use of expert opinion in its standards for Yucca Mountain. The NRC's licensing requirements and licensing process will govern the DOE's use of expert opinion in the development of its licensing case for a repository at Yucca Mountain. Further NRC staff response to this specific request is provided later in this document.

The NRC requests that those portions of the proposed standards that address the foregoing technical matters of compliance determination and implementation be removed or, at a minimum, that they acknowledge that the NRC, as the implementing authority, is not bound by implementation details that are contained in the standards. Additionally, the section entitled, "Who Will Be Regulated by These Standards?" should: 1) properly define the EPA role in standard development; 2) accurately describe the NRC's authority to establish technical requirements that are consistent with the EPA standards; and 3) acknowledge the time constraints established by the U.S. Congress that require the NRC to promulgate its rule within one year after the EPA issues its final standards.

Responses to Specific Questions for Comment in the Proposed Standards:

Question 1: The NAS recommended that we base the individual-protection standard upon risk. Consistent with this recommendation and the statutory language of the Energy Policy Act of 1992, we are proposing a standard in terms of annual committed effective dose equivalent (CEDE) incurred by individuals. Is our rationale for this aspect of our proposal reasonable?

Answer: Yes. The individual-protection standard should be specified in terms of an annual CEDE limit. The use of an "effective" dose limit correctly accounts for the variation in risk levels associated with different organs. Not using an effective dose provides widely varying degrees of protection depending on the organ and radionuclides used in the exposure scenario.

Question 2: We are proposing an annual limit of 150 μSv [equivalent to 0.15 mSv (15 mrem)] CEDE to protect the reasonably, maximally exposed individual (RMEI) and the general public from releases from waste disposed of in the Yucca Mountain disposal system. Is our proposed standard reasonable to protect both individuals and the general public?

Answer: No. An annual all-pathways individual dose limit of 0.25 mSv (25 mrem) is fully protective of public health and safety and is a more appropriate standard for a potential repository at Yucca Mountain. The 0.25 mSv/yr (25 mrem/yr) limit represents a small fraction of the national and international public dose limit of 1.0 mSv (100 mrem/yr) and provides a level of radiation protection that is consistent with our and EPA's regulations for related activities (e.g., low-level, high-level, and transuranic waste management, storage, and disposal; spent fuel storage and disposal). Although the EPA rule proposes a lower limit of 0.15 mSv (15 mrem), and the difference between 0.15 and 0.25 mSv (15 and 25 mrem) is small, the lower value is not necessary for protection of public health and safety and would provide little, if any, reduction in health risk when compared to 0.25 mSv (25 mrem). It is also important to consider that the average American receives approximately 3 mSv/year (300 mrem/yr) from natural background radiation. In addition to the lack of public health and safety benefit, there are regulatory concerns associated with lowering the dose limit to 0.15 mSv (15 mrem). Specifically, as the dose limit becomes smaller, limitations in the DOE's models used for estimating performance, and the associated uncertainties in supporting analyses, become more pronounced. Further, a 0.15 mSv (15 mrem) dose limit is likely to cause unnecessary confusion for the public and cause the NRC to expend resources without a commensurate increase in public health and safety.

A single, all-pathway standard is protective of both individuals and the general public health when the standard is applied to a CG (i.e., those individuals in the population expected to receive the highest dose equivalent using cautious but reasonable assumptions). An annual limit of 0.25 mSv (25 mrem) applied to the average member of the CG is protective of individuals in the CG. The general

public is comprised of the individuals within the CG group as well as all other individuals residing in the Yucca Mountain area who are not part of the CG (e.g., the DOE has considered individuals living within 80 km (50 miles) of the Yucca Mountain site for evaluating population doses in the Draft Environmental Impact Statement). Individuals within the CG will have estimated doses higher (i.e., at least 3-5 times higher) than individuals outside the CG. The dose limit is protective of individuals in the CG and is also protective of individuals outside the CG for whom doses will be lower.

Question 3: To define who should be protected by the proposed individual-standard, we are proposing to use a RMEI as the representative of the rural-residential CG. Is our approach reasonable? Would it be more useful to have the DOE calculate the average dose occurring within the rural-residential CG rather than the RMEI dose?

Answer: The NRC staff endorses the NAS recommendation for use of the average member of the CG as a basis for comparison with the risk limit.

The NRC staff disagrees with the EPA's use of "a RMEI as the representative of the rural-residential CG" because: 1) it unnecessarily confuses the CG concept, recommended by the NAS, by advancing a second, less widely-used, concept (i.e., RMEI); 2) the CG concept has been accepted both internationally and nationally and thus has meaning to a wider audience than the RMEI; and 3) specification of a particular group (i.e., rural-residential RMEI) is a matter of implementation to be determined in the NRC's implementing regulation. NRC routinely employs the CG approach in its licensing actions and for other regulatory applications (e.g., as part of our LLW and Decommissioning programs). We are also aware of documented applications of the CG approach by state regulatory authorities and by regulatory authorities in the United Kingdom, Sweden, Switzerland, and Canada. The EPA should replace the "RMEI" with the "average member of the CG" and remove any reference to the particular characteristics of the CG.

Question 4: Is it reasonable to use the RMEI parameter values based upon characteristics of the population currently located in proximity to Yucca Mountain? Should we promulgate specific parameter values in addition to specifying the exposure scenarios?

Answer: The NRC staff agrees with the NAS recommendation that specification of the CG is to be based on cautious but reasonable assumptions. In doing so, it is appropriate to use present day knowledge of the habits and characteristics of the local population in the vicinity of Yucca Mountain to inform the specification of the CG.

That being said, however, the NRC staff objects to specification of parameters of the exposure scenario because they are matters of implementation that are to be determined in the NRC's implementing regulation. Additionally, detailed specification of exposure parameters at this time unnecessarily pre-judges

ongoing efforts by the DOE to collect information in the Yucca Mountain vicinity relevant to exposure scenarios.

Question 5: Is it reasonable to consider, select, and hold constant today's known and assumed attributes of the biosphere for use in projecting radiation-related effects upon the public of releases from the Yucca Mountain disposal system?

Answer: Yes. As explained in the NRC's proposed 10 CFR Part 63, it is appropriate to hold constant today's known and assumed attributes of the biosphere. Specification of assumed attributes of the biosphere is a matter of implementation that should be accomplished in the NRC's implementing regulations.

The NAS recognized the difficulties in forecasting the characteristics of future society, especially those influencing exposure, and recommended specification of exposure scenario assumptions. The NAS indicated the purpose for making the exposure scenario assumptions was to provide a framework for evaluation of repository performance and not to identify or predict possible futures.

Question 6: In determining the location of the RMEI, we considered three geographic subareas and their associated characteristics. Are there other reasonable methods or factors which we could use to change the conclusion we reached regarding the location of the RMEI? For example, should we require an assumption that for thousands of years into the future people will live only in the same locations that people do today? Please include the rationale for your suggestions.

Answer: The NAS recommended that cautious and reasonable assumptions be used in defining an assumed exposure scenario, including the compliance location. The EPA should not go beyond considerations that are cautious and reasonable. Specification of additional assumptions for determining the compliance location are unnecessary. The NRC staff recognizes that the EPA has a need to discuss who is being protected by their standard. However, specification of the exposure scenario is a matter of implementation, and specification of the compliance location should be determined in the NRC's implementing regulation.

Question 7: The NAS suggested using a negligible incremental risk level to dismiss from consideration extremely low, incremental levels of dose to individuals when considering protection of the general public. For somewhat different reasons, we are proposing to rely upon the individual-protection standard to address protection of the general population. Is this approach reasonable in the case of Yucca Mountain? If not, what is an alternative, implementable method to address collective dose and the protection of the general population?

Answer: Yes, it is reasonable to rely on an all-pathway, individual protection standard. We agree with the NAS that "a health-based individual standard will provide a reasonable standard for protection of the general public" (p. 65 of NAS report).

By definition, it will ensure that every member of the general public will not receive more than the individual dose limit and is therefore protected. Additional regulatory criteria limiting collective dose are unnecessary for the protection of public health and safety and should not be included in the final EPA standards for Yucca Mountain.

Question 8: Is our rationale for the period of compliance reasonable in light of the NAS recommendations?

Answer: Yes. A 10,000-year compliance period is reasonable for the reasons identified in the NRC's proposed criteria at 10 CFR Part 63. The fact that it is feasible to calculate performance of the engineered and geologic barriers making up the repository system, for periods much longer than 10,000 years, does not mean that it is possible to make realistic or meaningful projections of human exposure and risk, attributable to releases from the repository over comparable time frames. NAS acknowledged that projecting the behavior of human society over long periods is beyond the limits of scientific analysis and recommended that "cautious, but reasonable" assumptions, based upon current knowledge, be made with regard to the selection of biosphere and CG parameters for Yucca Mountain. Determining just how far into the future current knowledge can no longer support "reasonable" assumptions about pathways affecting human exposure is clearly a subjective, policy judgment. The NRC staff believes that, for periods approaching 1,000,000 years, as suggested by NAS, during which significant climatic and even human evolution would almost certainly occur, it is all but impossible to make useful and informed assumptions about human behaviors and exposure pathways. The NAS explicitly acknowledged that selection of a time period over which compliance should be evaluated necessarily involves both technical and policy considerations (p. 56 of NAS report). We believe sound reasons–technical, policy, and practical– support the designation of a 10,000-year compliance period for evaluating compliance with an all-pathway, individual protection standard.

Question 9: Does our requirement that the DOE and the NRC determine compliance with §197.20, based upon the mean of the distribution of the highest doses resulting from the performance assessment, adequately address uncertainties associated with performance assessments?

Answer: Although the NRC staff agrees with the use of the mean of the distribution, we object to the EPA prescription of a specific statistical parameter that the NRC must use to evaluate compliance with the standard. Specification of approaches for determining compliance, given the uncertainties associated with performance assessment, is strictly a matter of implementation that is properly addressed in the NRC's regulation.

Question 10: Is the single-borehole scenario a reasonable approach to judge the resilience of the Yucca Mountain disposal system following human intrusion? Are there other reasonable scenarios which we should consider, for example, using the

probability of drilling through a waste package based upon the area of the package versus the area of the repository footprint or drilling through an emplacement drift but not through a waste package? Why would your suggested scenario(s) be a better measure of the resilience of the Yucca Mountain disposal system than the proposed scenario?

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

Question 11: Is it reasonable to expect that the risks to future generations be no greater than the risks judged acceptable today?

Answer: Yes. The NRC staff agrees with the basic principle that individuals in the future should be afforded a level of protection from actions taken today that is comparable to that found acceptable for the current generation. The primary objective of geologic disposal of high-level radioactive wastes is the protection of current and future generations from the radiological hazards posed by the wastes produced by the current generation. The NRC has long supported the national strategy to pursue deep geologic disposal in the belief that the current generation's responsibilities to provide comparable protection to future generations are better fulfilled by pursuit of long-term disposal than by indefinite reliance on temporary storage strategies. That being said, however, the NRC acknowledges that permanent, complete isolation is unlikely to be achieved by any repository at any site, including Yucca Mountain, and that some fraction of the waste inventory can be expected to migrate to the biosphere, giving rise to potential exposures thousands, or even hundreds of thousands of years in the future. Doses and risks to individuals over these very long time frames can only be estimated, and the reliability of such estimates diminishes, the further into the future they are calculated. Because doses and risks cannot be forecast with any certainty into the indefinite future and must instead rely on cautious, but reasonable assumptions, as noted by the NAS, it is only appropriate to use such estimates to evaluate whether a proposed repository system is adequate, over a compliance period within which those assumptions continue to be reasonable. For the reasons cited or referenced in the response to Question 8, the NRC staff believes 10,000 years is an appropriate compliance period.

Question 12: What approach is appropriate for modeling the groundwater flow system down-gradient from Yucca Mountain at the scale (many kilometers to tens of kilometers) necessary for dose assessments, given the inherent limitations of characterizing the area? Is it reasonable to assume that there will be some degree of mixing with uncontaminated groundwater along the radionuclides travel paths from the repository?

Answer: Determination of the appropriate model for groundwater flow will be an important part of the NRC's review of a possible DOE license application. It is inappropriate for the EPA to prescribe any degree of belief in potential modeling approaches that could be part of the DOE's license application.

Question 13: Which approach for protecting ground water in the vicinity of Yucca Mountain is the most reasonable? Is there another approach which would be preferable and reasonably implementable? If so, please explain the approach, why it is preferable, and how it could be implemented.

Answer: Although Maximum Contaminant Levels (MCLs) may have been considered reasonable standards during their development in 1975, current understanding of the risk posed to individual organs by radiation exposure demonstrates that the MCLs for individual radionuclides provide a level of protection that varies significantly. For example, consider the annual risk of developing a fatal cancer[2] from drinking water that contains Neptunium-237 (Np-237) and Iodine-129 (I-129) at their respective MCL. The risk of developing a fatal cancer from ingestion of Np-237 at its MCL is 30 chances in 1,000,000 (3×10^{-5})[3], while the risk from ingestion of I-129 at its MCL is 0.07 chance in 1,000,000 (7×10^{-8})[4]. More than a four-hundred fold difference exists between the risk levels prescribed for these two radionuclides. Therefore, this simple comparison shows an application of MCLs that results in non-uniform risk levels which are likely to lead to greater confusion about the level of risk which is acceptable and attainable, rather than confidence that the health and safety of the public are being protected.

Certain MCLs maintain a risk level so small that the individual, all-pathway dose limit is meaningless. EPA has proposed an annual, individual dose limit of 0.15 mSv (15 mrem) which is equivalent to an annual risk of developing a fatal cancer of 9 chances in 1,000,000 (9×10^{-6}). The MCL for I-129 (annual risk of 0.07 chance in 1,000,000) is more than 100 times below the risk of the individual dose limit. Consequently, the ground-water protection criteria become the de facto standards instead of the individual protection limit called for by the EnPA.

The EPA's current proposal is a continuation of EPA's practice of using the MCLs without appropriate justification. Specifically, EPA would have NRC require that groundwater in the vicinity of Yucca Mountain meet EPA's MCL, originally established to implement the Safe Drinking Water Act (SDWA). The MCLs were based on an analysis of treating contaminated water in public drinking water systems subject to the SDWA and not on an analysis of technology and costs of remediating groundwater at actual sites. In this rule,

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[2] The annual risk of developing a fatal cancer is 60 chances in 1,000,000 (6×10^{-5}) per mSv of exposure

[3] Based on a concentration of 15 picocuries per liter.

[4] Based on a 0.04 mSv (4 mrem) exposure to the thyroid.

EPA proposes to apply the same MCLs to groundwater supplies before treatment rather than "at the tap" after treatment. Therefore, in the absence of an appropriate and comprehensive cost-benefit analysis, EPA should not require the expenditure of potentially significant amounts of taxpayer money to prevent potential contamination of groundwater that may require treatment prior to use anyway. Instead, EPA's standards should permit a decision to spend much smaller sums for water treatment in the event that such contamination should occur. Finally, EPA's application of MCLs at DOE's Waste Isolation Pilot Plant (WIPP) site in New Mexico should not be considered a precedent for the Yucca Mountain site since the WIPP site is located in a salt formation and lacks potable groundwater making the application of MCLs irrelevant.

The EPA does not demonstrate a need for such overly conservative, separate ground-water limit to protect public health and safety. The all-pathway dose limit, by definition, ensures that risks from all radionuclides and all exposure pathways, including the groundwater pathway, are acceptable and protective. All radionuclides and all exposure pathways will have to be acceptably evaluated at Yucca Mountain, and will have to meet an individual protection standard that is fully protective of public health and safety and the environment. Therefore, the proposed standard should not contain separate ground-water protection requirements because they are unnecessary for protection of public health and safety and because they lead to inconsistent and unreconcilable results as described above, which we believe will cause confusion and diminish rather than enhance public confidence that adequately protective limits have been established.

Furthermore, the NRC staff is troubled by the discussion of ground-water protection that suggests additional options that are not representative of ground-water conditions at Yucca Mountain and further increase the conservatism in applying these unnecessary separate requirements. The preamble to the standard requests comment on alternative dilution volumes that are extremely small (e.g. 10 and 120 acre-feet). These dilution volumes are not reflective of the resource to be protected (the EPA states the representative volumetric flow is 4000 acre-ft/year for the sub-basin in which the proposed repository is located). The standard also requests comment on alternative locations for determining compliance (e.g., 5 kilometers) that are similarly not reflective of the resource. As explained in connection with the compliance location for the individual protection (e.g., 20 kilometers), cautious and reasonable assumptions for lifestyles and the practicality of obtaining water provide no basis for identifying the 5 kilometer location for protection of ground water.

Is there a better approach? Yes. An individual, all-pathway dose limit of 0.25 mSv (25 mrem) total effective dose equivalent (TEDE) properly accounts for the radiation sensitivity of individual organs, and ensures the risks from all radionuclides and all exposure pathways are acceptable and protective.

Question 14: Is the 10,000-year compliance period for protecting the RMEI and groundwater reasonable or should we extend the period to the time of peak dose? If we extend it, how could the NRC reasonably implement the standards while

recognizing the nature of the uncertainties involved in projecting the performance of the disposal system over potentially extremely long periods?

Answer: Yes, 10,000 years is a reasonable time period for evaluating compliance with an all-pathway individual protection standard for the reasons stated in the answer to Question 8 (above). For reasons stated in response to Question 3, we disagree with the EPA's use of the RMEI construct. For reasons given at Question 13, inclusion of separate groundwater protection criteria is unnecessary regardless of the compliance period applied.

Question 15: As noted by the NAS, some countries have individual-protection limits higher than we have proposed. In addition, other Federal authorities have suggested individual-dose limits with no separate protection of groundwater. Therefore, we request comment upon the use of an annual CEDE of 0.25 mSv (25 mrem) with no separate groundwater protection, including the consistency of such a limit with our groundwater protection policy.

Answer: The NRC staff believes that the application of a single, all-pathway standard is fully protective of public health and safety, and obviates the need for separate, single pathway limits. The purpose of a post-closure performance objective for a repository at Yucca Mountain is to ensure that members of the public will not receive doses, from all possible sources, exclusive of background radiation, in excess of 1 milliSievert (mSv) or 100 millirem (mrem) per year. 1 mSv (100 mrem) per year is the public dose limit established by the Commission at 10 CFR Part 20 and is the radiation protection basis upon which the Commission licenses all operating nuclear facilities. A limit of 0.25 mSv (25 mrem) to the TEDE, received in a year by the average member of the CG would limit the dose received from all possible pathways to the CG at Yucca Mountain, including direct exposure, drinking of contaminated water, eating food that was irrigated with contaminated groundwater or grown in contaminated soil, exposure to airborne releases, *etc.* The Commission established the 0.25 mSv (25 mrem) annual dose limit as the overall safety objective for both decommissioning of nuclear facilities (at 10 CFR Part 20.1402) and for low-level radioactive waste disposal facilities (at 10 CFR Part 61.41). It is within the range of international constraints that allocate doses from high-level waste disposal to between 0.1 and 0.3 mSv (10 and 30 mrem) per year, and is sufficiently below the public dose limit that no members of the public near Yucca Mountain would be expected to receive doses from all sources, excluding background radiation, in excess of 1 mSv (100 mrem) per year.

We believe that recent Congressional direction and NAS guidance, provided pursuant to that direction, are germane to the setting of acceptable risk levels for radionuclides received through the ground-water pathway — the primary pathway of concern at Yucca Mountain. The 1996 Amendments to the Safe Drinking Water Act directed the EPA to withdraw drinking water standards proposed for radon in 1991, that would have established an acceptable risk level for radon (a naturally-occurring isotope, not generally regulated by the NRC) comparable to current MCLs for other radionuclides. The same amendments called for the EPA to arrange for the NAS to conduct an individual risk

assessment for radon in drinking water. Based on the results of that assessment, the EPA was further directed to develop an alternative MCL that would represent a risk comparable to that incurred from naturally-occurring radon in outdoor air. By our calculations, such an alternative MCL for a single radionuclide would correspond to an annual risk of 3.8×10^{-5} or more than twice that arising from exposure to an all-pathway, all-nuclide limit of 0.25 mSv (25 mrem) for Yucca Mountain. In view of this, and for the reason cited above and in the NRC's notice of proposed rulemaking for Part 63, we continue to believe that an all-pathway limit of 0.25 mSv (25 mrem) per year is an appropriate level of protection for a repository, a level that is consistent with national and international radiation protection practice.

Question 16: We are proposing to require, in the individual-protection standard, that the DOE must project the disposal system's performance after 10,000 years. Are the specified uses of the projections appropriate and adequate?

Answer: We agree that the NRC should not be required to use the results of the DOE's analyses of repository performance after 10,000 years. However, should the DOE elect to use results of these calculations to further support its safety case, to demonstrate the capability of individual barriers, or to justify uncertainty estimates for data supporting its compliance demonstration, the Commission should not be constrained from considering such information. For this reason we object to the wording on p. 46993, that states that "...NRC is not to use the additional analysis in determining compliance with proposed §197.20." We recommend that the EPA modify this statement to read "...NRC is not **required** to use the additional analysis in determining compliance with proposed §197.20."

Responses to Further Requests for Comment in the Proposed Standard

Question (p. 46997)

Is it appropriate for the EPA to set guidelines for the use of expert opinion in this standard and, if so, what should those guidelines be?

Answer

It is inappropriate for the EPA to set guidelines for the use of expert opinion in its standards for Yucca Mountain. The NRC's licensing requirements and licensing process will govern the DOE's use of expert opinion in the development of its licensing case for a repository at Yucca Mountain. Furthermore, the NRC has already issued guidance on this matter (see Kotra, J.P. *et al.*., NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program," 1996).

Question (p.46998)

Is it appropriate for the EPA to establish assurance requirements...and, if so, what should those requirements be?

Answer

It is inappropriate for the EPA to establish additional qualitative "assurance requirements" to "add confidence that the Yucca Mountain disposal system will achieve the level of protection proposed in the quantitative standards." The degree of confidence that the NRC must have, in assessing whether DOE's compliance demonstration satisfies the EPA disposal standards, is inherently an implementation matter for the NRC licensing requirements and licensing process to determine. As a practical matter, the NRC has already included criteria, in its proposed Part 63 regulations, that address the issues cited by the EPA as potential "assurance requirements." Two of these are matters explicitly assigned to the NRC by statute [*i.e.* Section 121(b)(1)(B) of the Nuclear Waste Policy Act specifies that the NRC criteria "shall provide for the use of a system of multiple barriers in the design of the repository and shall include such restrictions on the retrievability of the solidified high-level radioactive waste and spent fuel emplaced in the repository *as the Commission deems appropriate* (emphasis added)].

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