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Secretary
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

DOCKET NUMBER
PROPOSED RULE **PR 2, 19, 20 et al.**
(64FR8640)

Attention: Rulemakings and Adjudications Staff

SUBJECT: Nuclear Energy Institute (NEI) comments on Proposed 10 CFR Part 63

The Nuclear Energy Institute (NEI),¹ on behalf of the nuclear energy industry, is pleased to submit these comments to the Nuclear Regulatory Commission (NRC) on the proposed 10 CFR Part 63 rulemaking, *Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada*, (64 Fed. Reg. 8,640 - February 22, 1999)

The industry commends the NRC for its leadership in carrying out its responsibilities under the Nuclear Waste Policy Act of 1982 by proposing licensing criteria for a geologic repository at Yucca Mountain (10 CFR Part 63). The proposed rule constitutes an essential piece of a regulatory framework that is urgently needed in order for the nation to safely and responsibly address the disposal of spent nuclear fuel and high level radioactive waste. We compliment the NRC not just for taking action, but for the general direction taken by the draft rule. The proposed 10 CFR Part 63 is appropriately risk- and performance-based standard and once finalized will, provide an effective platform for assuring adequate protection of public health and safety.

NEI, along with the Electric Power Research Institute (EPRI), has extensively reviewed this proposal. We appreciate having had the opportunity to discuss this review with the NRC technical staff in a public meeting on March 15. Our overall conclusion is that the proposed 10 CFR Part 63 appropriately carries out the 1995 recommendations of the National Academy of Sciences "*Technical Bases for Yucca Mountain Standards*" report. We endorse this approach and offer a number of specific proposals for further strengthening the rule. Our comments are enclosed.

Acknowledged by card JUL - 7 1999

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

In summary, our comments:

- Emphasize the importance of maintaining the current **schedule** for this rulemaking
- Recommend **legislative-type hearings** for repository licensing
- Endorse the proposal's **risk-based approach**
- Endorse the absence of **subsystem requirements** in the proposal
[note: an EPA **groundwater standard** would be a major subsystem requirement]
- Recommend the following ***improvements***
 - ⇒ The 25 mrem **post-closure "expected annual dose" performance objective**, is appropriate. The defensibility of this limit should be bolstered by adding a limit of 100 mrem on the 95th percentile of the probabilistic dose distribution and emphasizing the need for transparency in the licensee's safety case.
 - ⇒ The **specified biosphere and receptor characteristics** should balance conservatism in the specified critical group by also considering effects on broader populations and should be limited to current climate conditions (consistent with the existing limitation on present day behavior)
 - ⇒ A **multistage licensing process** that allows consideration for a license application for part of a repository, including early use authorization for the surface facility, should be provided for. The level to which post closure repository performance must be addressed at each stage should be defined.
- Recommend the following ***changes***
 - ⇒ The performance objective for **human intrusion** should be specified as a design basis event scenario
 - ⇒ The specified requirements for **performance confirmation** should be made less prescriptive
- Recommend the following ***clarifications***
 - ⇒ Requirements for **construction records, tests** should be modified to avoid conflicts with the design integrity of the repository
 - ⇒ Consideration of **design alternatives** in performance assessment should be limited to present day technology
 - ⇒ The **conditions of license** need not specify 70,000 MTU limit as that is already specified by the NWPA

Secretary
U.S. Nuclear Regulatory Commission
June 30, 1999
Page 3

NEI believes that these recommended changes will help strengthen this proposed regulation, which is an essential component of a credible program to meet the United States's high-level nuclear waste disposal needs.

NEI looks forward to continuing our dialogue with the NRC on the Part 63 rulemaking. We would be pleased to address any questions the NRC may have on our comments.

Sincerely,



Steven P. Kraft

Enclosure

cc: The Honorable Shirley A. Jackson, Chairman, NRC
The Honorable Greta J. Dicus, Commissioner, NRC
The Honorable Nils J. Diaz, Commissioner, NRC
The Honorable Edward McGaffigan Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
Dr. William Travers, Executive Director for Operations, NRC
Mr. Frank Miraglia, Jr., Deputy Executive Director for Operations, NRC
Dr. Carl Papariello, Director, NMSS, NRC

The Honorable Jared Cohen, Chairman, NWTRB
Dr. William Barnard, Executive Director, NWTRB

Dr. John Garrick, Chairman, ACNW
Mr. Richard Major, ACNW Staff

Mr. Lake H. Barret, Acting Director

ENCLOSURE

NUCLEAR ENERGY INSTITUTE (NEI) COMMENTS ON PROPOSED 10 CFR PART 63 DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A PROPOSED GEOLOGICAL REPOSITORY AT YUCCA MOUNTAIN, NEVADA

I. Timing of issuance of the rule

The Nuclear Energy Institute (NEI) endorses the Nuclear Regulatory Commission's (NRC) decision to move forward with 10 CFR Part 63 at this time. We believe that issuance of this rule as final is necessary to support a licensing process in which the Department of Energy (DOE) would be able to submit a license application in 2002 and begin waste emplacement by 2010 (as called for in DOE's *Viability Assessment of a Repository at Yucca Mountain*). The regulatory certainty established by promulgation of this rule is a vital prerequisite to the completion of repository design work that must be completed in advance of a 2002 license application submittal. We emphasize the importance of adhering to the NRC's schedule.

II. Hearing Process

NEI welcomes the NRC's study of a less formal, legislative-style, hearing process as mentioned in the Supplementary Information (Section I, *Background*) to the proposed rule. We believe that the application of a legislative-style hearing procedure in the Yucca Mountain licensing process is both necessary and appropriate.

NEI fully supports the NRC's "broader efforts" to consider such a change across the full scope of NRC licensing proceedings, including repository licensing. However, we do not believe that a decision on adopting a less formal procedure for repository licensing should be tied to the generic question of whether or not to revise the overall hearing process. We recommend that the statement made in this proposal that, "the Commission is inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste" be acted on in advance of the coming Yucca Mountain license application. Accordingly, we believe that the NRC should move forward immediately to propose such additional rulemaking as would be necessary to establish a legislative-style hearing process specifically for repository licensing.

The extensive level of scientific inquiry that must be made to support a credible licensing decision on Yucca Mountain can best be carried out in a less formal setting that provides for discussion of extensive scientific information. We agree with the assertion made in the proposed rule that the NRC already has the statutory authority to implement this concept. These principles are elaborated on further in the following paragraphs.

The need for effective scientific inquiry

As a matter of policy, formal, trial-type, adjudicatory proceedings – with the right to present and rebut evidence, and cross-examine witnesses – are poorly suited to the task of reaching a decision on complex technical and scientific issues. When honest, intellectual disagreements among scientists and engineers are removed from the world of objective inquiry and thrust into an adjudicatory arena, the very nature of the investigation will undergo a substantive change. The result can be that a methodical application of scientific principles and enlightened debate degenerates into a full-blown trial to find out who is “telling the truth.” Such an outcome would be especially problematic at Yucca Mountain, where science is being employed to objectively address matters that include both studies of events that occurred several centuries in the past and projections about events that may occur several centuries in the future.

A legislative-style hearing process is well suited to provide for an exchange of scientific evidence and testimony in support of a reasonable decision for Yucca Mountain. It will allow both those who are working to demonstrate the safety of the repository and those who are challenging such work to more openly communicate the rationale for their arguments. Scientific knowledge would then not have to be reshaped into a form prescribed by the rules of adjudicatory process and could be viewed on its own merits. The regulator will then have a much more coherent body of facts and opinions upon which to make a decision based on science - which, as emphasized repeatedly by Secretary of Energy Richardson, is what is required for Yucca Mountain.

Legislative-style hearings would provide a logical follow-on to the technical dialogue that has already been established ahead of the licensing process through the use of external peer review. The NRC pre-licensing process for Yucca Mountain, defined in the “*Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions*” dated November 16, 1998, is already being effectively applied to facilitate this dialogue. In NUREG-1297, “Peer Review for High-Level Nuclear Waste Repositories” (Feb. 1988), the NRC has documented a proven and effective way to deal with resolving complex technical and scientific issues

through scientific inquiry. This NUREG was adopted and formally codified by EPA for WIPP (see 40 CFR 194.27, "Peer Review"), and was implemented successfully by DOE at WIPP.

Legal basis for legislative-type hearings

The Supplementary Information (Section I, *Background*) to the proposed rule states that "No statute requires formal hearings in either case (construction authorization or license)". NEI supports this conclusion and we urge the adoption of an informal process by the Commission in conjunction with this rulemaking.

Nothing in the Nuclear Waste Policy Act (NWPAA) or Atomic Energy Act (AEA) requires a trial-type adjudicatory hearing. Section 114(d) of the NWPAA simply calls for the NRC to "consider an application for a construction authorization for all or part of a repository in accordance with laws applicable to such applications" (42 U.S.C. 10134(d)). In this regard, Congress provides for a "hearing" but does not require a formal adjudicatory determination.

Had Congress intended to require formal adjudicatory NRC hearings, it would have so stated. This principle has been upheld in the courts on numerous occasions. (See e.g. *United States v. Florida East Coast Railway Company*, 410 U.S. 224, 234-8 (1973); *Chemical Waste Management v. EPA*, 873 F. 2d 1477, 1480 (D.C. Cir. 1989); *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 757 (1972) citing *Siegel v. AEC*, 400 F.2d 778, 785 (D.C. Cir. 1968).

Section 189 of the Atomic Energy Act (AEA), which provides for "a hearing upon the request of any person whose interest may be affected by the proceeding," contains no requirement for a formal adjudicatory proceeding. (42 U.S.C. 2239(a)). Section 181 of the AEA provides that the Administrative Procedure Act is applicable to all actions taken by the agency under the Atomic Energy Act. Section 5 of the Administrative Procedure Act (5 USC 554) requires formal adjudicatory hearings only where "required by statute," which is clearly not the case for repository licensing.

The Commission has previously considered these requirements (*Kerr McGee Corporation* (West Chicago Rare Earth's Facility), CLI-82-2, 15 NRC 232, 253 (1982) and concluded "that the hearing requirement of (Section) 189a...should not be interpreted to hamstring the Commission into providing a [Section] 554 hearing in every licensing case." The NRC's discretion to determine when to use formal or less formal hearings, with respect to nuclear power plant licensing under part 52, is now codified in

10 CFR 52.103(d). The NRC's use of such discretion has been upheld by the courts (*Nuclear Information and Resource Service v. NRC*, 969 F.2d 1169, 1173 (D.C. Cir. 1992) and *Kelly v. Selin*, 42 F.3d 1501 (6th Cir. 1995)). Finally, the Energy Policy Act of 1992 amended the Atomic Energy Act (Section 189a.(1)(B)(iv)) to provide specifically that the Commission should determine "in its discretion" whether "informal or formal adjudicatory hearing procedures" should be used in a hearing on whether a licensee issued a combined construction permit and operating license has complied with the acceptance criteria of the license.

Relationship to other licensing processes

Legislative-style hearings for Yucca Mountain would also be highly compatible with recent changes to 10 CFR Part 2, which established an Internet-based Licensing Support Network to improve access to licensing information for all interested parties. Enhanced access to information and informal hearings should work hand in hand to facilitate an effective scientific dialogue on Yucca Mountain licensing.

In conclusion, legislative-style hearings are currently being used effectively in NRC licensing proceedings. This type of hearing process is the most effective way to publicly discuss and scrutinize the extensive and complex scientific and technical information related to repository licensing. A sound foundation of legal precedent exists for NRC to institute legislative-style hearings for repository licensing. It is recommended that NRC initiate action to ensure that such a hearing process is included in Part 63 to support the current Yucca Mountain licensing schedule.

III. Expected Dose and Post Closure Dose Limit (§ 63.113)

NEI strongly supports the risk-based standard proposed by NRC - a standard that specifies the use of probabilistic calculations to demonstrate compliance with dose criteria. This proposal is an appropriate extension of the "risk-informed" approaches now being applied elsewhere in NRC regulations. We believe that a risk-based regulation is the most credible, effective, and implementable means of assuring adequate protection of public health and safety at Yucca Mountain over future millennia. The proposed rule is an excellent example of the regulatory philosophy outlined in the Commission's recent policy statement entitled (*Risk-Informed and Performance-Based Regulation*, NRC (1999))

NEI further supports the 25 mrem limit for "expected annual dose" as an appropriately conservative measure to assure that "above background" annual radiation exposures to the public in the vicinity of Yucca Mountain

are maintained below the internationally accepted radiation protection threshold of 100 mrem. We also endorse the concept of using the mean of the calculated dose distribution, rather than the mode or median. The mean of the calculated dose distribution should provide a reasonable degree of conservatism.

However, the single probabilistic limit proposed by the NRC does not consider directly the shape of the distribution. Therefore, this limit by itself may not be sufficient to demonstrate a reasonable level of assurance that sufficient conservatism does, in fact, exist, unless the nature of the distribution of resultant doses from which it was derived is also communicated. This is because it is statistically possible to have an infinite number of different probabilistic distributions that result in the same mean.

We recommend two modifications to the fundamental risk-based approach proposed in Part 63, as discussed in more detail below.

Revision of the performance objective to include a second constraint on the upper end of the dose distribution (§ 63.113)

The performance objective should be restated to require that the expected annual dose shall not exceed 25 mrem and the 95th percentile of the distribution shall not exceed 100 mrem. This would provide additional confidence (beyond that gained by simply setting a conservatively lower limit on the mean) that the fundamental radiation protection objective (no more than 100 mrem above background) would be met.

The EPA, in 40 CFR Part 191, required the use of a complimentary cumulative distribution function (CCDF) to describe the complete uncertainty distribution of cumulative releases from the WIPP facility. In practice, however, EPA really used only two points of the distribution for compliance purposes. These were intended to be at the upper end of the distribution. This is reasonable since it is usually just the upper end of the distribution (scenarios or events with high potential consequence) that are of primary regulatory concern. EPA limited the cumulative release from a HLW or TRU waste repository by only allowing a certain probability that the specified cumulative release could be exceeded. The second cumulative release limit in Part 191 allowed for a higher cumulative release, but only if the probability of the higher release was significantly lower than that for the lower release level.

The International Commission on Radiological Protection (ICRP), in their guidance document *"Radiation Protection Principles for the Disposal of Solid Radioactive Waste"* (ICRP 46 (1985)), also suggests a constraint on

health risk in a form such that successively higher estimated health risks are acceptable only if the probabilities of obtaining those higher health risks are successively lower. A similar approach could be adopted in Part 63. The recommendation made here is similar in approach to the risk-based approach in 40 CFR Part 191 and ICRP 46.

Given that the primary radiation protection objective is 100 mrem/year (upon which the 25 mrem/yr is the dose apportioned by NRC to a single source), 100 mrem/yr would make a reasonable upper risk target /compliance point. The 95th percentile of the distribution would make a reasonable point with which to associate the 100 mrem/yr radiation protection threshold. This allows only a small chance that the actual dose rate would exceed a level approximately equivalent to that of natural background ($\sim 10^2$ mrem/yr). Choosing a percentile higher than the 95th for this second constraint would not be appropriate since the remaining few percentiles of the distribution are shaped purely by low consequence scenarios for which the probabilities themselves are generally exceedingly low.

Emphasis on the need for transparency of the probabilistic safety case

NEI recognizes the need for NRC to have a thorough understanding of the meaning of and quantitative influences on the final dose assessment DOE will provide for compliance purposes. Accordingly, we endorse the requirements found throughout Part 63 that: all relevant Features, Events, and Processes (FEPs) need to be described; all relevant conceptual model(s) must be considered; and the choice of final conceptual models and the parameter distributions to support those models must be defended. The criteria in both 40 CFR Part 194 (the EPA implementing regulation for WIPP) and in Part 63 requiring documentation of plausible alternative conceptual models is an appropriate means of addressing conceptual model uncertainty, providing this information allows an assessment of the potential effect of these alternatives on calculated results. We also endorse the Part 63 requirements to conduct various supporting analyses (e.g., sensitivity studies) that will shed further light on the impact of various systems, models, and parameter distributions on the assessed doses.

In the case of the WIPP analyses, DOE used a structured approach to deriving scenarios through the screening of FEP lists according to pre-defined criteria. Although not widely used at the time the DOE first adopted it for WIPP, this approach is now widely recognized in the international community as an appropriate means of establishing traceability and transparency. A similar approach for Yucca Mountain would allow

DOE to provide some of the needed traceability and transparency to support the final compliance analyses.

Furthermore, we echo the words of Advisory Committee on Nuclear Waste chairman John Garrick who, in appearing before the Commission on March 17, 1999, called for a "plain English" version of the Yucca Mountain performance assessment. It is critical that the public, who are concerned about these risks, be able to understand how they have been evaluated. We therefore urge the NRC to take every opportunity to encourage clarity and effective communication on this risk-based approach in its future regulatory actions concerning Yucca Mountain. It is particularly important that any guidance issued related to this aspect of the proposed rule address this communications issue.

IV. Specified Biosphere and Receptor Characteristics (§ 63.115)

NEI endorses the concept of a specified biosphere based on current conditions in the vicinity of Yucca Mountain. Furthermore, we agree that exposure group characteristics should be based on present-day behavior in the vicinity of the Yucca Mountain site. We endorse the need to fully define the characteristics of the exposure group (the hypothetical group of individuals for whom dose or health risk calculations are performed), and strongly recommend that the proposed 'critical group' characteristics be based on assumptions that are specifically applicable for the Yucca Mountain site. Because human behavior and the nature of the biosphere in which humans live are coupled (that is, one influences the other), the proposed rule should also limit consideration of the characteristics of the biosphere system to that of the present day. The discussion in the following paragraphs is intended to lend constructive reinforcement and improved consistency to NRC's proposed approach.

Support for use of "present day behavior"

In the Supplementary Information to the proposed rule (Section IV, *Reference Biosphere and Critical Group for Yucca Mountain*) the NRC has provided a thorough and valid basis for limiting consideration of human behavior to the present day. Since future human behavior is speculative, it is indeed appropriate to limit speculation to that of present-day behavior. There exists considerable support for this approach. The risks to future human generations due to disposal of radioactive waste should be limited to levels tolerated by present-day human society (see, for example, *The Principles of Radioactive Waste Management*. Safety Series No. 111-F. IAEA (1995)). It is only possible to determine if this general limit has been attained by making the assumption in the performance assessment

that future individuals have the same behavior as those today. *Guidance on the Definition of Critical and Other Hypothetical Exposed Groups for Solid Radioactive Waste Disposal*. BIOMASS Working Document No. 3, (IAEA (1999)). Finally, using present-day behavior similar to people currently living in the vicinity of the proposed repository has the advantage of providing additional confidence to the local community, (IAEA (1999)).

Concern regarding assumptions in the specified "critical group"

The National Academy of Sciences (NAS) emphasized (p. 52 "*Technical Bases for Yucca Mountain Standards*") (NAS (1995)) the importance of establishing the critical group on the basis of "cautious, but reasonable assumptions". NEI's belief that the proposed 'critical group' may not fully reflect this methodology is broadly supported by current thinking in the radiation protection science community. While the concept of a critical group is in common use (IAEA (1999)), guidance from the ICRP states that a regulator should consider more than just dose/health risk to the average individual in the critical group. *Radiological Protection Policy for the Disposal of Radioactive Waste*, ICRP Publication 77, Annals of the ICRP, Vol 27, Supplement 1997 (ICRP (1998)). In reflecting on the potential utility of collective dose to inform decision making, ICRP (1998) implies that it can be appropriate to consider the likely distribution of exposures that could occur in the future. Such thinking, related to the potential distribution of individual exposures, is, for example, also supported by the general guidance in national regulations of Finland on solid waste disposal, *General Regulations for the Safety of the Disposal of Spent Nuclear Fuel into Bedrock*, Finnish Radiation and Nuclear Safety Authority, June 1998 (STUK (1998)). It is therefore useful to reflect on how the assumptions adopted as a basis for quantitative calculations for individual dose relate to such a distribution.

As a general rule, it can be anticipated that there will be a relatively small group who, because of their location in the immediate vicinity of the potential discharge and/or their habits, could receive greater exposures as a result of future potential releases than the rest of the population. There may also be a somewhat larger group of people in the locality who could receive larger individual doses than those living further away. Finally, the vast majority of the hypothetical population may be expected to receive very little or no exposure. A middle ground between the critical group and collective dose approaches is the concept of a local population dose distribution, which may provide additional insight to the regulators and public. This concept was originally proposed by the BIOMOVs II Reference Biospheres Working Group. *Development of a Reference Biospheres Methodology for Radioactive Waste Disposal*, BIOMOVs II Techni-

cal Report No.6, Published on behalf of the BIOMOVs II Steering Committee by the Swedish Radiation Protection Institute, Stockholm (BIOMOVs II (1996)). It calls for estimating the *distribution* of annual or lifetime individual doses or health risks to the hypothetical population only in the vicinity of the radioactive waste disposal site. Such an approach avoids having to calculate minuscule doses to individuals located large distances from the site, yet provides some insight regarding the relationship between the doses/risks to the critical group and that of the larger local hypothetical population. This will provide insight, for example, on the level of conservatism of the critical group limit, and the effect of the characteristics of the geosphere/biosphere interface on dose/risk distribution.

The reason why consideration of exposure groups other than just a 'critical' group is important for the Yucca Mountain system is the likelihood of even a handful of individuals having *all* of the characteristics of the critical group as defined in the proposed rule is very small. This is because they are assumed to be located at the closest reasonable distance to the repository; they are located directly over the contaminant plume; they withdraw water from the highest concentration within that plume; they use the contaminated water for *all* of their nutritional needs (i.e., irrigating crops and livestock, and using it for all drinking, cooking, and bathing); and they breathe the dust from the soil irrigated with the contaminated water. Consistent with the risk based nature of the proposed rule, consideration should be given to not only the critical group dose, but also the likelihood (i.e. probability) that the hypothetical critical group represents even a handful of individuals. Because the number of individuals who might actually be members of the critical group can not be known, such consideration would be useful in evaluating the overall protectiveness of the critical group approach.

Therefore, we recommend an approach that makes use of information on the local population dose distribution like that described in Annex C of IAEA (1999). Such an approach not only provides information about the 'critical group' dose, but also puts such a dose in context by indicating the relative number of people receiving such a dose compared to doses received by the majority of the hypothetical local population. Such additional information would provide much needed regulatory insight. This insight would add value to the regulatory decision-making process.

We recommend the following changes (in italics) to § 63.102 to provide for this information to be considered in the licensing of Yucca Mountain:

§ 63.102 Concepts

(i) Reference biosphere, critical group, *and the local population dose distribution.* The performance assessment will estimate the amount of radioactive material released to water or air at various locations and times in the future. To estimate the potential for future human exposures resulting from release of radioactive material from a geologic repository at Yucca Mountain, it is necessary to make certain assumptions about the distribution, location and characteristics of the *hypothetical local population assumed to be located in the vicinity of Yucca Mountain.* *This hypothetical local population also includes the critical group.* The environment inhabited by the *hypothetical local population* and the critical group, along with associated human exposure pathways and dose assessment parameters, make up the reference biosphere. The critical group is selected to represent those persons in the vicinity of Yucca Mountain who are reasonably expected to receive the greatest exposure to radioactive material released from a geologic repository at Yucca Mountain. *In addition to information about the dose to the critical group, the distribution in doses to the local population, including an estimate of the number of persons exposed at a given level, will be provided to facilitate an assessment of the overall conservatism of the critical group approach.* *As such, the extent of the local population to be considered will be sufficiently large to allow estimates to be made of hypothetical individual dose within a few orders of magnitude of that of the critical group.* Characteristics of the reference biosphere, the local population, and the critical group are to be based on current human behavior and biospheric conditions in the region."

Also, we would propose the following definition changes to § 63.2:

add

Local population means the hypothetical group of adult individuals within the vicinity of Yucca Mountain reasonably expected to receive among the greatest exposure to radioactive materials released from the geologic repository (highest few orders of magnitude within the local population). Characteristics of the local population considered relevant for estimating the local population dose distribution are: (1) location relative to the estimated contaminant plume(s); (2) likelihood that a well penetrating into the aquifer used for drinking and/or other agricultural purposes is developed within the estimated contaminant plume(s); and (3) distribution of individual habits including: (a) eating habits (including variations in both the type and amount of food consumption); (b) fraction of food consumed from local sources; and (c) fraction of the time spent in the Yucca Mountain vicinity

and modify

Critical group means the hypothetical group of individuals within the local population reasonably expected to receive the greatest exposure (the highest order of magnitude) to radioactive materials released from the geologic repository

This approach would be based upon and consistent with the findings and recommendations contained in the NAS report (NAS 1995). In addition, application of such information should prove illuminating in regards to the high degree of conservatism inherent in the proposed critical group approach. The regulatory insight gained would provide a balanced perspective from which speculative arguments challenging the conservatism of any single aspect of the critical group may be evaluated in light of the overall conservatism of the construct.

Concern regarding consideration of future climates

The present-day biosphere in the Yucca Mountain region is termed 'arid'. In the 'Supplementary Information' section of the proposed rule NRC

notes: "The change from arid to semiarid conditions is not expected to alter the biosphere sufficiently to cause major changes in the potential exposure pathways to the critical group." NRC recognizes that future human behavior is speculative, so that NRC must define a set of future human characteristics that are based on behavior relevant to the arid site. It is not clear that there are large differences in human behavior in 'arid' versus 'semi-arid' environments. Thus, it is not evident what additional regulatory assurance is to be gained by requiring consideration of an alternate biosphere for Yucca Mountain (semi-arid), because it would *not* cause major pathway changes. Thus, we recommend that NRC eliminate proposed requirements to consider both biosphere change and climate evolution effects on the biosphere, because they will not provide any additional insight pertinent to the regulatory evaluation required. This can be accomplished by deleting § 63.115(a)(3) and revising § 63.115(a)(2) to read as follows:

§ 63.115 Required Characteristics of the reference biosphere and critical group

(a)(2) Biosphere pathways shall be consistent with *current climate* conditions.

V. Human Intrusion (§ 63.113(d))

The proposed rule requires a consequence analysis of a human intrusion scenario occurring "100 years after permanent closure" and taking "the form of a drilling event that results in a single, nearly vertical borehole that penetrates a waste package, extends to the saturated zone, and is not adequately sealed." The analysis would be separate from the performance assessment otherwise required to evaluate the repository but identical to that assessment in that it would be subject to the same dose limit which is that "the expected annual dose to the average member of the critical group shall not exceed 0.25 mSv(25 mrem) TEDE (Total Effective Dose Equivalent) at any time during the first 10,000 years after permanent closure, as a result of radioactive materials released from the geologic repository." However this scenario is inappropriate and should be modified.

The proposed scenario is not consistent with the National Academy of Sciences recommendation (p. 113 of NAS (1995)) that "the conditional risk as a result of the assumed intrusion scenario should be no greater than the risk levels that would be acceptable for the undisturbed repository case". The scenario's direct substitution of "dose limit" for "risk limit", without application of probability in the determination of dose (contrary to what

has been done elsewhere in the standard), results in a misapplication of the NAS concept.

The proposed stylized scenario is a credible effort to bound the potential consequences of possible human intrusion. However, it is not appropriate to compare the results of bounding analyses with the same "expected dose" consequences that are appropriate for probabilistic analyses. There is no reason at all to believe that human intrusion could occur as early as 100 years after closure. Institutional controls should last at least that long (they have in the past). If they fail, societal memory should still exist. If it doesn't, the likelihood that anyone would go to the top of a mountain to drill for anything is small. Even if they did, given the ratio of repository surface area to canister surface area, the chances are small that they would hit a canister, and they would most likely cease drilling once they initially made contact. Because the probability of such unlikely happenings can not be quantified, a stylized scenario is called for as recommended by NAS (1995). However, because risk is a function of both probability and consequence, any analyses constructed without accounting for probability must also apply some amount of judgment to what constitutes an acceptable consequence in order to provide a meaningful assessment of risk.

The NRC's judgment with respect to human intrusion should be guided by the same logic that has guided licensing requirements concerning design basis events throughout NRC regulations, including the pre-closure performance objectives in § 63.111. Such logic sets higher consequence limits for those things that are not expected to occur, but must be evaluated in order to provide assurance that the worst case is known and bounded (design basis events) than for those things expected to occur (normal operations). Failure of waste packages over time and the eventual leakage of radioisotopes into the biosphere is, from a regulatory perspective, an "expected" occurrence for a repository that must "operate" over several thousand years. In contrast, human intrusion only 100 years after closure may be bounding but would certainly not be "expected," even if possible. Accordingly, we recommend that the NRC revise its requirements for analysis of human intrusion in § 63.113(d) to treat this post-closure scenario in a manner analogous to the way pre-closure Category 2 design basis events are treated in § 63.111.

In making its recommendations on the conditional risk of human intrusion, the NAS also recognized that "because the assumed intrusion scenario is arbitrary and the probability of its occurrence cannot be assessed, the result of the analysis should not be integrated into an assessment of repository performance based on risk, but rather should be considered separately" (NAS (1995) p 109). The Design Basis Event (DBE) approach

recommended above is the most credible way to evaluate human intrusion outside of the context of the overall risk assessment and still determine an equivalent conditional risk. The DBE approach would also provide an effective measure for determining whether or not repository performance would be substantially degraded by human intrusion, which was the underlying reason for this NAS recommendation.

"Equivalent conditional risk" and "same resultant dose" are not interchangeable concepts. In establishing the same dose limit for Human Intrusion and the overall performance assessment, what substantively results is not a "separate" consideration of human intrusion but an inclusion of human intrusion into the risk assessment (albeit in a different part of the analysis) with an assumed probability of 1 at 100 years. This is neither reasonable, necessary, nor consistent with the intent of the NAS recommendations. The strong regulatory precedent already existing for deterministic design basis event analysis makes such undue pessimism unnecessary. Categorizing human intrusion as a design basis event, with consequence limits appropriately set above "expected dose" requirements, would free the NRC from the need to speculate on when human intrusion might be likely to occur.

VI. Multistage Licensing (§§ 63.31, 63.32, 63.41, 63.101, 63.102, & 63.111)

The proposed rule specifies a three stage licensing process (Construction, Operation, & Closure). We recommend that these provisions be refined to more explicitly describe what takes place at each stage. The recommended changes, described in the following paragraphs, will allow the licensing decision-making process to move forward in sequence with the likely progress of the repository program.

Provision for consideration of license application for part of a repository

Part 63 should more specifically provide for licensing of not only all, but part of, a repository, consistent with Section 114(d) of the NWPA (42 U.S.C. § 10134(d)). While nothing in the proposed rule precludes such licensing, it would be useful if the final regulation more clearly recognized the availability of such an approach. This could be done as follows:

§ 63.31 Construction authorization.

On review and consideration of an application and environmental impact statement submitted under this part, the Commission

may authorize construction of *all or part of* a geologic repository operations area *and/or early use of the surface facilities* at the Yucca Mountain site if it determines

and

§ 63.32 Conditions of construction authorization.

(a) A construction authorization for *all or part of* a geologic repository operations area *and/or early use authorization for the surface facilities* at the Yucca Mountain site shall include such conditions as the Commission finds to be necessary to protect the health and safety of the public, the common defense and security, or environmental values. . . .

Also, the term "substantially completed" construction in § 63.41 should be applied to that part of the repository for which license is issued, such as the surface facilities for early use.

Level to which post closure performance must be addressed at various stages of licensing

In addition, the regulation should address the level to which post-closure repository performance must be considered at various licensing stages. Repository development will naturally proceed in stages (*i.e.*, construction, operation, and permanent closure), with increasingly detailed information about repository design and long-term performance becoming available at each point. As long ago as 1979, in proposing 10 CFR Part 60, the NRC, itself, noted that, with each licensing stage, there will be a progressive increase in knowledge regarding repository features and a corresponding increase in the confidence with which a decision can be made concerning whether or not waste can be disposed of safely at the repository site. (44 Fed. Reg. 70,408.) The NRC has also noted that, because it believed that knowledge of expected repository performance could be substantially increased through a carefully planned program of testing during the period of repository operation, it wished to base its decision on permanent closure on such information. (48 Fed. Reg. 28,194 (final rule).)

Part 60, itself, reflects the NRC's anticipation that there will be gaps and uncertainties associated with information available at various licensing

stages. (e.g., 10 CFR §§ 60.24(b), 60.101(a)(2).) However, to facilitate the licensing process, Part 63 should more specifically address the staged nature of the licensing program. In particular, the Staff should address the specific level to which post-closure performance must be considered at each stage taking into account the state of knowledge and what can be known at the time of each licensing state. In addition, the regulation should provide for on-going programs of monitoring and testing to improve information.

More explicit recognition of the naturally staged character of repository licensing will result in a clearer, more effective process. The concepts discussed above may be accommodated by adding the language shown below in italics.

§ 63.31 Construction authorization.

(a) Safety. That there is reasonable assurance, *taking into account the scope of the authorization requested and information available*, that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to health and safety of the public. . . .

(b) Common defense and security: That there is reasonable assurance, *taking into account the scope of the authorization requested and information reasonably available*, that the activities proposed in the application will not be inimical to the common defense and security. . . .

§ 63.41 Standards for Issuance of a license.

(c) *Based on information reasonably available*, the issuance of the license will not be inimical to the common defense and security and will not constitute an unreasonable risk to the health and safety of the public. . . .

§ 63.101 Purpose and nature of findings.

(a)(1) Subpart B of this part prescribes the standards for issuance of a license to receive and pos-

sess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that, *based on information reasonably available*, the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. . . .

(b) Subpart B of this part also lists findings that must be made in support of an authorization to construct *all or part of* a geologic repository operations area at the Yucca Mountain site. In particular, § 63.31(a) requires a finding that *taking into account the scope of the authorization requested and information reasonably available*, there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and disposed of in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. . . .

§ 63.102 Concepts

This section provides a functional overview of this Subpart E. . . .

(c) Stages in the licensing process. There are several stages in the licensing process. *At each stage there will be gaps and uncertainties in information pertinent to performance. It is expected that DOE will provide for on-going programs of testing and monitoring to gather information and reduce gaps and uncertainties as the next stage is reached.* . . .

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(e) Retrievability of waste. (1) The geologic repository operations area shall be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter, until the completion of a performance

confirmation program and Commission review of the information obtained from such a program. To satisfy this objective, the geologic repository operations area shall be designed so that any or all of the emplaced waste could be retrieved on a reasonable schedule starting at any time up to 50 years after waste emplacement operations are initiated, unless a different time period *is requested by DOE and is approved or specified by the Commission*. This different time period may be established *and extended* on a case-by-case basis consistent with the emplacement schedule and the planned performance confirmation program.

Finality of decision at each of the various stages of licensing

Part 63 should provide for appropriate finality in the resolution of issues at each stage of licensing. Reconsideration of issues that have been satisfactorily resolved is not only unnecessary, but a waste of resources that could be either conserved or better expended elsewhere. Once an issue has been resolved at one stage, it should remain closed to further inquiry in subsequent stages in the absence of a showing that new information calls into question the earlier NRC finding that public health and safety and the environment would be adequately protected. Appropriate finality could be provided by adding the language shown below in italics.

§ 63.41 Standards for Issuance of a license.

In making the findings required for issuing a license to receive and possess source, special nuclear or by-product material at a geologic repository operations area at the Yucca Mountain site, the Commission shall treat as resolved those matters resolved in connection with the issuance of a construction authorization, except in the case of substantial new information sufficient to call into question the prior determination of adequate protection of the public health and safety, common defense and security, and environment. A license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site may be issued by the Commission on finding that:

§ 63.51 License amendment for permanent closure.

(c) In making the findings required for issuing a license amendment for permanent closure the Commission shall treat as resolved those matters resolved in connection with the issuance of a license to receive and possess source, special nuclear or by-product material at a geologic repository operations area at the Yucca Mountain site, except in the case of substantial new information sufficient to call into question the prior determination of adequate protection of the public health and safety, common defense and security, and environment.

§ 63.52 Termination of license.

(d) In making any findings required for terminating the license the Commission shall treat as resolved those matters resolved in connection with the issuance of the license amendment for permanent closure, except in the case of substantial new information calling into question the prior determinations.

VII. Subsystem Requirements

NEI endorses the proposed rule's determination that *total* system performance should provide the basis for evaluating the suitability of Yucca Mountain for development as a spent commercial fuel and HLW repository. The elimination of Yucca Mountain subsystem performance criteria is entirely appropriate. This recognizes the important coupling of the geologic features, events, and processes with those of the engineered barriers. It is, indeed, the *combined* behavior of the geology and engineered barriers that should be the basis of a licensing evaluation.

Accordingly, we support the use of total system performance requirements as opposed to subsystem performance criteria as the basis for assessing the acceptability of the Yucca Mountain site. In the 'Supplementary Information' section of the proposed standard, it was correctly noted that methods of total system performance assessment have progressed significantly since the promulgation of 10 CFR Part 60. Indeed, the implementation of these new methods can avoid "the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application (of Part 60 subsystem requirements)."

The NAS (1995) also noted that the use of subsystem requirements, rather than requirements based on human health impact "would obscure crucial information about the potential of the radionuclide releases for causing health effects." This is the primary reason why the NAS recommended against the use of subsystem performance criteria.

The proposed Part 63 does *not* mean that DOE will not have to rigorously defend, quantitatively, its reliance on the performance of individual barriers when making its case for compliance with the overall performance criterion. The proposed rule requires DOE to both describe the capability of each barrier DOE feels is important to waste isolation *and* provide the technical bases for the use of that barrier in making the overall safety case "taking into account uncertainties in characterizing and modeling the barriers" (§63.114(i)). We concur with this approach. The fact that NRC proposes to eliminate subsystem performance standards in Part 63 does not imply that the level of protection has been reduced. Simply because there is no particular "limit/constraint" for each barrier, does not mean that DOE will be allowed to make a poor case for any of the barriers needed to demonstrate compliance (e.g., §63.114(f)).

NEI is aware that the EPA is considering issuing a Yucca Mountain regulation that may include a standard for groundwater protection. A separate groundwater protection standard, however, would constitute a controlling subsystem requirement, which would substantially negate the reasonable and appropriate risk and performance based approach taken in the proposed rule.

The Energy Policy Act specifically *precludes* EPA from establishing a *groundwater* standard. Section 801 of the Act calls for the EPA to set generally applicable standards "based upon and consistent with the findings and recommendations of the National Academy of Sciences" which shall "prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository". A groundwater standard clearly goes beyond the mandate of dose to individuals. A groundwater standard is directly inconsistent with the NAS (1995), which addresses the topic of groundwater protection on p. 121 and concludes "We make no such recommendation, and have based our recommendations on those requirements necessary to limit risks to individuals". The Energy Policy Act specifically prescribes: "health and safety standards." The groundwater limit envisioned by EPA is clearly *not* related to "health and safety," but apparently based on a policy determination having to do with resource protection.

It is NEI's position that a separate groundwater standard, such as that in 40 CFR Part 191, would not accurately reflect human health risk, would be unnecessary, and would be inconsistent with the Energy Policy Act and the NWPA, which require a health based standard. As such, the industry is opposed to the addition of any separate groundwater standard in Part 63.

VIII. Performance Confirmation (§§ 63.131 through 63.134)

NEI believes that the proposed rule includes prescriptive requirements for performance confirmation, which are inconsistent with the overall performance based nature of this regulation and would be impractical to measure. In §§ 63.132-134 the rule contradicts what it has stated earlier regarding what has been learned about Total System Performance Assessment (TSPA) and why there is no need for subsystem performance requirements. It does this by placing detailed stipulations on the specific scientific and technical measures that must be taken to meet the already stated expectations (§63.131) for performance confirmation. We recommend that §§ 63.132, 133, & 134 be deleted as they are unnecessary and counterproductive to § 63.131 (in that they just provide more detail and remove flexibility from what is already called for).

In a similar vein, we also propose removing the words 'accurate and' from the definition of performance confirmation (p8665) and, in § 63.102(m), replacing "verify" with "assess the adequacy of" and "detect any" with "look for" to lessen the potential for overprescriptive interpretations of what is expected.

IX. Construction Records and Tests (§§ 63.72(b)(4) and 63.74(a))

These requirements should be modified to preclude the possibility of a conflict between what must be done to comply with these requirements and what is appropriate to preserve the design integrity of the repository. This may be accommodated by adding the language shown below in italics.

§ 63.72 Construction Records

(b)(4) Locations and amount of seepage *provided that collection of this information does not degrade repository performance*

§ 63.74 Tests

(a) DOE shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part *provided that conduct of these tests does not degrade repository performance*

X. Consideration of Alternative Designs in Performance Assessment (§ 63.21)

NEI recommends that the proposed rule should stipulate in § 63.21(b)(7) that the comparative evaluation of design features should be based on present technology to provide for better certainty and bound speculation consistent with the philosophy applied elsewhere in the regulation. This change is important to assure that the forward progress of the repository project is not continuously placed on hold to wait for additional research on technologies that are unproved at the time the performance assessment is conducted. It may be accommodated by adding the language shown below in italics.

§ 63.21 Concepts of application

(b)(7) An assessment of the performance of the proposed geologic repository for the period after permanent closure, as required by § 63.113(c). The assessment shall also include a comparative evaluation of alternatives, *based on present technology*, to the major design features that are important..."

XI. Conditions of license (§ 63.42(d))

NEI believes that since the capacity of the repository is already addressed by the NWPA, wherein the 70,000 MTU limit is codified, a limit does not also need to be stated in Part 63. § 63.42(d) should be modified to simply refer to the NWPA without repeating the quantity limit specified therein. Therefore if a need to change this limit ever arises, only legislation would be needed - not both legislation and rule-making.
