



NUCLEAR ENERGY INSTITUTE

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August 5, 2002

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28

**SUBJECT:** Nuclear Energy Institute (NEI) comments on the Draft Yucca Mountain Review Plan – NUREG 1804, Revision 2 (67 Fed. Reg. 15,257 - March 29, 2002)

Dear Mr. Lesar:

The Nuclear Energy Institute (NEI),<sup>1</sup> on behalf of the nuclear energy industry, is pleased to submit these comments to the Nuclear Regulatory Commission (NRC) on the draft Yucca Mountain Review Plan.

A review plan is an important piece of the regulatory framework that is urgently needed for the safe and responsible disposal of used nuclear fuel and high-level radioactive waste. It should provide the fundamental guidance by which NRC staff will review the risk- and performance-based repository license application required by 10 CFR Part 63 – *Disposal of High-level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada*. As such, it is critical that this review plan faithfully adhere to the regulatory vision articulated in 10 CFR Part 63 in a way that will assure NRC's review is appropriately focused on those matters most important to the protection of public health and safety. Our comments reflect the significant extent to which we believe that this has been accomplished in the draft review plan and highlight opportunities for further improvement.

NEI, the Electric Power Research Institute (EPRI), and experts from the nuclear industry have extensively reviewed the draft plan. This plan is a reflection of the high state of readiness achieved by the NRC staff to review a DOE repository

<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. NEI's members include all entities 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.

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license application. Notable aspects of this review plan include its strong recognition of the need for a risk- and performance-based review, provisions for increasing confidence in the long term repository safety case to be achieved in a stepwise fashion over the course of repository development, and explicit recognition of the distinction between NRC's licensing review and future NRC inspection activities. However, we also note that this document could be significantly improved in each of these and other areas. Accordingly, the enclosure to this letter contains our specific comments, which are offered to encourage NRC to further develop and refine the review plan, fall into the following categories:

- Emphasis of the importance of finalizing this review plan in a timely manner (recognizing the significant commitment made towards this objective at the July 31, 2002 DOE/NRC Management Meeting),
- Emphasis of the need for a risk-informed and performance-based NRC review and recommendations for strengthening the extent to which the review plan facilitates such a review,
- Commentary on the high value of elements of this review plan that support a step-wise licensing process and identification of opportunities to add further value,
- Emphasis of the distinction between licensing review and inspection activities and identification of areas where this distinction could be made more clear,
- A request that NRC clarify the difference between reasonable expectation and reasonable assurance,
- Other specific comments, as noted.

NEI believes that incorporation of the recommendations contained in these comments will help strengthen this review plan so that it is a more effective implementation tool for assuring that the requirements of 10 CFR Part 63 are appropriately satisfied.

NEI looks forward to continuing our dialogue with the NRC on Yucca Mountain repository licensing. We would be pleased to address any questions the NRC may have on our comments.

Sincerely,

  
Steven P. Kraft

Enclosure

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cc: The Honorable Richard Meserve, Chairman, USNRC  
The Honorable Greta J. Dicus, Commissioner, USNRC  
The Honorable Nils J. Diaz, Commissioner, USNRC  
The Honorable Edward McGaffigan Jr., Commissioner, USNRC  
The Honorable Margaret Chu, Director, Office of Civilian Radioactive Waste  
Management, USDOE  
Dr. William Travers, Executive Director for Operations, USNRC  
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Dr. John Garrick, Chairman, ACNW

## ENCLOSURE

### NUCLEAR ENERGY INSTITUTE (NEI) COMMENTS ON THE DRAFT USNRC YUCCA MOUNTAIN REVIEW PLAN

#### I. Importance of finalizing the review plan in a timely manner

The Nuclear Energy Institute (NEI) endorses the Nuclear Regulatory Commission's (NRC) decision to move forward with a Yucca Mountain Review Plan at this time. Recognizing the urgent national importance of high-level radioactive waste disposal, the Department of Energy (DOE) has committed to submitting a license application in order to begin waste emplacement by 2010.

The regulatory clarity provided by completion of this review plan is an important prerequisite to a successful licensing process. It establishes a basis for common expectations concerning the licensing review between the applicant and the regulator and, accordingly, should be in place early in the process. Therefore, NRC should actively consider and incorporate comments received, and finalize this review plan as soon as practicable after the close of the comment period.

We were impressed by the significant commitment towards this objective made by NRC at the July 31, 2002 DOE/NRC Management Meeting. We encourage NRC to strongly follow through with DOE in defining a milestone path forward as discussed in this meeting.

#### II. Need for a risk-informed and performance-based NRC review and recommendations for strengthening the extent to which the review plan facilitates such a review

NEI welcomes NRC's commitment, as stated at numerous points throughout the review plan, to conduct a risk-informed and performance-based review of DOE's license application. However, the application of risk-informed, performance-based principles in the review plan appears to be somewhat uneven.

For example, in each subsection of section 1.3 of the review plan, NRC provides a specific reason why each portion of the review should be risk-informed and performance-based. Qualifiers throughout Section 1.3 imply that risk-informed performance-based principles are to be applied only where there is some "reason" to do so. However, risk-informed performance-based principles should be a fundamental part of the foundation for *all* of NRC's review activities. Examples of these qualifiers include, "the extent to which each of these sections incorporates risk-informed performance-based principles varies" (Section 1.3.1), "This section is risk informed because the option is preserved to retrieve waste" (Section 1.3.2), "Because the performance assessment encompasses such a broad range of issues, the staff will use risk information" (Section 1.3.3), and "Where suitable the acceptance criteria are also risk informed" (Section 1.3.5). Rather

than applying risk-informed performance-based principles in a piecemeal fashion, “as appropriate,” NRC should universally focus its review on those elements of the license application most important to safety.

NRC should improve this review plan to more consistently apply risk-informed, performance-based principles. These improvements should, at a minimum, include the following 3 elements:

1. Recognition that it is up to the license applicant – DOE – to make risk-informed performance-based judgments as to what should be included in the license application at each step and it is NRC’s role to determine whether or not it agrees with these judgments (as opposed to NRC defining how risk information should be applied).
2. Revision of sections of the review plan that contain an excessive level of detail. While we agree with most of the general guidance in this review plan, we are concerned that there is too much detail in the draft Review Plan related to specific repository design and NRC assumptions about the relative importance of specific features, events, and processes. Providing a high level of detail and/or prescription for the early review steps (construction authorization and license to receive and possess) will preclude the flexibility needed for the licensee to appropriately develop its analysis of repository safety over time. Such inflexibility will continually encumber NRC in revising its review guidance as new approaches to assuring and evaluating repository safety become available.
3. Recognition that risk-informed performance-based principles are especially important in the case of repository licensing due to the step-wise nature of this process. An incomplete application of these principles could result in an inflexible license that would become a barrier to the application of scientific advances over the long time that will pass before the repository is closed. However, a thorough application of these principles will facilitate and encourage the learning and development that will occur over time and assure that the most up-to-date information is always applied in the protection of public health and safety.

The topics identified in the remainder of Comment II address specific areas where NEI believes this review plan does not adhere to risk-informed performance based principles, contains an excessive level of detail or prescription, and precludes necessary licensee flexibility (addressing elements 1 and 2 above). Comment III will similarly address both the existing elements of this review plan that support a step-wise approach as well as opportunities for improvement in this area (addressing element 3 above).

Specific areas where the review plan is most in need of modification to more appropriately reflect a risk-informed performance-based approach include the following:

### Review Plan for General Information (Section 3)

Section 3, in general, is overly detailed and prescriptive. For example, “Review Method 2,” pp. 3-30 to –33, repeatedly calls for descriptions of the “extent to which there are alternative, credible conceptual models or system state descriptions,” and information concerning the “extent to which uncertainty in geologic data, models or system states affects . . . compliance.” Such requirements seem inappropriately detailed for a summary section of the license application.

Further, because the license application will initially be prepared to support issuance of a Construction Authorization – i.e., many years in advance of repository operation – information addressing certain activities will be in rudimentary form as compared to that addressing others. Accordingly, the various subsections should explicitly recognize that information concerning certain topics – e.g., that called for in subsection 3.3, physical protection; and 3.4, material control and accounting – may not be as highly developed at the Construction Authorization stage as other areas.

In addition, Section 3.2.1, on p. 3-6, the third paragraph provides:

“Because some of the information contained in this portion of the license application is informational in nature and may not concern performance-related issues, some of the review methods used to evaluate this information may generally not be risk-informed, performance-based. In instances such as these, there will be no performance measures against which the review methods can be compared.”

(This concept appears elsewhere, as well)

While we agree that it would be inappropriate to include performance measures for information that is not risk-informed and performance-based, the review plan should take more care to specifically instruct the NRC Staff to require only sufficient detail in such informational areas as is necessary to provide a qualitative description of activities.

### Model Abstraction (Section 4.2.1.3)

This section, encompassing 109 pages of guidance, should be significantly streamlined. It is not necessary for this review plan to separately address, in great detail, each and every individual existing category of model abstraction – as is done in the Revision 2 draft. This unnecessarily precludes flexibility by DOE and NRC and would require revision of the review plan every time a new type of model abstraction was developed or the accepted methodology of any existing abstraction changed by scientific advance. It is also redundant as, in each sub-section, most of the same guidance is repeated. We propose revising

this section to address model abstraction in a more general sense, offering sound review guidance applicable to a wide range of abstractions and removing the need to define specific guidance for each and every known type of abstraction. This approach would result in a complete rewrite of this section resulting in about 10 pages of more useful guidance that could be applied with both improved consistency to current model abstraction methods and improved flexibility to facilitate future advances in model abstraction techniques. We strongly urge NRC to pursue this approach.

#### Performance Confirmation (Section 4.4)

NEI believes that the draft review plan includes prescriptive requirements for performance confirmation that are inconsistent with the overall risk-informed performance-based nature of 10 CFR Part 63 and would be impractical to measure. Section 4.4 of the draft review plan contradicts NRC's statements in connection with 10 CFR Part 63 regarding what has been learned about Total System Performance Assessment (TSPA) and why there is no need for subsystem performance requirements. This section does this by placing detailed stipulations on the specific scientific and technical measures that must be taken to meet the already stated expectations for performance confirmation.

There are many specific requirements for monitoring and testing in this section not relevant to a risk-informed and performance-based approach. NRC's own comments made in the promulgation of 10 CFR Part 63 should be noted in this regard. In the proposed Part 63, NRC was overly detailed in its performance confirmation requirements. NRC acknowledged this in comments included with the final regulation, which then did not include the overly detailed requirements. For the same reasons, many of the detailed monitoring and testing requirements in this section should be deleted or substantially modified. Examples include the "Confirmation of geo-technical and design parameters" bullet on page 4.4-2 and the two dashed bullets in the middle of page 4.4-12 beginning with "It commits to."

#### Quality Assurance (Section 4.5.1)

The acceptance criteria specified in Section 4.5.1.3 governing the DOE Quality Assurance Program Description (QAPD) are: 1) too restrictive, 2) inconsistent with other NRC criteria for QAPD's, and 3) will necessitate the need for continual implementation of the QAPD change program/process. NEI bases this conclusion on the following passage from the General Acceptance Criteria in Section 4.5.1.3:

"The criteria in the following introductory paragraphs and the 22 numbered acceptance criteria are based on meeting the relevant requirements of 10 CFR Parts 21, 63.21(c)(20), 63.44, 63.73, and 63.141-144, as they relate to the quality assurance program. The U.S. Department of Energy quality assurance program description

document must describe how the applicable requirements of 10 CFR 63.142 will be satisfied. The U.S. Department of Energy quality assurance program and associated quality assurance program controls and implementing procedures regarding activities performed must be in place before activities begin.

*It is not sufficient for the U.S. Department of Energy documents to assert that particular requirements are met or provided for. The description of the quality assurance program submitted in the license application and any subsequent quality assurance program changes must identify individuals and organizations that are responsible for meeting particular requirements, in order to allow the reviewer to understand the process by which the U.S. Department of Energy expects to meet specific requirements and to determine whether or not following that process would lead to compliance with requirements. Defining a process involves establishing authorities, assigning responsibilities, and issuing instructions and procedures.”*

(Italics added for emphasis.)

We have the following comments on this approach:

- a. The QAPD that is required to be submitted for a construction permit or operating license, under the provisions of 10 CFR Part 50, does not require a similar level of detail. NUREG - 0800, Sections 17.1 and 17.3 are the primary criteria for the acceptance criteria for these QAPDs. While both require the inclusion of QA Program responsibilities regarding organizations/positions, there has been no requirement for the “identification of individuals.” Albeit there have been requests, as part of the Request for Additional Information process, for resumes, details regarding members of the initial “construction” and “startup” organizations, but these responses were not included in the QAPD itself.
- b. If this level of detail were required in the QAPD, then changes in individuals would necessitate a “change” to the QAPD. Such changes would have to be made in accordance with the criteria of 10 CFR 63.144, undoubtedly the majority of which would be considered a “non-reduction” based on the allowances of 10 CFR 63.144(a). However, this would still require DOE to process the change through its “QA Program change process” and include the change in the 24-month submittal.
- c. In a similar manner, the acceptance criteria does not allow for the assertion that a particular requirement (criterion) will be met. If this criterion stands, the QAPD will be required to be very detailed. This has not typically been the case for QAPDs submitted for construction permits and operating licenses.

The typical 10 CFR Part 50 QAPD is a “slight” elaboration of the acceptance criteria, with minimal details. The process has relied upon the details of the QA Program to be contained in implementing procedures. The NRC verification of satisfactory implementation has been accomplished through the Inspection program.

Additionally, the approach outlined in Section 4.5.1 does not appear to be consistent with the “criteria/process” depicted in Figure 1-1, “Schematic of U.S. Nuclear Regulatory Commission Licensing and Inspection Process and Applicability to Licensing Documents.” The figure would appear to support the practice of the “Licensing Review” to require one level of detail while the “Inspection” program would cover the “implementing procedures.”

Further, Chapter 2300, “Yucca Mountain Pre-Operation Inspection Program,” of the NRC Inspection Manual has specific inspection procedures to be used for verification of implementation of the QA program.

There appear to be differences among sections of the review plan itself, the Inspection process that will be implemented, and “normal” NRC practice/policy for QAPD detail. For example, Section 4.5.1 “Quality Assurance Program” contains four items in addition to the 18 items described in the regulation 10 CFR 63.142 (e.g., software, field surveys). It is not clear why these additional items need to be called out as separate elements or why they cannot be satisfactorily addressed by the original 18 criteria, because there is nothing special about these items. The practice of “breaking out” elements of a licensee program for a specific and unique application of quality assurance is without precedent and inconsistent with other existing NRC regulations. This section should be revised to remove the four additional items from the scope and to mimic the corresponding regulation. 10 CFR 63.142 is similar to 10 CFR Part 50 Appendix B, which contains 18 quality assurance criteria for commercial nuclear power plants.

Finally, Acceptance Criterion 1 – which discusses the organizational roles – should contain a minimum level of detail, considering that it is impossible to envision the structure of an organization over the long course of repository operations (in the year 2300, for example).

### **III. Value of a step wise licensing process and identification of opportunities to add further value**

The principle of step-wise repository development has long been a guiding influence on scientific and regulatory thinking concerning Yucca Mountain. The National Academy of Sciences’ Board on Radioactive Waste Management, in its 2001 report *Disposition of High-Level Waste and Spent Nuclear Fuel* reaffirmed this consensus view in concluding that:

“National programs should proceed in a phased or stepwise manner.”

The Board further explained:

“A ‘phased approach’ to regulation of a geological repository, as expounded 10 years ago in the Board on Radioactive Waste management’s *Rethinking High Level Waste Disposal* (1990) remains sound advice. A key corollary is that the regulator must strive to avoid overly prescriptive rules too early in the multi-decade process of regulatory approval and oversight.”

NEI endorses step-wise licensing and applauds NRC focusing on such an approach in the final repository regulation (10 CFR Part 63).

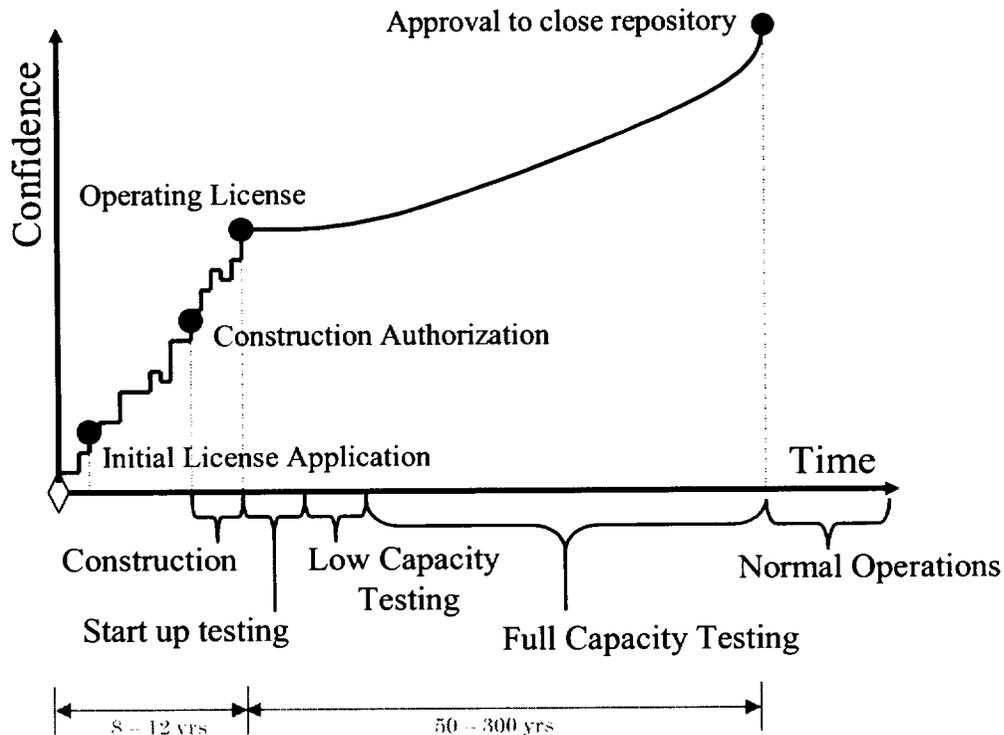
10 CFR Part 63 provides for a step-wise approach to licensing in two ways. First, the regulation calls for three major licensing decisions over the life of the repository – construction authorization, license to receive and possess, and license amendment to close the repository. Second, and perhaps more important, the regulation provides mechanisms for incremental steps to be taken between each of the major license decisions so that new scientific knowledge can be applied as it is gained (this is particularly important, because of the long time period and significant opportunity for additional scientific work that exists prior to the third and final step).

Two features of the regulation, articulated in the Yucca Mountain Review Plan, are essential to the effective implementation of this incremental progression of scientific understanding of post-closure repository performance – *Research and Development Program to Resolve Safety Questions* (Section 4.3) and *Performance Confirmation Program* (Section 4.4). The NRC is to be commended for providing these important step-wise licensing implementation tools (although the Performance Confirmation section is, itself, too prescriptive and should be revised as discussed above in Comment II). We encourage NRC to further advance the utility of these tools by explicitly recognizing the role they play in a step-wise licensing process and by revising the review plan to address elements that represent barriers to a step-wise approach in as much as they are overly prescriptive (as noted in Comment II above).

A step-wise approach has the effect of providing for increasing confidence in post-closure repository safety over time as science continues to introduce new information into the licensing process over the long period of time that precedes closure. The figure below illustrates this concept.

# Step-wise licensing

## *Post-closure reactor equivalents*



It is important to note that, for post-closure repository performance, the point equivalent to “normal operations” (analogous to the beginning of a commercial reactor’s operating life) does not come until the repository is closed. There is therefore significant opportunity for open issues to be addressed and questions to be answered by scientific investigation and testing conducted over the several decades, if not centuries, before a decision to close is made. The review plan’s provision for a *Research and Development Program to Resolve Safety Questions* (Section 4.3) provides an excellent tool for addressing uncertainties stemming from issues upon which NRC and DOE have not yet reached closure. The review plan’s provision for a *Performance Confirmation Program* (Section 4.4), once revised to be less prescriptive, can provide an equally powerful tool for assuring that closure on issues is reinforced, as the inevitable remaining uncertainties are better understood through new information becoming available. It should be noted that the applicability of these tools is mostly limited to the post-closure licensing case, as substantive technical issues regarding the pre-closure licensing case need to be closed, with uncertainties sufficiently understood, before the facility begins receiving waste.

The review plan should emphasize step-wise licensing up front in the review plan beginning with the following sections:

## Executive Summary, Introduction (Section 1), & Acceptance Review (Section 2)

Improvements are needed to facilitate a more effective implementation of the step-wise licensing tools already provided in accordance with 10 CFR Part 63. NRC should go beyond merely providing tools that can be applied in a step-wise licensing process. The step-wise concept should be described from the outset in the review plan and it should be made clear that this concept is a fundamental underpinning of NRC's review. This is essential, because the principal purpose of the review plan is to ensure the quality and uniformity of the NRC staff's licensing reviews of the application submitted by DOE. Accordingly, the review plan should be written such that it provides flexibility to both the applicant (DOE), and the NRC, in selecting the methods for demonstrating compliance with the regulatory requirements. The level of detail should be kept at a minimum to avoid the need for frequent changes in commitments, as a result of evolving scientific and regulatory information. This is explicitly recognized in the regulation at 10 CFR 63.21 that in "Content of application", states: "The application must be as complete as possible in the light of information that is *reasonably available* at the time of docketing" (Italics added for emphasis).

In addition to the overall need to more explicitly recognize the step-wise approach up front in the review plan, corresponding improvements are needed in the area of quality assurance, as follows:

### Quality Assurance (Section 4.5.1)

The acceptance criteria will require a Quality Assurance Program Description (QAPD) that will have to encompass all phases of the construction, operation, and closure of the geological repository at Yucca Mountain. Typically, such a QAPD is prepared in stages, i.e., there are specific elements of the QAPD required to be submitted and reviewed for the design and construction phase/activities, and another QAPD is submitted that covers the operations phase.

Although some of the elements of the QAPD's are similar, there are different policies, organizations, programs, and procedures that will be implemented for each phase.

Such is the case for the license applications for a commercial nuclear power plant. 10 CFR Part 50 "requires the submittal of the QAPD that will be used for the construction permit and upon submittal of the application for the Operating License, the QAPD for the operating phase."

The NRC has established criteria for the review of these QAPD's in NUREG-0800, as follows:

- Section 17.1, "Quality Assurance for the Design and Construction Phases"
- Section 17.2, "Quality Assurance During the Operations Phase"

- Section 17.3, “Quality Assurance Program Description”

A review of the Acceptance Criteria of Section 4.5 indicates that YMRP was primarily developed based on the acceptance criteria of Standard Review Plan Sections 17.1 and 17.2. Additional criteria were added to address specifics such as Software, Sample Control, Scientific Investigation, and Field Surveys.

These additional criteria provide a level of detail that is not necessary for the staff's review and reduce flexibility to accommodate the progression in the QAPD through the stages of repository design, construction, and operation. As mentioned above in comment II, the additional criteria should be deleted. Furthermore, specific consideration should be given to the use of a stepwise approach to the content and detail of the QAPD required for the different phases of the Yucca Mountain Project.

#### **IV. Distinction between licensing review and inspection activities and identification of areas where this distinction could be made more clear**

NEI commends NRC for explicitly recognizing in the draft review plan the distinction between licensing review and inspection review. In this regard, review plan Figure 1.1 represents an excellent communication tool to show that the greater level of detail belongs on the inspection side of the line. However, as we have noted (see comments II and III above), there are several instances (most notably quality assurance and performance confirmation) where the draft review plan – a licensing review tool – crosses the line into a level of detail more appropriate for inspection review. We recommend that NRC conduct a comprehensive review of the review plan to specifically assure that the level of detail is consistently appropriate for a licensing review. We also encourage NRC to more extensively articulate this principle at the beginning of each section of the review plan.

#### **V. Clarification of the difference between “reasonable expectation” and “reasonable assurance”**

The usage of the terms “reasonable expectation” and “reasonable assurance” in the draft review plan seems to convey the notion that these terms mean approximately the same thing. We do not believe that this was what was intended when NRC chose, in 10 CFR Part 63, to assign the former term to describe post-closure compliance expectations and the latter to describe pre-closure compliance expectations.

We agree that NRC's expectations for pre-closure safety should be exactly the same as those for any other licensed nuclear facility – hence the term “reasonable assurance” should be applied in exactly the same fashion as at these facilities.

However, the term “reasonable expectation” implies a distinctly different standard of proof that recognizes the inherent uncertainties in predicting repository performance far into the future, the need for more realistic (rather than bounding) modeling approaches, and takes into account the step-wise nature of repository licensing. A “reasonable expectation” approach should allow for considerable information to be added to the safety case after the initial licenses are granted but before the facility is closed – through the safety question and confirmatory research tools. This “expectation” should explicitly recognize that it is acceptable that some gaps in understanding exist at the time the initial licenses are granted provided efforts to continue to address these uncertainties over the long time period of repository operations are adequately planned.

We also note that EPA, in 40 CFR 197, originally defined “reasonable expectation” with the intention that it be explicitly different than “reasonable assurance.” The EPA appropriately provided NRC with the flexibility to delineate how this term would be implemented. As the review plan is the key element of NRC implementation guidance, it is particularly important that NRC be clear about this distinction in this document.

We recommend that NRC explicitly clarify the distinction between “reasonable assurance” and “reasonable expectation” in the review plan and assure that the pre-closure and post-closure acceptance criteria are graded accordingly. This recommendation relates to our subsequent recommendation, in Comment VII, under *Use of ‘Bounding Values’ in a risk-informed, performance-based license application* that NRC give greater consideration to realistic approaches to performance assessment. Such realistic approaches have a unique applicability in the post-closure context.

## VII. Other comments

### Quality Assurance Commitment to NQA-1-1983 (Section 4.5.1.5)

The Draft Yucca Mountain Review Plan, rev.2 is not clear on the use of the “non-mandatory guidance” in NQA-1-1983. Although the document requires a commitment to NQA-1-1983 (reference paragraph 4.5.1.5) it is unclear as to the need to follow all sections of NQA-1-1983. There appears to be a contradiction in the guidance. The draft review plan states:

“The exceptions to, and the U.S. Nuclear Regulatory Commission positions on, the use of NQA-1-1983, provided in the acceptance criteria in Section 4.5.1.3 of the Yucca Mountain Review Plan, apply. Also, the U.S. Nuclear Regulatory Commission positions provided in Section C of the U.S. Nuclear Regulatory Commission Regulatory Guide 1.28, Revision 3. apply.”

Reg Guide 1.28. position C states: " The basis and supplementary requirements that are included in ANSI/ASME NQA-1-1983.....are acceptable to the NRC staff....." Based on the NRC position on Reg Guide 1.28, the "non mandatory requirements" of NQA-1-1983 do not have to be followed; but the draft review plan does not have such "disclaimer." This leaves the question of "non-mandatory requirements open and could create difficulties in the review if the QA submittal is based on not using the non mandatory guidance and the reviewers are looking for adherence to this guidance. This should be clarified.

Clarification of the meaning of the term "complete" in Section 2 (Acceptance Review)

There is repeated reference in Section 2 to the need for "complete" information; e.g., on p. 2-1, the Staff will "check whether the information is *complete*," the application must be "*complete* enough to conduct a detailed technical review," and the application "will be acceptable to docket if the information is *complete* in scope and detail about the site and engineering design" (emphasis added). In fact, however, "completeness" will vary enormously with the licensing decision point, i.e.: construction authorization; license to receive and possess; or repository closure. This point is vividly illustrated by a review of the items in the "Acceptance Review Checklist" in Section 2.2. The Checklist specifies, among other things:

- A description of the detailed security measures for the physical protection of high-level radioactive waste (p. 2-2);
- A description of the plans for retrieval and alternate storage of radioactive wastes (p. 2-5);
- A description of the performance confirmation program (p. 2-7);
- Information concerning activities at the geologic repository operations area, including plans for start-up activities and start-up testing, and plans for permanent closure and the decontamination and dismantlement of service facilities (p. 2-8); and
- A description of controls to restrict access and regulate land use at the site and adjacent areas, including a conceptual design of monuments that would be used to identify the site after permanent closure (p. 2-9).

The "Acceptance Review" section should be revised to clarify the meaning of the word "complete." In particular, it must emphasize that the degree of information available for addressing various topics will vary significantly with the stage of repository development, and must be evaluated accordingly.

Definitions of "Important to Safety," "Important to Performance" and "Important to Waste Isolation"

All three of the above terms are used in the draft review plan. The terms "Important to Safety" and "Important to Waste Isolation" appear to be applied

consistent with their definitions in 10 CFR Part 63.2. However, the term “Important to Performance” is not defined in the regulation. We recommend that the review plan be revised to include only the defined terms and instances where “Important to Performance” is currently in use be carefully considered to determine whether the item being discussed is “Important to Waste Isolation or Safety” or alternately is not important enough to rise to the level of detail appropriate for a license review. NRC should consider adding the terms “Important to Safety” and “Important to Waste Isolation” to the glossary.

#### Relationship Between Pre-licensing Interactions and License Review

DOE and NRC have already engaged in a significant number of pre-licensing interactions over many years. These interactions have given NRC considerable opportunity to conduct reviews of DOE’s work of a breadth and depth that would normally not occur before a license application is submitted. This review plan should explicitly recognize progress made during the pre-licensing review. Where appropriate, it should be revised to clearly and explicitly communicate the extent to which NRC staff should consider the results of these pre-application reviews.

#### Use of “Bounding Values” in a Risk-informed, Performance-based License Application

We are concerned that NRC is relying too heavily on the use of “bounding values” in the draft Revision 2 of the Review Plan. Overuse of bounding values is not consistent with a “reasonable expectation” approach. While we recognize that limited data may sometimes make it difficult to have confidence in developing a “best estimate” value or “best estimate” uncertainty range, it may be necessary to use expert judgment to supplement the data to develop such best estimates. The Review Plan should be revised to require that, in the event that sensitivity analyses *using a credible range of parameters* shows the selected value within the range to substantially affect overall repository safety, then DOE should be allowed to supplement the existing data with expert judgment, or other sources of information with which to develop an alternative to the exclusive use of a bounding value. This approach is described in more detail in the following paragraphs.

For the development of reactor PRAs, industry’s current recommendation is to first develop as completely as possible an ‘expected behavior’ approach. This is because it is necessary to understand the ‘true’ sensitivities and relative importance of each component of the system regarding its contribution to safety. Adopting conservative approaches early in an assessment has been found to skew the relative importance of particular components of the system. A skewed assessment may lead to sub-optimal expenditure of resources and have results counter to the intended goal of improving safety. Only after the important components of the system have been identified using an ‘expected behavior’

model, should one then adopt some conservative assumptions for the purposes of licensing where robust defensibility is required for public acceptance and NRC approval. The initial 'expected behavior' model can then be used to provide an estimate of the degree of conservatism introduced in the 'conservative' model used for licensing.

While there are many similarities between licensing nuclear reactors and licensing the proposed Yucca Mountain facility, there are also differences that may require a somewhat different approach. Both systems involve many thermal, mechanical, structural, chemical, and radiological processes. Both systems have base case and 'off normal' or 'accident' scenarios that require analyses. Yet the degree of heterogeneity, time, and spatial scales for the Yucca Mountain system are much larger than that for nuclear reactors. Because the time and spatial scales are so great at Yucca Mountain, there are little to no direct frequency data for many of these processes. Natural analogue information will be necessary in many cases to supplement the active data acquisition program that DOE is conducting. Furthermore, it will likely be necessary to collect additional data over a longer period of time (tens to hundreds of years) to 'confirm' some of the models used to defend the safety of the Yucca Mountain system.

Thus, while a conservative approach may have somewhat greater utility in a repository licensing case than in a reactor licensing case (due to greater long term uncertainties), the modeling approach in an NRC-regulated environment for a repository is still fairly similar to that recommended for nuclear reactors. That is, a dual modeling approach should be used. An 'expected behavior' model should be developed first using a combination of data (wherever available), analogue information, and engineering/scientific judgment. A second modeling approach, using conservative assumptions in those areas where it may be difficult to accurately define the 'expected' conditions, may then be developed for licensing purposes. The 'expected behavior' model can then be used to inform NRC and the public about the relative degree of conservatism in the 'conservative' model used for licensing. The intent is that the 'conservative' model would form the main basis for the licensing decision, while the 'expected behavior' model would be used to provide regulatory insight.

To summarize, we recommend a 'dual-model' approach. The first is an 'expected behavior' model that would use some engineering/scientific judgment. A second, 'conservative' model should then be developed that will be used in licensing. Use of the 'expected behavior' model in licensing should be restricted to informing NRC and the public about the probable degree of conservatism (and internal margin) in the result of the 'conservative' model. This will facilitate a more reasoned assessment of whether or not the "reasonable expectation" test has been met.

Clarification of Multiple Barriers (Section 4.2.1.1)

Section 4.2.1.1 addresses the review of the repository system description and demonstration of multiple barriers in connection with evaluation of information provided pursuant to 10 CFR 63(c)(1), (9), (10), (14), and (15). Among the factors addressed is the need for identifying barriers relied upon for post-closure performance, including “at least one barrier from the engineered system and one from the natural system,” (see, e.g., p. 4.2-3).

While the general discussion of Review Methods and Acceptance Criteria generally appears adequate, it would be helpful to further emphasize that neither the natural barriers nor geologic barriers need be, as a category, primary to containing material within the repository. This point should be made more explicit in one of the Acceptance Criteria to further emphasize that total system performance is key, rather than any subsystem containment requirement.

Use of the terms “Spent Nuclear Fuel” and High-Level Radioactive Waste”

The draft review plan is inconsistent in its use of the terms “spent nuclear fuel” and “high-level radioactive waste”. In some cases, the review plan refers specifically to one or the other categories of material. At other times, the term high-level waste is used apparently to encompass all spent nuclear fuel and high-level radioactive waste rather than specifically high-level radioactive waste. For example, on pages 4.1-15 and 4.1-16, the review plan asks for information specific to spent nuclear fuel and to high-level radioactive waste. This specific use of the terms is appropriate in this subsection. On page 4.1-38 in regard to calculating a source term, the review plan requests “characteristics of high-level radioactive waste used in the source term calculation (e.g., enrichment, burn-up and decay time). This is an incorrect use of the term “high level radioactive waste”. In this instance, the review plan should use either the term “spent nuclear fuel” or perhaps a generic “spent nuclear fuel/high-level radioactive waste (SNF/HLW).” We suggest that NRC evaluate its use of these terms to determine whether the specific waste forms should be used or rather a generic term to cover all waste forms that might be disposed of in the proposed repository.

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