

Dr. George M. Hornberger, Chairman
Advisory Committee on Nuclear Waste
U.S. Nuclear Regulatory Commission
Washington, DC 20555

November 20, 2001

SUBJECT: RESPONSE TO THE ADVISORY COMMITTEE ON NUCLEAR WASTE
LETTER DATED SEPTEMBER 28, 2001

Dear Dr. Hornberger:

I am responding to your letter dated September 28, 2001, on the U.S. Nuclear Regulatory Commission (NRC) staff's issue resolution process for risk-informing its sufficiency review of the U.S. Department of Energy's (DOE's) technical basis documents for the Yucca Mountain, Nevada, site recommendation. In the letter, the Advisory Committee on Nuclear Waste (ACNW) made a number of specific observations and recommendations to the NRC staff. The following is the NRC staff's response to the ACNW's observations and recommendations. Please note that in some instances the observations and recommendations have been grouped together.

Observation/Recommendation 1 and 2:

The staff appears to be well equipped with analytical tools, technical capability, and guidance for conducting the sufficiency review and an eventual license application (LA) review, particularly in light of the staff's ongoing upgrades to the Total-system Performance Assessment (TPA) code for analyzing the waste package and source term. It is not obvious, however, whether or how the staff used information and performance assessment tools to focus its sufficiency review on the most risk-significant issues, and whether or how it used its TPA code to develop risk insights to support the sufficiency review.

The NRC staff should continue to use its TPA code in conducting sensitivity analyses to explore important contributors to risk at the subissue level. We also encourage the staff to continue to enhance its use of the TPA code to allow for greater realism in its analyses and to conduct its own risk-informed assessments to quantify the uncertainties associated with the important risk contributors.

NRC Staff Response:

The NRC staff agrees with the ACNW that it has the necessary tools and technical capabilities to conduct the sufficiency and potential license application reviews. The NRC staff used the issue resolution meetings and the agreements reached during the meetings as the basis for the staff's sufficiency comments. In preparation for the issue resolution meetings, the NRC staff used information from the NRC and DOE performance assessment analyses (e.g., risk insights); DOE documents; independent investigations; and outside literature, to focus its

comments and concerns on the most risk-significant issues, including those associated with DOE's at depth site characterization and waste form proposal. The agreements reached during the meetings form the basis for staff's sufficiency review and the path forward, and represent those items where the NRC staff believes that it needs additional information or documentation to conduct a detailed license application review. Although the logic behind deciding what additional information the staff believes it needs for license application may not be explicit in all cases, the staff did use results from NRC and DOE performance assessment analyses (i.e., risk insights) in both the issue resolution and sufficiency review processes. For example, the level of detail was developed for the NRC staff's review of the waste package environment was based on TPA insights.

The NRC staff plans to complete a risk-insights report that will address: (1) the risk insights that have been determined by DOE and the NRC staff; and (2) how the NRC staff could use these risk insights during future reviews, for both pre-closure operations and post-closure performance. This work is scheduled to be completed during fiscal year 2002. The NRC staff would like to discuss, with the ACNW, during the next presentation on performance assessment and NRC's TPA code, how to make risk insights that are used in the NRC staff reviews, such as the sufficiency review, more transparent.

The NRC staff agrees with the ACNW recommendations on the importance of conducting further sensitivity studies and to continue enhancing the TPA code. The staff will document sensitivity studies it has completed and plans to publish the results in a NUREG in 2002. The staff intends to use the TPA code to conduct future analyses, as it prepares to review a potential license application.

The next version of the TPA code will be influenced by the comments from the external peer review of TPA version 3.2, by the desire (consistent with the performance goal to make NRC activities and decisions more effective, efficient, and realistic) to increase realism in the TPA code, where appropriate, and by the goal of improving the usefulness of the TPA code during a potential licensing review.

Observation/Recommendation 3-7:

Through its issue resolution process, the staff appears to be addressing the issues that are likely to be important for conducting a license application review for the proposed Yucca Mountain repository.

The technical exchange meetings have proven very valuable in resolving issues and establishing substantial and essential communication between NRC and DOE staffs.

The NRC staff used the ongoing issue resolution process efficiently and effectively to conduct its review in a timely manner.

The staff seems to be doing an excellent job of tracking issue resolution as the emphasis shifts from key technical issues to integrated subissues. The integrated subissue format appears to effectively capture and integrate material from the key technical issues.

In the areas where the Committee focused its vertical slice review, the staff's issue resolution process is logical, defensible, and well documented in the issue resolution status reports.

NRC Staff Response:

The NRC staff agrees that the NRC/DOE issue resolution meetings have been very valuable in addressing the technical issues associated with the proposed repository at Yucca Mountain. As discussed earlier in this letter, the NRC staff used information from the NRC and DOE performance assessment analyses (i.e., risk insights), DOE documents, independent investigations, and outside literature in preparation for the issue resolution meetings. The information was used by the NRC staff to emphasize the most important issues and to assess whether additional information or documentation may be needed. The agreements reached during the meetings form the basis for the path forward and represent those items that the staff believes are needed to allow a detailed review of the potential license application. The NRC staff is tracking the agreements and is currently reviewing those DOE documents that have already been provided to assess whether the documents address the underlying staff questions or comments.

After the release of the Yucca Mountain Review Plan (YMRP), the NRC staff plans to emphasize the integrated subissues in subsequent issue resolution meetings. By focusing on the integrated subissues, the NRC staff hopes to align its efforts with the YMRP more effectively and to continue to integrate the contribution of the specific technical disciplines associated with the key technical issues.

Observation/Recommendation 8:

DOE's inconsistent use of conservatism throughout the Total System Performance Assessment for Site Recommendation (TSPA-SR) models makes it difficult to identify issues that are important to risk, and precludes a risk-informed analyses of the proposed repository on the basis of the evidence.

NRC Staff Response:

This ACNW observation/recommendation parallels a comment that was made in the ACNW's letter of September 18, 2001, on DOE's TSPA-SR. As discussed in the NRC staff response to that letter, the staff recognizes that if DOE introduces conservatism into their performance assessment, then DOE may have difficulty making optimal design decisions and communicating the risk associated with their design, because they would not have their best estimate of the risk. The staff also recognizes and agrees with the ACNW that the inconsistent use of conservatism may make it difficult to identify the importance of particular issues to risk (i.e., that in this respect the analyses are not "risk-informed," as used by the ACNW). However, objective regulatory decisions can be – and have been – made based on the results of performance assessments that include conservatism.

The NRC/DOE agreements resulting from the issue resolution meetings will lead to information that will help the NRC staff conduct a risk-informed review of DOE's license application, should one be submitted. Specifically, a number of the agreements address: (1) the use of conservatism; (2) representation of uncertainty; (3) the process used to develop abstracted models from detailed models; and (4) the need to consider the effects of non-linear models when judgements are made to use conservatism to address uncertainty.

Observation/Recommendation 9:

The NRC staff should clarify and publish in its YMRP how it will tailor its licensing review of the abstractions (integrated subissues) on the basis of their importance to safety.

NRC Staff Response:

Now that 10 CFR Part 63 has been finalized, the NRC staff plans to submit the YMRP (revised to be consistent with 10 CFR Part 63) to the Commission for review. The staff will document how it will risk-inform its licensing review, based on repository risk insights, in the review plan. In addition, as previously mentioned, the staff intends to complete a risk insights report, where the staff will document the risk insights that are being used by the staff and how the staff plans to use risk insights to focus its review of a potential license application. This report will provide a baseline that may change as new information becomes available.

Observation/Recommendation 10:

The staff should clarify in the YMRP how to use “conservatism” appropriately to treat uncertainty, while providing a risk-informed analysis and understanding of the risks associated with the proposed repository.

NRC Staff Response:

NRC has developed regulations that are risk-informed and performance-based. DOE is able to use the flexibility afforded by the regulations to develop a realistic performance assessment or to introduce conservatism. As part of the issue resolution process, the staff reached agreements with DOE that are expected to result in the information necessary to conduct a risk-informed review of the potential license application, whether DOE uses analyses that are realistic or conservative.

The NRC staff agrees that how DOE uses conservatism in its analyses is an important issue. The NRC staff has recently completed its review of the pre-closure safety assessment, the TSPA-SR, and the supporting documentation for each. The staff will use lessons learned from its pre-closure operations and post-closure performance reviews to evaluate whether future changes are needed in the YMRP. We anticipate that some changes to the YMRP will be made to clarify the use of conservatism.

Observation/Recommendation 11:

According to the staff, the issue resolution agreements that emerged from the technical exchange meetings formed the basis for the staff’s sufficiency comments. However, the existing Issue Resolution Status Reports (IRSRs) do not reflect the most current information supporting the recent agreements. This discrepancy will make it difficult to trace the bases and criteria that the staff used to develop its sufficiency comments. We understand that the staff intends to update the IRSR to reflect the most recent information and acceptance criteria in the integrated IRSR, but this document is still under development and may not become publicly available for some time. The traceability, clarity, and transparency of the sufficiency comments will not be complete without this integrated IRSR. Therefore, we recommend that the staff release this document to the public as soon as feasible.

NRC Staff Response:

The materials presented at the issue resolution meetings and the agreements reached during the meetings did form the technical bases for the staff's sufficiency comments. The materials, agreements, and discussions at the meeting, which are documented in the associated meeting summaries, are publicly available now. The criteria that the NRC staff used to develop its sufficiency comments are contained in the existing IRSRs and were discussed in the public issue resolution meetings. The NRC staff is preparing an Integrated IRSR that will formally document the status of issue resolution. In this document, NRC plans to integrate the information discussed during the issue resolution meetings into the 14 specific post-closure integrated subissues, as well as the pre-closure issues. The staff is currently incorporating the information provided during the recent Pre-Closure Safety, Total System Performance Assessment and Integration, Igneous Activity, and Range of Operating Temperature meetings into the Integrated IRSR. The NRC staff will release the document, as soon as it can after incorporating the new information and completing an internal review.

NRC Staff Conclusion Related to Sufficiency Review

As discussed above and consistent with the NRC Chairman's letter to DOE dated November 13, 2001, the NRC staff believes that sufficient at-depth site characterization analysis and waste form proposal information, although not available now, will be available at the time of a potential license application such that development of an acceptable license application is achievable.

Sincerely,

/RA/

William D. Travers
Executive Director
for Operations

cc: Chairman Meserve
Commissioner Dicus
Commission Diaz
Commissioner McGaffigan
Commissioner Merrifield
SECY

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Sincerely,
/RA/
 William D. Travers
 Executive Director
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cc: Chairman Meserve
 Commissioner Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 SECY

* See Previous Concurrence

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