

NMSS/RGN M&S-001

UNITED STATES
NUCLEAR REGULATORY COMMISSION
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February 25, 2000



Stephan J. Brocoum, Acting Assistant Manager
Office of Licensing and Regulatory Compliance
U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 30307
North Las Vegas, NV 89036-0307

SUBJECT: Q-LIST METHODOLOGY AND GRADED QA

Dear Mr. Brocoum:

As you know, the U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) staffs, along with their contractors, have been discussing issues related to DOE's quality assurance (QA) program. One related issue, which has been discussed for some time, is the methodology for classifying items important to safety and waste isolation (Q-list process). Based on the extensive discussions held between our staffs during recent interactions, it has become clear to us that you and we have the opportunity to address the issue of Q-list process during the pre-licensing period, and thereby avoid potential unresolved questions during the license review.

We understand that the DOE Q-list process, which is still at a "systems level," will be refined after detailed designs are available. While your current approach of categorizing various items on the Q-list as QL-1, 2, or 3 based on safety/isolation significance seems to be fundamentally sound, we have questions regarding how much of the process depends upon functional descriptions and how much upon risk significance. We also have questions regarding how you define "indirect impact" on public health and safety as well as on waste isolation in classifying items and barriers under QL-2 category. The information we will be seeking pertains to our requirements for a license application and, in particular, to the adequacy of your QA program for design activities and the basis for grading of QA requirements. However, we favor receiving the information now rather than awaiting submission of a possible license application. Given the limited time available for license review, we believe it is more efficient to focus efforts and attention on this issue now. We propose one or more technical exchanges, both to be held in early 2000 on a mutually agreed upon date. From discussions with the DOE staff, we understand that such near-term meetings are likely to be a mutually acceptable way to proceed.

We appreciate receiving information from you already, regarding DOE's efforts at reorganizing and regrouping several of the procedures that govern activities related to the Q-list process. We have questions regarding how the process is currently working and how the transition will take place. While, as we have noted, QA is a requirement for a license application, we would appreciate the opportunity to address these matters with you now, rather than await a license application. We have noted some of your Analyses Model Reports and Process Model Reports dated as recently as November 1999 are still continuing to use your earlier QA

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classification system (e.g., QA-1, QA-2) instead of the most recent categorization consisting of three levels. In general, we would favor the use of a consistent classification system on your documents. Further, we would encourage you to consider formally updating your Quality Assurance Requirements Document (QARD) by including a discussion on the categorization process, the three classification levels, and identifying the QA controls to be applied to each category. This requested QARD change is consistent with the current NRC policy on risk-informed decision making in the area of graded QA. You may also want to consider whether it would be prudent for you to seek NRC's approval for your proposed graded QA classification process and the related graded QA controls before proceeding further with detailed design activities. Similarly, we would encourage you to consider updating your QARD to describe the graded QA process used for site characterization.

In summary, we would like to meet with you in the near future to discuss your current approach to the Q-list process and possible alternative approaches, as well as their strengths and limitations in terms of furthering a potential licensing process. No written response is required for this letter. We look forward to meetings in the near future to discuss the items contained in this letter. If you or your staff have any questions on the issues discussed in this letter, please contact Dr. Mysore Nataraja of my staff who is available at (301) 415-6695 or by e-mail at, <msn1@nrc.gov>.

Sincerely,

[Original signed by:
Sandra L. Wastler for:]

C. William Reamer, Chief
High-Level Waste and Performance
Assessment Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

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S. Brocoum

three levels. We take this opportunity to encourage you to use a consistent classification system on your documents and to formally update your Quality Assurance Requirements Document by including a discussion on the categorization process and identifying the QA control to be applied to each category. It would be prudent for you to seek NRC's approval for your proposed graded QA classification process before proceeding with detailed design activities.

In summary, we encourage you to meet with us in the near future to discuss the implications of your current approach and to consider alternative approaches for avoiding a potential delay in the licensing process. If you or your staff have any questions on the issues discussed in this letter, please contact Dr. Mysore Nataraja of my staff who is available at (301) 415-6695 or by e-mail at <msn1@nrc.gov>.

Sincerely,

C. William Reamer, Chief
High-Level Waste and Performance
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