

January 30, 2003

U.S. Department of Energy
Office of Repository Development
Attn: Mr. Dennis Brown, Director
Office of Quality Assurance
P.O. Box 364629 - M.S. 523
North Las Vegas, NV 89036-8629

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION STAFF REVIEWS OF REVISION
10, 11, AND 12 OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE
MANAGEMENT QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

Dear Mr. Brown:

This is in response to the Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), letters dated February 28, 2001, May 6, 2002, and September 30, 2002, regarding Revisions 10, 11, and 12, respectively, of the DOE, OCRWM, Quality Assurance Requirements and Description (QARD), DOE/RW-033P. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the changes to the QARD described in Revisions 10, 11, and 12 in accordance with the requirements of 10 CFR 63, "Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada." The staff has determined that the changes incorporated into Revision 10, 11, and 12 of the QARD are acceptable, and that the QARD is considered adequate for controlling DOE's present work activities.

The NRC regulatory requirements contained in Subpart G-Quality Assurance, of 10 CFR 63, specify the quality assurance (QA) criteria that the DOE Yucca Mountain project QA program must meet. Pursuant to 10 CFR 63.21(c)(20), the DOE Yucca Mountain Project Safety Analysis Report must include a description of the QA program to be applied to the structures, systems, and components (SSCs) important to safety and to the engineered and natural barriers important to waste isolation. The description of the QA program must include a discussion of how the applicable requirements of 10 CFR 63.142 will be satisfied.

Because DOE is not yet an applicant for the potential High Level Waste Repository at Yucca Mountain, the NRC staff did not perform a complete review of the QARD in accordance with the guidance in the Yucca Mountain Review Plan Draft Report for Comment, NUREG-1804, Draft Revision 2, which has been published for public comment. However, prior to any license application, DOE should modify certain sections of the QARD to clarify the DOE commitments and adequately describe QA program requirements for design, procurement, construction and preclosure activities. These modifications should include, but not be limited to, changes to sections such as those addressing the organization structure, including delegation of QA program responsibilities, QA program commitments, graded QA, commercial grade item dedication, records, including storage of records using electronic media, and audits.

Prior to any license application, DOE should also modify the QA program to identify the SSCs covered by the QA program, the major participating organizations and their functions, and the control of activities affecting the quality of the identified SSCs, consistent with their importance to safety. The categorization process, methods, and criteria for determining the SSC functional requirements and grading of QA controls must be defined. The Q-list process and QL-1, 2, or 3 SSC categorization were discussed in the April 25-26, 2002, U.S. NRC/DOE Technical Exchange on the Preclosure Safety Analysis Guide, and were addressed in the NRC letter, C. William Reamer, NRC, to Stephen J. Brocoum, DOE, Subject: Q-List Methodology and Graded QA, February 25, 2000.

Should DOE submit a license application, we would expect that modifications, such as those discussed above, would be incorporated in the QARD prior to license application. However, DOE should consider revising the QARD now, since a variety of organizational changes and delegations are in progress, and various organizations are currently performing activities that utilize the Q-list process and SSC QL categorization methods.

If you have any questions regarding this letter, please contact me at (301) 415-7264, or Tom Matula of my staff at (301) 415-6700.

Sincerely,

/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Nuclear Material Safety
And Safeguards

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