



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SEP 02 1993

Mr. Dwight E. Shelor, Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. Shelor:

SUBJECT: REVIEW OF THE U.S. DEPARTMENT OF ENERGY RESPONSES TO U.S.
NUCLEAR REGULATORY COMMISSION COMMENTS ON THE QUALITY ASSURANCE
REQUIREMENTS AND DESCRIPTION DOCUMENT

On May 24, 1993, the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) forwarded its responses to the four NRC staff comments resulting from its review of the OCRWM Quality Assurance Requirements and Description document (QARD) as documented in the May 8, 1993, letter from J. Holonich to D. Shelor. These responses were also briefly discussed at the July 20, 1993, NRC/DOE Quality Assurance (QA) meeting in Rockville, MD. The purpose of this letter is to provide you with the results of the NRC staff review of the OCRWM responses.

Issue (1) OCRWM proposes to audit principal suppliers on a triennial basis instead of annually as stated in the NRC staff position for principal contractors.

Position: (OCRWM)

- Audit frequency based on nature of items/services performed.
- Triennial audits to be supported by performance based audits.
- External audits for compliance performed triennially.
- Annual performance review/evaluation for all organizations required.
- If annual evaluations insufficient to justify not performing an audit, then audit will be performed.

Response: (NRC) The NRC staff has not observed any of the planned OCRWM actions and therefore, cannot attest to the new proposal being adequate or effectively implemented. This will remain an open issue until such time as the OCRWM demonstrates it does not reduce the confidence in the suppliers QA programs afforded by the original commitment to the NRC staff position of auditing principal suppliers on an annual basis.

Issue (2) Clarifications requested for acquired software in QARD Supplement I, Section I.2.6, paragraphs A, B, C, and D.

Position: (OCRWM) OCRWM will clarify in next revision to QARD.

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Response: Acceptable. Item will remain open pending NRC staff review of the (NRC) OCRWM revision to QARD.

Issue (3) Clarifications requested for Model Validation in QARD Supplement III, Section III.2.6.B of the QARD.

Position: OCRWM will clarify in next revision to QARD. (OCRWM)

Response: Acceptable. Item will remain open pending NRC staff review of the (NRC) OCRWM revision to QARD.

Issue (4) The QARD should include a description stating that the OCRWM has overall responsibility for QA for the transportation system under the OCRWM program. When DOE is supported in this activity by various organizations, it is understood that these organizations have the delegated authority to implement the applicable requirements of Parts 21 and 71 of Title 10 Code of Federal Regulations (CFR).

Response: This matter was discussed between K. Hooks and R. Clark in a July (NRC) 27, 1993, telephone conversation. DOE stated that the issues raised by the NRC are adequately described in Sections ii, 1.0, Appendix B of the QARD. The NRC staff finds this response acceptable. However, for the design, fabrication, assembly, testing, and modification of transportation packages, the NRC staff requests that OCRWM apply for a QA program approval from the NRC (Charles J. Haughney, Acting Chief, Source Containment and Devices Branch). This application could indicate that the current QARD will be applied to 10 CFR Part 71 activities. Questions concerning this request should be directed to John Jankovich on (301) 504-2454.

Based on the NRC staff review of the responses to the four NRC issues, we find once these issues are acceptably resolved, the QARD will receive full NRC staff acceptance.

Should you have any questions regarding our review, please contact William Belke on (301) 504-2445.

Sincerely,



Joseph J. Holonich, Director
Repository Licensing and Quality Assurance
Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

cc: See next page

Mr. Dwight E. Shelor

- cc: R. Loux, State of Nevada
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