



Department of Energy

Washington, DC 20585

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Mr. Joseph J. Holonich, Director  
Repository Licensing and Quality  
Assurance Project Directorate  
Division of High-Level Waste Management  
Office of Nuclear Material Safety  
and Safeguards  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Mr. Holonich:

This is in response to the U. S. Nuclear Regulatory Commission (NRC) review of the U. S. Department of Energy (DOE) Quality Assurance Requirements and Description Document

On December 21, 1992, the NRC was requested to review and accept the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description Document (QARD), DOE/RW-0333P, Revision 0, dated December 18, 1992. The NRC staff documented the results of their review in a letter to Mr. Dwight Shelor, dated March 8, 1993. The letter indicated that the DOE/RW-0333P QARD continues to meet the NRC conditions for acceptance of the OCRWM Quality Assurance (QA) program with the exception of four open issues. The OCRWM responses to the four open issues are described below.

Issue (1) It is the NRC's position that the principal contractors be audited on an annual basis or justification be provided as to why longer time periods would be acceptable. The NRC understands OCRWM's intent for its proposed reduction of auditing frequency to a triennial basis; however, the staff has reservations on completely accepting this new practice until it can monitor its effectiveness. The NRC will monitor this position and indicate, in writing, any unsatisfactory results.

Response: The DOE/RW-0333P QARD, requires that the need for and frequency of all external audits be determined after an affected organization has been selected to perform work for the OCRWM program. The determination is based on the nature of the items or services being performed. External audits for compliance shall be performed triennially, as a minimum. Triennial compliance audits will be supported by performance based audits on selected work products. Annual performance evaluations for all affected organizations are required to be

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conducted and documented. These annual evaluations provide the justification for not performing annual compliance audits. If the annual evaluations cannot justify not performing an audit within the triennial period or indicate the need for additional audits, then an audit will be performed. Based on the QARD requirements, OCRWM will proceed with scheduling audits on a triennial basis, and as always, the NRC is welcome to monitor this practice.

Issue (2) It is the NRC's understanding that OCRWM has agreed to revise Supplement I of the DOE/RW-0333P QARD, to clarify that acquired software must meet the requirements of Supplement I, Section I.2.6, paragraphs A, B, C and D.

Response: OCRWM has agreed to make this change in its next revision of the DOE/RW-0333P, QARD.

Issue (3) It is the NRC's understanding that OCRWM has agreed to revise Supplement III, of the DOE/RW-0333P QARD, to clarify, in Section III.2.6.B, that "Model Validation" is limited to validation by peer review in those instances where data cannot be collected.

Response: OCRWM has agreed to evaluate Section III.2.6.B for a change in its next revision of the DOE/RW-0333P, QARD. We do not recall that specifics were discussed. The proposed change to Supplement III will be coordinated with the NRC staff before making the change.

Issue (4) The NRC Transportation Branch, Division of Industrial and Medical Nuclear Safety, maintains the position that the QARD include a description that the DOE has overall responsibility for quality assurance for the transportation system under the OCRWM program. This is with the understanding that DOE will be supported in this activity by other various organizations and that these organizations will be delegated authority and responsibility to implement the applicable requirements of 10 CFR Parts 71 and 21.

Response: The DOE/RW-0333P, QARD, is applicable to all program elements including transportation. Section 1.3.2.A states that the Director of OCRWM has the overall responsibility for carrying out the program. Section 1.2.4 states that positions or organizations delegating work shall retain overall responsibility for the delegated work. Section 1.3.2.6 states that the OCRWM Office of Storage and Transportation is responsible for managing the transportation system.

OCRWM has maintained its responsibility for Quality Assurance for all program elements, including transportation, by issuance of the QARD and imposition of requirements therein to all program participants.

OCRWM assures compliance with the QARD requirements by required QA overview activities.

With regard to 10 CFR Parts 71 and 21, the QARD, Appendix B, imposes 10 CFR Part 71. 10 CFR Part 21, however, while applicable to the OCRWM program through the OCRWM technical baseline, is not a Quality Assurance requirement and, therefore, will not be referenced in the QARD. This is consistent with NRC guidance contained in NUREG-0302, Revision 1.

Should you have any questions regarding this reply, please contact Donald G. Horton, at (202) 586-7220.

Sincerely,



Dwight E. Shelor  
Associate Director for  
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