

MAR 8 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, D.C. 20585

Dear Mr. Shelor:

SUBJECT: REVIEW OF THE U. S. DEPARTMENT OF ENERGY QUALITY ASSURANCE
REQUIREMENTS AND DESCRIPTION DOCUMENT

On December 21, 1992, the U.S. Department of Energy (DOE) forwarded the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description document (QARD), DOE/RW-333P, Revision 0, dated December 18, 1992, to the NRC staff for review and acceptance. The QARD consolidates the currently issued and implemented OCRWM Quality Assurance Requirements Document and the Quality Assurance Program Description document into a single document. In its November 21, 1991, letter from J. Holonich to J. Roberts, the NRC staff documented its acceptance of these two documents. The purpose of this letter is to provide you with the results of the U.S. Nuclear Regulatory Commission review of the QARD.

The NRC staff used the NRC Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, March 1989, to determine whether the consolidated QARD continues to meet the appropriate Title 10 Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B). The QARD was also reviewed to determine whether it reduced any of the commitments previously accepted by the NRC staff as documented in its November 21, 1991, letter to OCRWM.

A meeting was held between the NRC staff and OCRWM (see October 28, 1992, Meeting Minutes transmitted from J. Holonich to J. Roberts dated November 18, 1992) whereby OCRWM presented an overview of the proposed revisions to the QARD and requested the NRC staff to review and provide its comments on Revision No. Draft OD of the QARD. The State of Nevada also attended this meeting. The results of the NRC staff review of Draft OD of the QARD required additional information and clarification from OCRWM (primarily in the areas of organizational responsibility, contractor/supplier auditing, and software quality assurance) in order to complete its review. The NRC staff's request for additional information and clarification was discussed with OCRWM and the State of Nevada in a November 19, 1992, conference call. OCRWM discussed its response to the NRC staff in a December 4, 1992, conference call with the NRC staff and the State of Nevada. As a result of the aforementioned discussions, OCRWM formally submitted the QARD on December 21, 1992, for the NRC staff review and acceptance.

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Based on its review of the revised QARD, the NRC staff finds the QARD continues to meet the NRC staff's conclusions as documented in the NRC staff Safety Evaluations from J. Linehan to R. Stein dated May 8, 1989, and May 2, 1989, respectively, for the earlier Quality Assurance Requirements Document and Quality Assurance Program Description document except for resolution of the following open issues:

(1) The QARD takes exception to the OCRWM commitment previously accepted by the NRC staff regarding the scheduling of external audits for its suppliers. Suppliers, as defined in the Glossary section of the QARD, is any individual or organization who furnishes items or services in accordance with a contract. It is an all exclusive term used in place of any of the following: vendor, seller, participant, contractor, or subcontractor. The exception now allows for the scheduling of audits of external organizations (suppliers, other DOE offices and other government agencies) to be performed on a triennial basis instead of the annual basis previously required.

The NRC position on scheduling external audits in Regulatory Position C.3.2 of Regulatory Guide (RG) 1.28, Revision 3, dated August 1985, allows for triennial audits of suppliers subject to certain provisions. RG 1.28 is primarily applicable to the design and construction of nuclear power plants with Regulatory Position C.3.2 being formulated from that basis. The C.3.2 Position was developed with the intent of reducing the proliferation of unnecessary audits, especially for the smaller type suppliers providing a limited quantity of items or services. Although not specifically stated, it was not intended to relieve the responsible organization of auditing/evaluating the larger type suppliers (e.g., architect engineer, nuclear steam supply system vendor, and principal contractors) entire QA program on an annual basis. The NRC staff considers OCRWM's principle contractors to be: Lawrence Livermore National Laboratory, Los Alamos National Laboratory, Civilian Radioactive Waste Management System Management & Operating Contractor, Raytheon Services Nevada, Reynolds Electric & Engineering Co., Inc., Sandia National Laboratories, Science Applications International Corporation, and the U.S. Geological Survey.

It is the NRC staff's position that the principle contractors be audited on an annual basis or justification be provided as to why longer time periods would be acceptable. The NRC staff recognizes that there is no requirement mandating annual audits of principle suppliers in the regulations or national standards documents. However, based on the NRC staff's nuclear power reactor experience and "lessons learned," it would appear prudent that the DOE physically audit its principle contractors at least annually or provide ample justification for not doing so. The NRC staff understands the OCRWM intent for its proposed reduction of auditing frequency in the previous commitment. However, the NRC staff has reservations on completely accepting this new practice until it can monitor its effectiveness. Should the NRC staff monitoring of this position indicate unsatisfactory results, we will notify you in writing.

(2) In its next revision to the QARD, OCRWM has agreed to incorporate a change to clarify its position on acquired software in Supplement I, "Software." It is the NRC staff understanding that the proposed change will

state that acquired software must meet the requirements of Supplement I, Section I.2.6, paragraphs A, B, C, and D.

(3) OCRWM has also agreed in its next revision to incorporate a change to clarify that QARD Section III.2.6.B, "Model Validation," is limited to validation by peer review in those instances in which data cannot be collected.

(4) The QA Section of the NRC Transportation Branch, Division of Industrial and Medical Nuclear Safety, was responsible for reviewing Appendix B, "Transportation," of the QARD. The results of their review indicate that the QARD is acceptable for the transportation aspect subject to one condition. It is the position of the NRC Transportation Branch 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 a program that meets the applicable requirements of 10 CFR Parts 71 and 21.

Based on the NRC staff review of the QARD, we find that once the above issues are resolved, the QARD can serve as an adequate framework for OCRWM and its participants to develop specific policies, plans, and procedures to implement their respective programs.

Except for the four issues noted above, the consolidated QARD continues to meet the NRC staff conclusions as documented in the NRC staff acceptance letter for the earlier Quality Assurance Requirements Document and Quality Assurance Program Description document. The QARD also continues to meet the NRC staff conclusions as documented in the NRC staff Safety Evaluations from J. Linehan to R. Stein dated May 2, 1989, and May 8, 1989, for the earlier QA program documents.

Changes may be made to the QARD if they do not downgrade OCRWM commitments previously accepted by NRC. However, changes that downgrade the QARD commitments should be submitted to the NRC staff for review and acceptance.

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

Sincerely,

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

See next page for cc's and distribution.

* See previous concurrence:

OFC	HLPD*		HLPD*		HLPD*		IMTB*		HLPD
NAME	WBelke/dh		JBuckley		KHooks		CMacDonald		JHolomich
DATE	02/ /93		02/ /93		02/ /93		02/ /93		02/3/93

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

See next page for cc's and distribution.

OFC	HLPD	C	HLPD	C	HLPD	C	IMTB	C	HLPD
NAME	WBelke/dh		JBuckle		KHooks		CMacDonald		JHolonich
DATE	02/25/93		02/25/93		02/25/93		02/25/93		02/ /93

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Mr. Dwight E. Shelor

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OF THE U.S. DEPARTMENT OF ENERGY QUALITY ASSURANCE REQUIREMENTS AND
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