

WB/QARD/QAPD AOC LETTER

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DEC 3 1990

Mr. Dwight Shelor, Acting Associate Director
 Office of Systems and Compliance
 Office of Civilian Radioactive Waste Management
 U. S. Department of Energy, RW 30
 Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: REVIEW OF THE U.S. DEPARTMENT OF ENERGY (DOE) QUALITY ASSURANCE
 REQUIREMENTS DOCUMENT (QARD) AND QUALITY ASSURANCE PROGRAM
 DESCRIPTION (QAPD)

The purpose of this letter is to provide you with the results of the U.S. Nuclear Regulatory Commission (NRC) staff review of the DOE Office of Civilian Radioactive Waste Management (OCRWM) QARD, DOE/RW-0214, Revision 4, dated September 1990, and the DOE OCRWM QAPD, DOE/RW-0215, Revision 3, dated September 1990. DOE revised the QARD and QAPD to consolidate the OCRWM and Yucca Mountain Project Office (YMPO) quality assurance (QA) program documents, namely, the OCRWM QARD, DOE/RW-0214, Revision 2; OCRWM QAPD, DOE/RW-0215, Revision 1; YMPO QA Plan, NNWSI/88-9, Revision 4; YMPO QA Program Plan, 88-1, Revision 3; and OCRWM QA Requirements For High-Level Waste Form Production, OGR/B-14, February, 1988.

The NRC staff used the NRC Review Plan For High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, March 1989, (RP) to determine whether the revised QARD and QAPD met the appropriate 10 CFR Part 50 Appendix B criteria. The QARD and QAPD were also reviewed to determine whether the revisions reduced the commitments previously accepted by the NRC staff in the Safety Evaluations for Revisions 1 of the QARD and QAPD, and Revision 2 of NNWSI/88-9 (Safety Evaluations from J. Linehan to R. Stein dated May 8, 1989, May 2, 1989, and December 30, 1988 respectively).

As a result of the NRC staff review, nine comments were developed and discussed with DOE in a June 5, 1990 conference call. The comments involved clarifying: organizational requirements, responsibilities, and reporting relationships; the term "item" to be inclusive of software; how the QARD and QAPD comply with the NRC RP; the difference between "conceptual" and "advanced conceptual" design; and that "root cause" as opposed to the "cause" is performed when analyzing nonconformances.

At the July 19, 1990 Bi-monthly QA Meeting between representatives of NRC and DOE Headquarters at Rockville, Maryland, DOE presented responses to the NRC staff comments. Other participants included representatives from the State of Nevada and the Utility Nuclear Waste Management Group. The responses were reviewed by the NRC staff and discussed with DOE at NRC Headquarters on September 10, 1990. The NRC staff requested additional clarifications from DOE to address "root cause," software, and annual evaluations of personnel qualifications.

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Draft copies of the QARD, Revision 4, dated July 16, 1990, and QAPD, Revision 3 (not dated), were provided by DOE to the NRC staff on September 10, 1990. These drafts highlighted the DOE responses to the NRC staff comments in addition to incorporating recent organizational and policy changes. The DOE approved QARD, Revision 4, dated September 1990, and QAPD, Revision 3, dated September 1990 were provided by DOE to NRC on October 4, 1990.

Although the formats of the QARD and QAPD have been slightly changed, the NRC staff concludes that, with the possible exception of the six issues listed below, both documents continue to meet the requirements of Appendix B to 10 CFR Part 50, and the guidance contained in the NRC RP with no decrease in commitments previously accepted by the NRC staff. The QARD and QAPD continue to support the NRC conclusions as documented in the NRC Safety Evaluations as noted above except for the following open issues:

- (1) Sections 1.4 of the QARD and 1.1.16 of the QAPD state that OCRWM will develop a system for reporting allegations of inadequate quality. The DOE participant QA Program Plan descriptions state that such allegations are to be resolved in accordance with Yucca Mountain Project Administrative Procedure AP-5.8Q, "Resolution and Reporting of Quality Concerns." This is an apparent inconsistency which needs to be resolved between DOE and its participants.
- (2) Section 16 of the QARD and QAPD states that identification of root cause will be accomplished by analyzing the information contained in trend analysis reports. The NRC staff recognizes that certain root causes may be uncovered through a trend analysis, whereas others may be uncovered by analyzing the individual condition adverse to quality. The NRC staff also recognizes that there may be isolated instances where the determination of a root cause may be inappropriate or unnecessary due to an obvious nonconforming condition. The NRC staff believes that when a nonconforming condition is discovered, it should be analyzed to determine, where appropriate, what actually caused the nonconforming condition, i.e., "root cause." The QARD and QAPD should describe measures to assure that the corrective action and reporting systems include provisions to determine the "root cause" of a condition adverse to quality in order to take timely effective corrective action.
- (3) Section 17 of the QARD has deleted the reference to DOE/RW 0194, "Records Management Policies and Requirements." This DOE document formed the basis for NRC acceptance of the scope of the DOE QA records program for the geologic high-level waste repository. DOE should provide a description of what the scope of their quality records system consists of, including a listing of typical post-closure and lifetime records most applicable to the geologic high-level waste repository.
- (4) The revised Appendix A of the QAPD lists additional support contractors and affected organizations performing work related to the geologic high-level waste repository. Several of these QA programs have not been submitted to the NRC staff nor have they been

observed by the NRC staff as being audited by DOE. DOE should state whether it will submit these QA programs to NRC and provide a schedule of when they will be audited by DOE.

- (5) In Appendix E, "Glossary" of the QARD, the definition of "Procurement Document" indicates that revisions to procurement documents that do not modify the scope of an item or activity to which the QA program is applied to, are not subject to the procurement controls of the QA program. Those revisions that add quality assurance or technical requirements to procurement documents, are subject to QA or technical review. It is not clear in Appendix E of the QARD or in any other sections of the QARD or QAPD, what individual(s) or organization(s) are responsible for determining whether a review of revisions to procurement documents necessitates involvement by the QA or technical organizations.
- (6) During its review of the QARD and QAPD, the NRC requested clarification from DOE concerning where certain of the RP criteria pertaining to software QA controls were addressed. In response to the NRC concern, DOE has stated, that a matrix will be provided to the NRC staff specifically delineating how and where the QARD and QAPD meet the RP criteria concerning software QA controls. This matrix will be required for final review by the NRC staff for verifying the acceptability of the software QA controls of the QARD and QAPD.

Based on the NRC staff review of the QARD, we find that once the above issues are satisfactorily resolved, it can serve as an adequate requirements document to establish QA requirements applicable to the Mined Geologic Disposal System and Waste Acceptance Process Activities of High-Level Waste Form Production. Likewise, the QAPD, once the above issues are satisfactorily resolved, will contain adequate requirements and systematic controls to address each of the Appendix B to 10 CFR Part 50 criteria in an acceptable manner to implement the QA programs for the Civilian Radioactive Waste Management Program. With the resolution of the above open issues, we find these documents can serve as an adequate framework for DOE and its project participants to develop specific policies, plans, and procedures to implement their respective QA programs. The above open issues will be listed and tracked on the NRC/DOE Open Issues List pending satisfactory resolution by DOE.

We did not perform a review of the QARD section pertaining to Transport of Spent Fuel and High-Level Nuclear Waste and Monitored Retrievable Storage. Should DOE request a review on these QARD sections, this request should be submitted to the NRC staff in writing.

Except for the six open issues noted above, the QARD and QAPD continue to meet the NRC staff conclusions as documented in the NRC Safety Evaluations as noted above for Revisions 1 of the QARD and QAPD, and Revision 2 of NNWSI/88-9. The NRC staff expects that DOE will expeditiously and satisfactorily resolve the aforementioned six issues resulting from the NRC staff review of the QARD, Revision 4, and QAPD, Revision 3.

Changes may be made to the QARD and QAPD if they do not downgrade DOE commitments previously accepted by NRC. Changes that downgrade the program commitments should be submitted to NRC for review and acceptance.

Should you have any questions concerning our review, please contact William Belke on (301) 492-0445 or FTS 492-0445.

Sincerely,

JSI

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

- cc: R. Loux, State of Nevada
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