

February 21, 2003

Joseph D. Ziegler, Acting Director
Office of License Application and Strategy
U.S. Department of Energy
Office of Repository Development
P.O. Box 364629 M/S 523
North Las Vegas, NV 89036-8629

SUBJECT: REVIEW OF OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION, DOE/RW-
0333P, PROPOSED REVISION 13

Dear Mr. Ziegler:

This is in response to the Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), January 30, 2003, letter regarding the proposed Revisions 13 to the DOE, OCRWM, Quality Assurance Requirements and Description (QARD), DOE/RW-0333P. DOE stated that it would obtain NRC acceptance of all changes to its QARD before those changes are implemented. DOE also stated that it would provide adequate justification for changes to its QARD that constitute reductions in commitments.

We reviewed the changes to the QARD described in the proposed Revisions 13 in accordance with the requirements of 10 CFR 63, "Disposal of High-level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada." During the review, staff identified several points requiring clarification. Furthermore, it appears that DOE has reduced commitments in proposed Revision 13 to the QARD that were made in Revision 12. Therefore, please provide the additional information listed in the enclosure to this letter within 30 days of the date of this letter. If you have any questions, please call Thomas Matula of my staff at 301-415-6700.

Sincerely,
/RA/

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

Attachment: Additional Information Needs

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Office of Repository Development
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DATE:	02/13/03		02/14/03		02/21/03	

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Additional Information Needs

U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Quality Assurance Requirements and Description
Proposed Revisions 13

A. QUALITY ASSURANCE POLICY

The QA Policy statement in Revision 12 to the QARD states the following:

Central to our mission is the protection of the health and safety of the public and workers, the quality of the environment and meeting the regulatory basis for the licensing of a storage and/or Monitored Geologic Repository.

As the Director of OCRWM, I have endorsed the quality assurance requirements necessary to ensure these vital protections. This document, the *Quality Assurance Requirements and Description*, embodies these requirements. These requirements, as applicable, apply to every level of every organization participating in this mission.

The quality assurance provisions described in the *Quality Assurance Requirements and Description* have my unqualified support. All organizations performing work for, or to be accepted by, OCRWM shall comply with the *Quality Assurance Requirements and Description*.

The QA Policy statement in the proposed Revision 13 to the QARD shows that the above listed commitments were deleted from the QARD. Please provide your justification for deleting these DOE top management commitments.

B. SUPPLEMENT III, SCIENTIFIC INVESTIGATION

1. Paragraph III.2.3 states that "Data shall be identified in a manner that facilitates traceability to its qualification status," and that "Identification and traceability shall be maintained throughout the lifetime of the data." As a result of Corrective Action Report LVMO-98-C-002, Procedure AP-3.15Q, "Managing Technical Product Inputs," was revised on December 15, 1999, to reflect application of a graded approach to data management and a data verification process. Specifically, data (Qualified - Verification Level 2 (QL-2) data) entered into the Technical Data Management System prior to June 30, 1999, was flagged as "To Be Verified" because this QL-2 data was qualified under the DOE QA program using a limited documented basis. DOE committed to subject all QL-2 data, relied upon to address safety and waste isolation issues, to the data confirmation/verification process described in Procedure AP-3.15Q. However, the proposed Revision 13 to the QARD identifies data as either "qualified" or "unqualified," and does not account for possible use of QL-2 data, that has not been verified under Procedure AP-3.15Q, and that may be used in support of the license application. Please clarify in the proposed Revision 13 of the QARD the identification, control, and verification of QL-2 data.

ATTACHMENT

2. In Revision 12 of the QARD, Paragraph III.2.4B.1. is applicable to “data qualified from origin,” (i.e., qualified data). However, in the proposed Revision 13 to the QARD, it is not clear as to what type of data (i.e., qualified or unqualified) this paragraph applies.

C. GLOSSARY

1. In Revision 12 of the QARD, Paragraph III.2.4B.1. referred to “acquired” and “developed” data, which were also defined in the Glossary. In the proposed Revision 13 to the QARD, these terms were replaced with “collected” and “reduced,” respectively. However, the new terms are not defined in the Glossary. What are the definitions for the new terms and how do they differ from the previous terms?
2. In Revision 12 to the QARD, the term “Data” was defined to include “...information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analysis.” This definition matches the definition of “Data” in Procedure AP-3.15Q, “Managing Technical Product Inputs.” However, the definition of “Data” in the proposed Revision 13 to the QARD excludes reference to information obtained from performance assessment analysis. Please provide your justification for this exclusion. Also, please provide your intentions regarding changing the definition of “Data,” as well as the other terms, in Procedure AP-3.15Q to match those definitions in the proposed Revision 13 of the QARD.
3. In the proposed Revision 13 of the QARD, the term “Accepted Data” was replaced by “Established Fact.” However, this new term is apparently not used elsewhere in the QARD. Please describe the differences between these terms, and identify where “Established Fact” is used in the QARD.
4. In the proposed Revision 13 of the QARD, a “qualification process” is identified in the definition of “Qualified Data.” Please clarify where the “qualification process” is addressed in the QARD.
5. While reviewing the changes to the Glossary in the proposed Revision 13 to the QARD, we noted that reference is made to 10 CFR Part 60. Please note that 10 CFR 63.1 states that “As provided in 10 CFR 60.1, the regulations in part 60 of this chapter do not apply to any activity that is subject to licensing under...part [63].” Please clarify why Part 60 is referenced in the QARD.