

March 18, 1996

0482

Mr. Ronald A. Milner, Director
for Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW 30
1000 Independence Avenue, S.W.
Washington, D.C. 20585

SUBJECT: REVISION 5 OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION DOCUMENT

Dear Mr. Milner:

Thank you for your letter of December 28, 1995, transmitting Revision 5 of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description document (QARD - DOE/RW-0333P) dated October 2, 1995. We have reviewed Revision 5 of the QARD. As your letter indicates, it reduces the commitments made in Revision 4. Revision 4 was noted as being acceptable in my letter to you dated January 18, 1996. The reductions in commitments and the justification for them provided in Enclosure 2 of your letter are acceptable. However, we do have some questions/comments regarding some of the other changes. These are enclosed as a "Request for Additional Information."

Please respond to the enclosure to this letter within thirty days of receipt of this letter. If you have any questions, please call Jack Spraul of my staff on (301) 415-6715.

Sincerely,
(original signed by)

John H. Austin, Chief
Performance Assessment and High-Level
Waste Integration Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached list

DISTRIBUTION w/enclosure: FILE CENTER PUBLIC LSS
NMSS r/f DWM r/f HLUR r/f CNWRA ACNW
NEisenberg KMcConnell TMcCartin On-site reps EEaston
FSturz CChappell JJankovich MBell
DISTRIBUTION w/o enclosure: MWeber RJohnson

DOCUMENT NAME: S:\DWM\PAHL\JGS1\QARDRev5.Ltr
In small box on "OFC" line enter: C = Cover only, E = Cover and enclosure, N = No copy

OFC	PAHL	E	PAHL	E	GAO		PAHL		
NAME	JSpraul:kv*		JThoma ^{MPL}		WReamer*		JAustin		
DATE	03/11/96		03/15/96		03/14/96		03/18/96		

* See previous concurrence

Delete file after distribution: Yes ___ No X OFFICIAL RECORD COPY

200049

409.55
496.1
NH16/11
WM-11

9603200368 960318
PDR WASTE
WM-11 PDR

Mr. Ronald A. Milner, Director
 for Program Management and Integration
 Office of Civilian Radioactive Waste Management
 U.S. Department of Energy, RW 30
 1000 Independence Avenue, S.W.
 Washington, D.C. 20585

SUBJECT: REVISION 5 OF THE OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
 QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION DOCUMENT

Dear Mr. Milner:

Thank you for your letter of December 28, 1995, transmitting Revision 5 of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description document (QARD - DOE/RW-0333P) dated October 2, 1995. We have reviewed Revision 5 of the QARD. As your letter indicates, it reduces the commitments made in Revision 4. Revision 4 was noted as being acceptable in my letter to you dated January 18, 1996. The reductions in commitments and the justification for them provided in Enclosure 2 of your letter are acceptable. However, we do have some questions/comments regarding some of the other changes. These are enclosed as a "Request for Additional Information."

Please respond to the enclosure to this letter within thirty days of receipt of this letter. If you have any questions, please call Jack Spraul of my staff on (301) 415-6715.

Sincerely,

John H. Austin, Chief
 Performance Assessment and High-Level
 Waste Integration Branch
 Division of Waste Management
 Office of Nuclear Material Safety
 and Safeguards

Enclosure: As stated

cc: See attached list

DISTRIBUTION: FILE CENTER PUBLIC LSS NMSS r/f
 DWM r/f HLUR r/f CNWRA ACNW KMcConnell
 TMcCartin On-site reps EEaston FStutz CChappell
 JJankovich MBell RJohnson

DOCUMENT NAME: S:\DWM\PAHB\JGS1\QARDRev5.Ltr
 In small box on "OFC" line enter: C = Copy, N = No copy

OFC	HLUR	C	HLUR	GAO	HLUR		
NAME	JSpraul:kv		JThoma	WReamer	JHolonich		
DATE	03/11/96		03/ /96	03/ /96	03/ /96		

OFFICIAL RECORD COPY

Delete file after distribution: Yes ___ No X

CC List for Letter to Milner dated: March 18, 1996

cc: C. Johnson, State of Nevada
J. Meder, Nevada Legislative Counsel Bureau
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
W. Cameron, White Pine County, NV
R. Williams, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Hoffman, Esmeralda County, NV
C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
A. Melendez, NIEC
R. Arnold, Pahrump, NV
N. Stellavato, Nye County, NV
S. Brocoum, YMPO
W. Barnes, YMPO
D. Horton, YMPO

REQUEST FOR ADDITIONAL INFORMATION

1. Revision 5 of the QARD no longer requires that the Idaho Operations Office and the Oak Ridge Operations Office operate in accordance with the QARD as was required in Section 1.3.3.A.1 of Revision 4. Replace the commitment or indicate why this would be inappropriate.
2. In Revision 4, Section 2.2.2 indicated there was one Q-List, maintained by OCRWM. Revision 5 indicates there may be more than one Q-list, with the responsibility for maintenance not specified. This appears to be a reduction in commitment. Section 17.2.1 has changed terminology from "the Q-List" to "a Q-List." Discuss why the changes are appropriate.
3. Clarify why Section 2.2.3B no longer includes the activities of "dismantling, decommissioning, and permanent closure."
4. Revision 5 of the QARD has taken the responsibility for management assessments from the senior management of each affected organization and assigned it to the Office of Civilian Radioactive Waste Management. Discuss how the Office of Civilian Radioactive Waste Management is meeting this new responsibility.
5. Revision 5 of the QARD (Section 2.2.9) has limited the documents requiring review to "implementing documents and documents that specify technical and quality requirements." This could be interpreted to mean that documents such as data analyses and software program descriptions no longer require review in accordance with the section. Justify or delete the limitations added in Revision 5.
6. The last item of the QARD Section on document review (2.2.10F) still requires documentation and resolution of only "Mandatory comments." Expand this requirement to all comments or describe why this is inappropriate.
7. The section, "Quality Assurance Program Information Management" (2.2.10) no longer requires that "Each manager of a quality assurance organization shall report quality assurance information to ... the quality assurance organization of the next-higher-level affected organization." Justify this apparent reduction of commitment or replace the commitment.
8. QARD Section 3.2.3C no longer addresses calculations, QARD Section 3.2.3D.4 no longer addresses the designation of assumptions "that must be verified (confirmed?) as the design proceeds," and QARD Section 3.2.5E no longer addresses the requirement that necessary verification (confirmation?) requirements be specified in the design documents or in supporting implementing documents. Justify these apparent reductions of commitment or replace them. (QARD Section 3.2.5B refers to assumptions that require "confirmation" rather than verification.)
9. QARD Section 6.2.3 no longer requires document reviews "prior to approval and issuance," nor is this a requirement in Section 2.2.10 that is referenced in Section 6.2.3. Justify this apparent reduction of commitment or replace the commitment.

10. QARD Section 6.2.5A now indicates that documents may be "made available to" rather than "distributed to" the work location. Describe how this revised system functions; include a description of how disposition of such documents is controlled to ensure that they are not used to perform work after they are obsolete or superseded (6.2.5C).

11. QARD Section 12.2.3A.2 no longer requires the calibration of measuring and test equipment that produces results suspected to be in error. Justify this apparent reduction of commitment or replace the commitment.

12. QARD Section 16.2.3 no longer requires that responsible management document the extent of the adverse condition (or the investigation of conditions adverse to quality) and remedial action. Justify this apparent reduction of commitment or replace the commitment.

13. QARD Section 17.2.5A no longer requires that the implementing document for storing and preserving QA records provides "a method for verifying that the quality assurance records are legible and complete." Justify this apparent reduction of commitment or replace the commitment.

14. Because of the extensive revision to Supplement I and the fact that all changes thereto are not highlighted with revision lines (for example, see page 6), it is difficult to determine whether there has been a commitment reduction. It appears that the following requirements in Revision 4 of the QARD may not be in Revision 5: Sections I.2.6B.3, I.2.6D, I.2.6E.1, I.2.9, and the second requirement of I.2.10B. Identify where these requirements are in Revision 5, justify their elimination, or replace them.

15. It appears that the requirements of III.2.2D, III.2.3A, III.2.4A, III.2.4D.3, and III.2.5 in Revision 4 of the QARD may not be in Revision 5. Identify where these requirements are in Revision 5, justify their elimination, or replace them.

16. QARD Section III.2.4 requires that: "A documented independent review of acquired and developed data shall be performed to confirm technical adequacy." Clarify what is meant by "technical adequacy" as used in this context.

17. QARD Revision 5, in Section III.2.5, uses "unqualified data;" and this term is defined in the glossary. In its use and in its definition, the term appears to be equivalent to the term "existing data" in NUREG 1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories," February 1988. QARD Revision 5 deleted the use of "existing data." The term, "unqualified data" has an implication that the data cannot be qualified that the term "existing data" does not have. We request that DOE again adopt the terminology of NUREG 1298 or discuss why this is inappropriate.

18. The first sentence in III.2.5A, "Unqualified (Existing) data may be used without qualification in scientific investigation and design activities," appears to be too general; particularly in the light of the first portion of Section III.2.5D that says: "Unqualified (Existing) data directly relied upon to address safety and waste isolation issues shall be qualified" Clarify.

19. QARD Section III.2.5C, "Data considered as established fact by the scientific and engineering community do not require qualification" conflicts with Section II of NUREG 1298 that states: "All data used in support of the license application that is important to safety or waste isolation must ultimately be qualified to meet the requirements of 10 CFR 60, Subpart G." This conflict should be resolvable (and resolved) with the understanding by both DOE and NRC that the "weight" given to data during the licensing process will be dependent upon its documented quality and reliability or "goodness." Since this item is beyond the scope of QARD review, it will be carried as a separate open item in NRC's Open Item Tracking System until resolution.

20. The commitment in QARD Section III.2.6B that states: "Models of natural phenomena shall be validated ..." may not be achievable in all cases. We suggest inserting words like "to the extent possible" or "to the extent practical" after "validated." Also, since model validation requires data as stated in Section III.2.6C, we suggest inserting words like "as a surrogate" after "used" in Section III.2.6C.1 so that the section reads: "When data are not available from these sources, alternative approaches shall be documented and used as a surrogate for model validation."

21. QARD Supplement V requires Affected Organizations to establish controls for the electronic management of data. Discuss why these controls do not require the inclusion of the qualification status of the data and traceability of the data to a specified source.