



Department of Energy

Washington, DC 20585

MAY 07 1996

Dr. John H. Austin, Chief  
Performance Assessment and High-Level  
Waste Integration Branch  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Dr. Austin:

This letter is in response to your letter dated March 18, 1996, in which you provided a list of questions/comments associated with the Office of Civilian Radioactive Waste Management Revision 5 of the Quality Assurance Requirements Description (QARD), DOE/RW-0333P.

Responses to your request for additional information are enclosed. These responses were informally discussed with Mr. Jack Spraul of your staff during a video conference on April 15, 1996.

If you have any questions or require additional information, please contact either Robert W. Clark at (202) 586-1238 or Richard E. Spence at (702) 794-5583.

Sincerely,

*Ronald A. Milner*

Ronald A. Milner, Director  
Office of Program Management  
and Integration  
Office of Civilian Radioactive  
Waste Management

Enclosure

cc:  
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W. L. Belke, NRC, Las Vegas, NV  
R. Loux, State of Nevada  
R. Price, NV Legislative Committee, NV

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M. Federline, NRC

**RESPONSES TO THE NRC'S  
REQUEST FOR ADDITIONAL  
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**CONCERN:**

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.

**RESPONSE:**

The operations offices identified in the QARD, Revision 4, no longer perform work for OCRWM. The work for which these offices have responsibility has either been terminated or transitioned to the M&O.

**CONCERN:**

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.

**RESPONSE:**

As indicated in the Introduction and Section 1, the QARD applies to more than just the Yucca Mountain element. Rather than a reduction in commitment, this change is an expansion of the guidance contained in NUREG 1318 (regarding Q-lists) to other program elements (e.g., interim storage). Responsibility for maintenance of Q-lists is described in implementing documents.

**CONCERN:**

3. Clarify why Section 2.2.3B no longer includes the activities of "dismantling, decommissioning, and permanent closure."

**RESPONSE:**

Since dismantling, decommissioning, and permanent closure are future activities, they were deleted to provide focus on current needs. It was always the intent of the QARD to apply only through operation. The inclusion of these post-operation activities in the examples of Section 2.2.3.B was in error. At the appropriate time the QARD will be reviewed and revised as necessary for these post-operation activities.

**RESPONSES TO THE NRC'S  
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**CONCERN:**

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.

**RESPONSE:**

OCRWM is meeting this new responsibility through the implementation of OCRWM Quality Assurance Procedure QAP 2.7, Revision 3. This activity was elevated to the Director, OCRWM, level since there is a single Quality Assurance (QA) program, as described in the QARD. This QA program is implemented by several Affected Organizations. Since the purpose of the management assessment is to verify the adequacy and effectiveness of the OCRWM QA program, OCRWM management is of the opinion that a macro look at the QA program within and across organizational boundaries would be more effective from a QA program point of view than several micro view assessments, none of which look at the entire QA program. This philosophy is consistent with the recent reengineering of the OCRWM audit program whereby the OCRWM Office of Quality Assurance has assumed responsibility for all audit activities within Affected Organizations.

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**CONCERN:**

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.

**RESPONSE:**

In previous QARD revisions, Section 2.2.9 read, " Documents shall be reviewed....." The term "Documents" is an all inclusive term; i.e., Nonconformance Report, Deficiency Report, etc. As a result of the term not being bounded, implementation of the requirement was not consistent among the Affected Organizations. The change made in QARD, Revision 5, has provided clarification of the intent of the requirement as well as the intent of 10CFR50, Appendix B.

Documents other than Implementing Documents and those documents that prescribe technical and quality requirements would be the output of an Implementing Document or a document that specifies technical or quality requirements. Review criteria for these documents are as prescribed in the governing document.

Section 2.2.10 requires that, "Any additional requirements specified by the applicable section of the QARD" also apply. Several QARD sections impose specific review criteria; i.e., Section 3, Section 5, Supplement I, etc. The examples of documents identified in your concern are, in fact, required to be reviewed by Section 3 and Supplement I, respectively.

Additionally, Section III.2.4 will be clarified in the next revision of the QARD to address the review of technical reports.

**CONCERN:**

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.

**RESPONSE:**

QARD, Section 2.0, Paragraph 2.2.10F, was not revised in Revision 5. This limitation has been invoked in an effort to solicit all comments, whether or not they are within the review criteria considerations specified in the QARD, Section 2.0, Paragraph 2.2.10. These non-mandatory comments are evaluated by the document preparer, and if deemed appropriate, they are incorporated. Mandatory comment is defined in our implementing document. This definition will be incorporated into the next QARD revision.

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**CONCERN:**

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.

**RESPONSE:**

The change made provides clarification relative to the types of information to be provided to management in order to appraise the QA program. The types of information to be provided to Affected Organization management; i.e., audit reports, surveillance reports, trend reports, and management assessment reports, mandate the distribution of these reports to appropriate management. The commitment to keep appropriate management appraised has not been reduced. However, the self imposed requirement for this information to be transmitted to the "next-higher level organization" has been deleted with no impact to the effectiveness of the QA Program. Further, now that OQA performs all audits and program trending, we (the highest level QA organization) have access to all pertinent information through the common Deficiency, NCR, and Trend Data Bases.

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**CONCERN:**

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.)

**RESPONSE:**

1. QARD Section 3.2.3C- Section 3.2.3.C as stated in the QARD, Revision 4, will be incorporated into the next revision of the QARD.
2. QARD Section 3.2.3 D.4- This section was modified with the idea to add words that strengthen the entire scenario in sections 3.2.3 D.4, 3.2.1 D, and 3.2.5 B. The intent is to assure that assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds (reference section 3.2.5 B).
3. Verification versus confirmation- The word "verification" was replaced by the word "confirmation" in the appropriate text of section 3.0 in order to eliminate apparent confusion over the implementation of Design Verification. The changing of these words now clearly points out the requirements for the appropriate implementation of Design Verification as is detailed in sections 3.2.4, 3.2.5, 3.2.6, and 3.2.7. Regardless, intermittent "confirmation" of the design process occurs through the various design control process checks, i.e. Discipline Checking, Interdisciplinary Checking, and various management reviews.
4. Regarding your comment concerning Section 3.2.5 E, the wording was modified to clearly express the requirements for the conduct of a Design Review. This was done to remove the confusion in the section related to the word "verification," which is inappropriate, and the reference to "implementing documents," which is covered in Section 5.0 of the QARD. The requirements to assure that design inputs have been "correctly selected and incorporated" still exists and is appropriate to the "interfacing organizations."

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**CONCERN:**

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.

**RESPONSE:**

The term "prior to approval for release" will be incorporated into the next revision of the QARD. Implementing documents require that reviews be completed prior to the release of the document. Consequently, this omission has had no impact to the effectiveness of the QA Program.

**CONCERN:**

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).

**RESPONSE:**

QARD Section 6.2.5A - "Made available to" was added to accommodate the electronic distribution of procedures. OCRWM procedures are now available "on-line" as well as through normal distribution as "hard copy." Essentially, the system is the same, we just revised terminology.

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**CONCERN:**

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.

**RESPONSE:**

The requirement is now addressed in QARD, Section 12.2.1D.

**CONCERN:**

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.

**RESPONSE:**

The requirement to "investigate" conditions adverse is now addressed in QARD Section 16.2.3B. The new wording clarifies the purpose of the investigation; i.e., to determine "the extent of condition." The need to "document" the investigation is specified in the QARD.

**CONCERN:**

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.

**RESPONSE:**

The responsibility for ensuring that records are legible and complete rests with the individual(s) creating the record. The records "storage" procedure is not the appropriate place for this requirement to be implemented. This requirement is now more appropriately addressed in QARD Sections 17.2.2B and 17.2.3.D.

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**CONCERN:**

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.

**RESPONSE:**

Section of Revision 4, I.2.6B.3 is now covered in the Configuration Management section of Revision I.2.6B.2.c. This section requires the information be submitted to those organizations affected by the change.

Section I.2.6D from Revision 4 is now covered in Revision 5, Sections I.2.1A.3 and I.2.1B.4. The requirement is imposed on both developed/modified and acquired software. There is no longer the category, "Scientific and Engineering," in Revision 5.

Section I.2.6E.1 from Revision 4 is now included in the Section I.2.5A in Revision 5. The two sections of I.2.5A are considered satisfactory, since there was no specific information included in this section of Revision 4, "Functional Requirements."

Section I.2.9 of Revision 4 was deleted. The requirements in I.2.6 of Revision 5 cover this information in concert with the records requirements of Section 17 (see 17.2.3C and 17.2.5B).

The second requirement of Section I.2.10B, Revision 4, is covered in Section 3 and Supplement III of Revision 5 (see 3.2.3D.5, 3.2.5, III.2.3, and III.2.4).

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**CONCERN:**

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.

**RESPONSE:**

Section III.2.2D. - This section was a repetitive requirement and did not need to be included in Supplement III of the QARD. Sections 5.0 and 6.0 already apply, just as other applicable requirements apply without being repeated in this section, such as training requirements from section 2.0 and record requirements from 17.0.

Section III.2.3.A. - This requirement is still addressed in Section III.2.3.A., Revision 5. Changes were intended to simply clarify intent. The phrase "indicate usability, and document validation status," caused confusion. The intent is that data be identified in a manner that supports the traceability of the data; this includes traceability to the documentation that initially identifies or presents this data and to documentation of activities that subsequently use the data.

III.2.4.A. - This requirement is embodied in Section III.2.4, Revision 5. The term "validation" caused confusion; the intent was that the data were technically reviewed. That the review must be documented and the reviewer independent from the data "acquirer" or "developer" is clearly stated in Revision 5. A review for technical adequacy is a broad term that includes aspects such as technical correctness, compliance with the implementing documents, and/or scientific notebooks that control the acquisition or development of the data; and in the case of developed data, the appropriateness or suitability of the source data for the application.

III.2.4.D.3. - OQA agrees that it would be beneficial to include these attributes in the QARD, however, it has been determined that their deletion has not adversely impacted the QA program. By eliminating these two attributes we have essentially taken a more conservative approach; two attributes which expand our ability to confirm the credibility of the data have been eliminated. We will add the criteria in the next revision to Supplement III.

III.2.5. - The requirement stated in Revision 4, Section III.2.5.A., is already addressed by Section III.2.3.B. which requires that data be identified and traceable throughout the lifetime of the data. Whenever data are used they will be cited as source (input) data. Section III.2.4 also requires a documented, independent review of developed data to confirm the technical adequacy. This review would include confirming the suitability of the source (input) data for the application. This is comparable to QARD Section 3.2.1 A. which requires design inputs to be identified and their selection reviewed and approved.

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**CONCERN:**

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.

**RESPONSE:**

A review for technical adequacy is a broad term that includes aspects such as technical correctness, compliance with the implementing documents, and/or scientific notebooks that control the acquisition or development of the data; and in the case of developed data, the appropriateness or suitability of the source data for the application.

**CONCERN:**

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.

**RESPONSE:**

The term "unqualified data" was incorporated as a suggested clarification and it was not intended to imply that the data cannot be qualified. As we move further away from the era before an approved 10 CFR 60, Subpart G, program the meaning of the term "existing data" is not as readily understood as "unqualified data" even though the basis of the definition of "unqualified data" is NUREG 1298. Please note that a definition for qualified data has been added to the Glossary which clarifies that qualified data are that data which are either initially acquired or developed under a NRC approved quality assurance program or unqualified data that have been qualified in accordance with the QARD.

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**CONCERN:**

18. The first sentence in III.2.5A, "Unqualified (Existing) data may be used without qualification in scientific investigations 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.

**RESPONSE:**

QARD Supplement III.2.5A was incorporated for consistency with QARD Section 3.2.4E which authorizes the use of "unverified" designs, provided the "unverified portions of the design are clearly identified and controlled." However, the "unverified" portion of the design must be verified prior to "relying on the item to perform its function." Similarly, unqualified data may be used in scientific investigation and design activities provided traceability to the "unqualified" status is maintained. QARD Supplement III.2.5D further requires that "unqualified data directly relied upon to address safety and waste isolation issues shall be qualified." The use of either unverified designs or unqualified data is a risk methodology. However, in both cases the design/data must be verified/qualified prior to relying on the item to perform its intended function or the data relied upon to address safety or waste isolation issues. The relationship between Supplements III.2.5.A and III.2.5.D will be clarified in the next QARD revision.

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**CONCERN:**

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 resolved.

**RESPONSE:**

The change made to the QARD, Supplement III.2.5C, is not a departure from that which was accepted by the NRC in the QARD, Revisions 0 through 4. NUREG 1298, Section III, excludes "information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.)" from the definition of "existing data." OCRWM has opted, for clarification purposes, to use the term "unqualified data" in lieu of "existing data." The definition of "unqualified data," as delineated in the QARD glossary, is almost identical to the definition for "existing data" in NUREG 1298. Therefore, "information which is accepted by the scientific and engineering community as established facts," is not considered to be "existing" or "unqualified" data. Since this data is not "existing" or "unqualified" data, the requirements specified in NUREG 1298, Section IV, relative to "qualification of data" do not apply to this data. This position was agreed upon during the March 27, 1996, DOE/NRC Quality Assurance Information Exchange Video Conference.

**CONCERN:**

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 II.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."

**RESPONSE:**

Suggestion will be considered for incorporation in the next QARD revision.

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**CONCERN:**

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.

**RESPONSE:**

The requirements for data qualification status and traceability to its source are in Section 3 or Supplement III (see 3.2.1, III.2.3, and III.2.5). Supplement V is written to address the tool used as a controlled source, to place the data into for later retrieval and use in further investigative studies (e.g., data bases, spreadsheets, matrices, etc.).