



Department of Energy
 Office of Civilian Radioactive Waste Management
 Yucca Mountain Site Characterization Office
 P.O. Box 98608
 Las Vegas, NV 89193-8608

NOV 08 1995

Robert W. Craig
 Acting Technical Project Officer
 for Yucca Mountain Site
 Characterization Project
 U.S. Geological Survey
 101 Convention Center Drive, Suite 860
 Las Vegas, NV 89109

**EVALUATION OF RESPONSE TO DEFICIENCY REPORT (DR) YMQAD-95-D017
 AND YMQAD-95-D018 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
 DIVISION'S (YMQAD) AUDIT YM-ARP-95-20 OF U.S. GEOLOGICAL SURVEY
 (SCPB: N/A)**

The YMQAD staff has evaluated the responses to DR YMQAD-95-D017 and YMQAD-95-D018. The responses have been determined to be unsatisfactory because of reasons stated in the enclosed DRs. An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Alan W. Rabe at 794-7042.

Richard E. Spence, Director
 Yucca Mountain Quality Assurance Division

YMQAD:RBC-442

Enclosure:
 DRs YMQAD-95-D017 and
 YMQAD-95-D018

cc w/encl:
~~J. G. Spraul~~ NRC, Washington, DC
 S. W. Zimmerman, NWPO, Carson City, NV
 T. H. Chaney, USGS, Denver, CO

cc w/o encl:
 W. L. Belke, NRC, Las Vegas, NV
 D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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Robert W. Craig

-2-

bcc w/encl:

A. W. Rabe, YMQAD/QATSS, Las Vegas, NV

J. R. Summerson, YMSCO, NV

S. B. Jones, YMSCO, NV

D. R. Williams, YMSCO, NV

E. R. Cooper, YMSCO, NV

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: DOE/RW-0333P, Rev. 4	2 Related Report No. YM-ARP-95-20
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3 Responsible Organization: US Geological Survey (USGS)	4 Discussed With: Warren Day, Tom Chaney
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5 Requirement/Measurement Criteria:

QARD III.2.1.A Scientific investigations shall be planned in accordance with Section 2.0 of the QARD.

QARD 2.2.4 Planning shall be performed to ensure work is accomplished under suitably controlled conditions.

 2.2.4.C Identification of applicable standards and criteria.

QARD 2.2.2.B.3 The system shall provide positive control over external interfaces ...

YLP-4.1Q-YMSCO Par. 5.1.1.e determines the applicability of QARD requirements to the scope of work that is defined in the Procurement Plan

6 Description of Condition:

The Technical Data Information Form (TDIF) GS950708314211.033 for report "Stratigraphic Relations and Hydrologic Properties of the PTn Hydrogeologic Unit, Yucca Mountain, Nevada" by Moyer, Geslin, and Flint identifies that the report is not qualified because of the inclusion of some non-qualified borehole data. Most of the supporting data for the report is qualified. However, the WBS is classified as Q by DOE and is also so classified in the Participant Planning Sheet in the Planning and Control System (PACS). USGS also has classified this milestone as Q. The report should be qualified as required by the governing procurement documents and in order for it to be used in subsequent activities. The submittal of the report to DOE did not include a completed copy of the TDIF as required by YAP-5.1Q. Therefore, DOE had no formal notification that the report was not qualified. There is no documentation of any DOE change to the PACS requirements.

7 Initiator Alan W. Rabe <i>[Signature]</i> Date 09/21/95	9 QA Review QAR Alan W. Rabe <i>[Signature]</i> Date 09/21/95
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10 Response Due Date 20 working days after issuance	11 QA Issuance Approval QAR (PR)/AOQAM <i>[Signature]</i> Date 9/27/95
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12 Remedial Actions:

13 Remedial Action Response By: Date	14 Remedial Action Due Date Date
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15 Remedial Action Response Acceptance QAR Date	16 PR Verification/Closure QAR Date
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17 Recommended Actions:

Revise the TDIF to show the report as qualified. The provisions of YAP-SIII.3Q, Par. 3.15 must be followed when qualifying a report. Several options are available to correct the report qualification.:

1. Upgrade the data in accordance with procedure xxxxxx.
2. Clearly identify in the report which data is not qualified and include an evaluation that states that the conclusions are not dependent upon the nonqualified data.
3. Exclude the nonqualified data from the report.

Alternatively, obtain written approval of the nonqualified classification from DOE.

Also review the extent of this condition and identify corrective actions as appropriate.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response by:

Date

22 Corrective Action Completion Due Date:

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

Date

26 Amended Response Accepted

AOQAM

Date

27 Corrective Actions Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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Block 12: Remedial Actions:

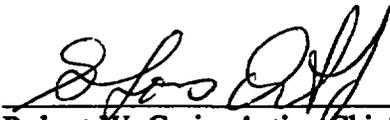
None

Block 18: Investigative Actions:

The Participant Planning Sheet in the Planning and Control System (PACS) states "QARD applies to this effort". This statement does not necessarily equate to the position that the product will be labelled "qualified" in the data tracking system. The work was done under the controls of the QA Program, one of which is YAP-SIII.3Q. The TDIF for the subject report was prepared under the guidance of YAP-SIII.3Q which states that developed data cannot be classified as "Qualified" if derived from unqualified data sources. The newly approved QARD (Revision 5, approved but not yet in effect) specifically states that unqualified data may be used without qualification in scientific investigations and design activities. See section III.2.5.A.

The USGS believes that it met the requirements of the PACS statement. If the requirements conveyed on the PACS Participant Planning Sheet do not meet the needs of DOE, then discussions should be initiated between DOE and the Participants to assure that the product requirements are clearly expressed in the planning sheets and that the two parties agree about their meaning.

Block 21: Response by:



Robert W. Craig, Acting Chief, Yucca Mountain
Project Branch

10/26/95
Date

For

Block 22: Corrective Action Completion Due Date:

Not applicable

10/26/95 CRAIG TO SPENCE

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Response Evaluation:

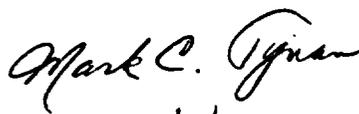
The USGS has misunderstood the requirement of both the Participant Planning Sheet (PPS) in the Planning and Control System (PACS) and the ~~QARD~~ ^{QARD} requirements. Designation of the activity as having the QARD applicable in the PPS is the interface control established by DOE to have a qualified product delivered. The QARD has included provisions to allow work to proceed when not all items can be qualified. It then establishes the controls that are required in order for quality work to be properly documented and controlled. It does not give authorization to produce unqualified products which do not meet PPS requirements. Lessons Learned/Program Clarification No. 94-002 is useful to further understand the provisions established in the QARD. Please note the reference therein to AP-5.9Q for qualifying existing data.

It should be noted that there are several options available when one is contemplating using unqualified existing data. These were delineated in Block 17. If it is felt that production of an unqualified report is in the best interests of the project, then DOE written approval and/or revision of the PPS can be accomplished. However, it is unacceptable to ignore quality interface requirements established as required by the QARD as delineated in Block 5.

Based on the above, this response is rejected.


10/31/95

Alan W. Rabe
Sr. QA Specialist


11/2/95

MARK C. TYNAN
Physical Scientist
US DOE, YA SCO

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PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document: DOE/RW-0333P, Rev. 4, Quality Assurance Requirements and Description	2 Related Report No.: YM-ARP-95-20
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3 Responsible Organization: US Geological Survey (USGS)	4 Discussed With: Warren Day, Tom Chaney
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5 Requirement/Measurement Criteria:

QARD 2.2.9 Document Review
Documents shall be reviewed to the following requirements...

- A. criteria shall include correctness
- B. Pertinent background information or data shall be made available to the reviewers

6 Description of Condition:
The referenced section of the QARD was implemented in procedures governing software, procurement documents, procedures and scientific notebooks, but was not incorporated in Procedure YMP-USGS-QMP-3.04, Rev. 6, Review and Approval of YMP-USGS Data, Interpretations of Data, and Manuscripts. The implementation of the requirement must clearly direct the performance of an adequate review as specified in QARD 2.2.9.

In the case of procedure YMP-USGS-QMP-3.04, although the procedure does provide for a review, it fails to require the reviewers to assure the correctness of the document they are reviewing. YMP-USGS-QMP-3.04, R. 6, Par. 5.2 states, "The author, through the YMP-USGS Reports Specialist, shall provide the reviewers with copies of the manuscript accompanied by appropriate documents ..., as well as a copy of the data review documentation...." Therefore, the reviewer need only assure that a data review was done, not that the data was correctly transferred to the technical report they are reviewing. As an example, the technical reviewers for report "Fracture Character of the Paintbrush Tuff Non-welded Hydrologic Unit, Yucca Mountain, Nevada" did not refer to the supporting data packages when performing their reviews. The scope of review was documented by one reviewer

7 Initiator Alan W. Rabe <i>AWR</i> Date 09/27/95	9 QA Review Alan W. Rabe <i>AWR</i> Date 09/27/95
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12 Remedial Actions:

13 Remedial Action Response By: Date	14 Remedial Action Due Date Date
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15 Remedial Action Response Acceptance QAR Date	16 PR Verification/Closure QAR Date
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17 Recommended Actions:

Revise YMP-USGS-QMP-3.04 to clearly specify the responsibility for review of the transfer of data into the report (ie. correctness of the final report). Document the review of this transfer for the report referenced in Block 6, evaluate the extent and impact of the condition on other reports, and identify corrective actions if necessary. Revise the RTN to show incorporation of QARD Section 2 requirements in QMP-3.04.

18 Investigative Actions:

19 Root Cause Determination:

20 Action to Preclude Recurrence:

21 Response by:

Date

22 Corrective Action Completion Due Date:

23 Response Accepted

QAR

Date

24 Response Accepted

AOQAM

Date

25 Amended Response Accepted

QAR

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26 Amended Response Accepted

AOQAM

Date

27 Corrective Actions Verified

QAR

Date

28 Closure Approved by:

AOQAM

Date

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6. (continued)

as only being of the report itself. The other technical reviewer stated that the review was only of the report and did not include looking at the data in the data packages. The problem is that there is no review to assure that data from the data package was properly transcribed into the report. Discussions with management confirmed that the normal expectation does not require the technical reviewers to do such a review. The USGS in practice considers this the sole responsibility of the author. An example of a clear incorporation of the requirement is given in OCWRM procedure QAP 6.2, Rev. 2, Attach. 9.4, Par. 2.10, which states, "Does the final document correctly incorporate technical input?"

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Block 12 Remedial Actions:

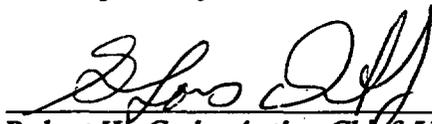
None

Block 18: Investigative Actions:

QMP-3.04 does recognize "correctness" as a review criteria however the USGS application of the term differs from the auditor's interpretation. QMP-3.04, R6, paragraph 5.2.2 and 5.2.2.1 state "The review of a manuscript shall, at a minimum, consider the following elements: Technical Correctness: Is the manuscript technically sound? Are all computations correct? Are assumptions reasonable and clearly stated? Are the interpretations of data supported by the data as presented or referenced in the manuscript?".

The USGS does not expect technical reviewers to check for transcription errors between the source data and it use in the interpretive report. However, the reviewer does have access to the source data upon request (see paragraph 5.2) if anything should look suspicious to him/her. The check for technical correctness as defined by the auditor does not have to be an independent review and is more appropriately the author's responsibility.

Block 21: Response by:



Robert W. Craig, Acting Chief, Yucca Mountain
Project Branch

10/26/95
Date

Block 22: Corrective Action Completion Due Date:

Not applicable

10/26/95 CRAIG TO SPENCE

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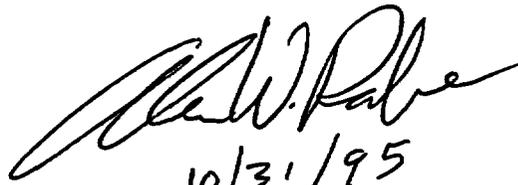
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Response Evaluation:

The USGS response correctly identifies that their procedures limit the extent of application of the word "correctness" in the way that a review needs to be performed. They further make it clear that a check of technical correctness does not have to be an independent review and is in their position appropriately the sole responsibility of the author.

This position does not meet the requirement of QARD 2.2.9. An independent review for correctness of quality affecting documents is required.

Based on the above this response is rejected.


10/31/95
Alan W. Rabe