



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

DEC 12 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 AMENDED RESPONSES TO DEFICIENCY REPORTS (DR)
YMQAD-95-D017 AND YMQAD-95-D018 RESULTING FROM YUCCA MOUNTAIN
QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YM-ARP-95-20 OF THE
U.S. GEOLOGICAL SURVEY (SCPB: N/A)**

The YMQAD staff has evaluated the amended responses to DRs YMQAD-95-D017 and YMQAD-95-D018. The amended responses have been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective dates provided. Any extension to these dates must be requested in writing, with appropriate justification, prior to the date.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Alan W. Rabe at (702) 794-7042.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-718

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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8 Performance Report
 Deficiency Report
NO. YM/QAD-95-D017
PAGE 1 OF 2
QA: L

PERFORMANCE/DEFICIENCY REPORT

1 Controlling Document:
DOE/RW-0333P, Rev. 4

2 Related Report No.
YM-ARP-95-20

3 Responsible Organization:
US Geological Survey (USGS)

4 Discussed With:
Warren Day, Tom Chaney

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

Date 09/21/95

9 QA Review

QAR Alan W. Rabe

Date 09/21/95

10 Response Due Date

20 working days after issuance

11 QA Issuance Approval

QAR (PRI)/AOQAM

Date 9/27/95

12 Remedial Actions:

13 Remedial Action Response By:

Date

14 Remedial Action Due Date

Date

15 Remedial Action Response Acceptance

QAR

Date

16 PR Verification/Closure

QAR

N/A

Date

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8
DR NO. YMQAD-95-017
PAGE 2 OF 2
QA: L

DEFICIENCY REPORT

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:
See amended response
Date

22 Corrective Action Completion Due Date:
See amended response

23 Response Accepted
QAR Date

24 Response Accepted
AOQAM Date

25 Amended Response Accepted
QAR *[Signature]* Date *12/7/95*

26 Amended Response Accepted
AOQAM *[Signature]* Date *12/12/95*

27 Corrective Actions Verified
QAR Date

28 Closure Approved by:
AOQAM Date

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WASHINGTON, D.C.

- Performance Report
- Deficiency Report

NO. YM QAD-95-0017

PAGE _____ OF _____
QA:L

PR/DR CONTINUATION PAGE

Block 12: Remedial Actions:

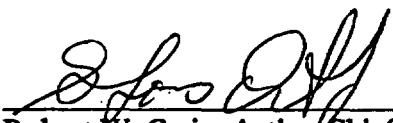
None.

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:



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

10/26/95
Date

Block 22: Corrective Action Completion Due Date:

Not applicable

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8 Performance Report
 Deficiency Report

NO. YMQAD-95-D017
PAGE OF
QA: L

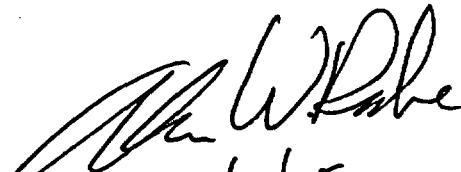
PR/DR CONTINUATION PAGE

Response Evaluation:

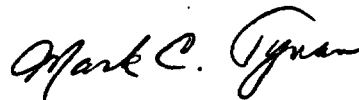
The USGS has misunderstood the requirement of both the Participant Planning Sheet (PPS) in the Planning and Control System (PACS) and the ~~QARD~~^{QARD} requirements. Designation of the activity as having the QARD applicable in the PPS is the interface control established by DOE to have a qualified 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 Report
 Deficiency Report

NO. YMQAD-95-D017

PAGE _____ OF _____

QA:L

PR/DR CONTINUATION PAGE

AMENDED RESPONSE YMQAD-95-D017

Block 12 USGS will discuss the subject report with YMPO Assistant Manager for Scientific Programs to determine the appropriate actions. These actions will be provided to YMQAD as a supplemental response.

Block 14 12/15/95 (Supplemental response)

Block 18 The TDIF for the subject report was prepared in accordance with YAP-SIII.3Q, R0. No further root cause investigative is necessary.

This is not necessarily an isolated case. However, further extent of conditions or impact determination is not necessary to perform at this time, as the need for upgrading other reports to Q status will be identified in an individual basis as the licensing process evolves.

Block 19 N/A

Block 20 All FY 96 USGS Milestones will be prepared in accordance with the guidance provided in the 11/15/95 letter from Susan Jones to L. Dale Foust and Bob Craig re: U.S. Department of Energy Policy on Synthesis Reports and YAP-SIII.3Q, R1.

Block 21 Response by:


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

11/30/95
Date

Block 22 N/A

11/29/95 CRAIG TO SPENCE

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8 Performance Report
 Deficiency Report
NO. YMQAD-95-D018
PAGE 1 OF 3
QA: L

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 QAR Alan W. Rabe <i>AWR</i> Date 09/27/95
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10 Response Due Date 20 working days after issuance	11 QA Issuance Approval QAR (PRI)/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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⁸
DR NO. YMQAD-95-D018
PAGE 2 OF 3
QA: L

DEFICIENCY REPORT

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:

See amended response
Date

22 Corrective Action Completion Due Date:

See amended response

23 Response Accepted

QAR Date

24 Response Accepted

AOQAM Date

25 Amended Response Accepted

QAR *[Signature]* Date *12/7/95*

26 Amended Response Accepted

AOQAM *[Signature]* Date *12-12-95*

27 Corrective Actions Verified

QAR Date

28 Closure Approved by:

AOQAM Date

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8 Performance Report
 Deficiency Report

NO. YMQAD-95-D018

PAGE 3 OF 3

QA: L

PR/DR CONTINUATION PAGE

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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- Performance Report
 Deficiency Report

NO. YM00D-95-0018

PAGE _____ OF _____
QA:L

PR/DR CONTINUATION PAGE

Block 12 Remedial Actions:

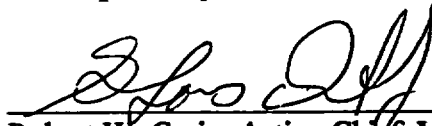
None

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:



RC
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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8 Performance Report
 Deficiency Report

NO. YMQAD-95-D018

PAGE OF

QA: L

PR/DR CONTINUATION PAGE

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

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- Performance Report
 Deficiency Report

NO. YMQAD-95-D018
PAGE _____ OF _____
QA:L

PR/DR CONTINUATION PAGE

AMENDED RESPONSE YMQAD 95-D018

Block 12 A review for correctness of the subject report will be performed.

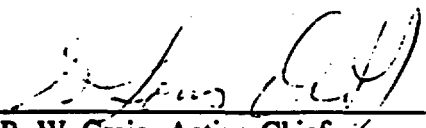
Block 14 1/8/96

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 the interpretations of data supported by the data as presented or referenced in the manuscript?"

"Correctness" as defined by the auditor is not addressed on a consistent basis within QMP-3.4 review process. However, the impact of these inconsistencies is believe to be minimal. For interpretative reports such as the subject report, the included data is essentially transcribed from other sources. As a result other editorial checks would be likely to catch any errors in a report's tables and figures.

Block 19 N/A

Block 20 Action to Preclude Recurrence:
USGS will modify QMP 3.04 to specifically include correct transcription of data in the criteria for technical correctness of the data as one of their acceptance criteria.

Block 21 Response by: 
R. W. Craig, Acting Chief
Yucca Mountain Project Branch

11/30/95
Date

Block 22 Corrective Action Completion Date: 1/16/96

11/29/95 CRAIG TO SPENCE