



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

JAN 17 1995

Larry R. Hayes
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 RESPONSE TO CORRECTIVE ACTION REQUEST
(CAR) YM-94-043 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-06 OF U.S. GEOLOGICAL SURVEY
(SCPB: N/A)

The YMQAD staff has evaluated the amended response to CAR
YM-94-043. The amended response has been determined to be
satisfactory. Verification of completion of the corrective
action will be performed after the effective date provided.
Any extension to this date must be requested in writing, with
appropriate justification, prior to the date. Please send
a copy of extension requests to Deborah Sult, YMQAD/QATSS,
101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

If you have any questions, please contact either Robert B.
Constable at 794-7945 or James Blaylock at 794-7913.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-1738

Enclosure:
CAR YM-94-043

cc w/encl:

~~J. G. Spraul~~, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV
T. H. Chaney, USGS, Denver, CO
R. W. Craig, USGS, Las Vegas, NV
D. D. Porter, SAIC, Golden, CO

cc w/o encl:

W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

246129

YMP-5

9501250440 950117
PDR WASTE
WM-11 PDR

102.7
WM-11
MHO3

**OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

8 CAR NO.: YM-94-043
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document QARD, Revision 0	2 Related Report No. YMP-94-06
--	-----------------------------------

3 Responsible Organization USGS	4 Discussed With L. Hayes
------------------------------------	------------------------------

5 Requirement:
QARD Supplement III 2.2.A states: "Scientific investigations shall be performed using scientific notebooks, technical implementing documents, or a combination of both."

6 Adverse Condition:
Contrary to the above, Tectonic Modeling and Synthesis Activity 8.3.1.17.4.12 does not use a scientific notebook or technical implementing documents. Furthermore, YMP-USGS-ACS-G12328412-2, Revision 0, graded the requirement as not applicable to the activity.

9 Does a Significant Condition Adverse to Quality exist? Yes <u> </u> No <u>X</u> If Yes, Circle One: A B C D E	10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	3 Response Due Date: 20 Working Days From Issuance
---	---	---

11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Provide for the use of a Scientific Notebook for Activity 8.3.1.17.4.12.
2. Investigate to identify any other cases of inappropriate grading.

7 Initiator James Blaylock <i>C.L. Warren for</i> 6-30-94	14 Issuance Approved by: QADD <i>[Signature]</i> for Date 7-4-94
---	---

15 Response Accepted QAR <i>James Blaylock</i> Date 9/12/94	16 Response Accepted QADD <i>N/A</i> Date
--	--

17 Amended Response Accepted QAR <i>James Blaylock</i> Date 9/12/94	18 Amended Response Accepted QADD <i>James Blaylock</i> Date 9/12/94
--	---

19 Corrective Actions Verified QAR Date	20 Closure Approved by: QADD Date
--	--------------------------------------

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. YM-94-043
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. 94-043

A. **REMEDIAL ACTION:** See investigative actions described in "B" below.

B. **EXTENT OF THE DEFICIENCY:** Study 8.3.1.17.4.12. Tectonic Modeling and Synthesis does not yet have an approved study plan. Work performed under Tectonic Modeling and Synthesis was evaluated to ensure that no Site Characterization quality affecting work had been performed. Only scoping activities used to prepare the study plan had been undertaken. These activities include literature searches, attendance at professional meetings, reconnaissance, and a boundary element modeling scoping study. Quality Assurance Grading Report (QAGR) G12328412 and Activity Controls Specification Report (ACSR) YMP-USGS-ACSR-G12328412-1 take no exceptions to criterion 5. Analysis and synthesis activities under this study plan will be appropriately documented in a scientific notebook.

Activity Controls Specification Report (ACSR) YMP-USGS-ACSR-G12328412-2, Revision 0, was created and approved to allow for the conduct of a boundary element scoping task. This step will allow the USGS to assess whether the boundary element approach is adequate for use as the vehicle for presentation and analysis of the interim tectonic model of Yucca Mountain, which is due in 1996. If these results are positive, the model will be considered for use as part of the site characterization program and will be validated and documented in accordance with QARD requirements. This level of quality assurance control is appropriate for a scoping task that takes place during the development of a study plan and does not produce site characterization data. The ACSR is not intended to grade out criterion 5 for the entire study, only the aforementioned task. This distinction was not clearly understood or relayed by the USGS personnel interviewed during Audit YMP-94-06.

All USGS QAGRs and ACSRs that take an exception to criterion 5 and/or QMP-5.01 and QMP-5.05 have been reviewed to determine if the specified grading is appropriate for the work being performed. Two QAGRs and three ACSRs were identified that have exempted the use of technical procedures or scientific notebooks for interpretive and analytical Site Characterization work. The five grading reports will be revised or rescinded and scientific notebooks or technical procedures will be used.

C. **ROOT CAUSE DETERMINATION:** The YMP-USGS QA Program did not generically require the use of scientific notebooks or technical procedures for analytical and interpretive work. The program ultimately relied upon the controls specified in QMP-3.04 for peer review of this type of work. This level of control was based on USGS interpretation of YMP QA requirements in effect prior to issuance of the Quality Assurance Requirements and Description document DOE/RW/0333P.

D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Formal memoranda will be distributed to technical management, Principal Investigators, and the Quality Assurance Grading Acceptance

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. YM-94-043
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Committee clarifying the requirement that all Site Characterization analytical and interpretive studies must be documented in a technical procedure or a scientific notebook.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

1.A. & B. Investigation of Grading Reports:

08/11/94

M.H. Mustard, YMP-USGS Quality Assurance Specialist
A.M. Whiteside, YMPB QA Implementation Advisor
T.M. Mendez-Vigo, Quality Assurance Implementation Specialist

Revision/Rescission of Grading Reports:

09/15/94

T.H. Chaney, Quality Assurance Manager

1.D. T.H. Chaney, Quality Assurance Manager
L.R. Hayes, Technical Project Officer

08/31/94

3. RESPONSE APPROVED:

Thomas H. Chaney
for Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8-15-94
Date

Larry R. Hayes
Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/15/94
Date

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. YM-94-043
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. 94-043

- A. **REMEDIAL ACTION:** See investigative actions described in "B" below.
- B. **EXTENT OF THE DEFICIENCY:** Study 8.3.1.17.4.12. Tectonic Modeling and Synthesis does not yet have an approved study plan. Work performed under Tectonic Modeling and Synthesis was evaluated to ensure that no Site Characterization quality affecting work had been performed. Only scoping activities used to prepare the study plan had been undertaken. These activities include literature searches, attendance at professional meetings, reconnaissance, and a boundary element modeling scoping study. Quality Assurance Grading Report (QAGR) G12328412 and Activity Controls Specification Report (ACSR) YMP-USGS-ACSR-G12328412-1 take no exceptions to criterion 5. Analysis and synthesis activities under this study plan will be appropriately documented in a scientific notebook.

Activity Controls Specification Report (ACSR) YMP-USGS-ACSR-G12328412-2, Revision 0, was created and approved to allow for the conduct of a boundary element scoping task. This step will allow the USGS to assess whether the boundary element approach is adequate for use as the vehicle for presentation and analysis of the interim tectonic model of Yucca Mountain, which is due in 1996. If these results are positive, the model will be considered for use as part of the site characterization program and will be modified, controlled, validated, and documented in accordance with QARD requirements. This level of quality assurance control is appropriate for a scoping task that takes place during the development of a study plan and does not produce site characterization data. The ACSR is not intended to grade out criterion 5 for the entire study, only the aforementioned task. This distinction was not clearly understood or relayed by the USGS personnel interviewed during Audit YMP-94-06.

All USGS QAGRs and ACSRs that take an exception to criterion 5 and/or QMP-5.01 and QMP-5.05 have been reviewed to determine if the specified grading is appropriate for the work being performed. Two QAGRs and three ACSRs were identified that have exempted the use of technical procedures or scientific notebooks for interpretive and analytical Site Characterization work. The five grading reports will be revised or rescinded and scientific notebooks or technical procedures will be used.

- C. **ROOT CAUSE DETERMINATION:** The YMP-USGS QA Program did not generically require the use of scientific notebooks or technical procedures for analytical and interpretive work. The program ultimately relied upon the controls specified in QMP-3.04 for peer review of this type of work. This level of control was based on USGS interpretation of YMP QA requirements in effect prior to issuance of the Quality Assurance Requirements and Description document DOE/RW/0333P.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Formal memoranda will be distributed to technical management, Principal Investigators, and the Quality Assurance Grading Acceptance

8/31/94 Ltr. Nayoko Spence

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. _____
PAGE _____ OF _____
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST YM-CAR-94-043

This amended response replaces part 1D (Action to Preclude Recurrence) and updates part 2 (the schedule) of the previous response.

1D ACTION TO PRECLUDE RECURRENCE

BACKGROUND AND DISCUSSION: A draft memorandum was prepared as required by our previous response to disseminate the position that scientific notebooks were required for all site-characterization analytical and interpretive studies. During internal review of this memorandum, it was discovered that such an approach was too broad in its scope. The following YMP-USGS position was developed.

- Technical procedures or scientific notebooks are required to document more complex analysis and synthesis activities that are iterative in nature and in which subsequent steps taken are dependent on results from previous steps. Such activities generally take place over a significant period of time (months, years). For such activities, the pathway taken to arrive at the end result may be technically significant and should be documented along with the end result. The scope of this requirement requires the documentation of the development of numerical models of natural phenomenon.
- Technical procedures or scientific notebooks are not required to document syntheses of information derived solely from the published literature, statistical analysis of data, or straightforward, "once-through" analyses that involve the application of previously published analytical or other methods to transform sets of field measurements into properties or parameters (permeability, transmissivity, rock compressive strength, thermal conductivity). Such "analyses" may be documented through the publication review and approval process (QMP-3.04).

ACTIONS: A formal memorandum stating the above position has been distributed to affected technical personnel. A highlight sheet will be prepared and distributed to formalize the training for the above stated position.

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. YM-94-043
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

Committee clarifying the requirement that all Site Characterization analytical and interpretive studies must be documented in a technical procedure or a scientific notebook.

2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

1.A. & B. Investigation of Grading Reports: 08/11/94

M.H. Mustard, YMP-USGS Quality Assurance Specialist
A.M. Whiteside, YMPB QA Implementation Advisor
T.M. Mendez-Vigo, Quality Assurance Implementation Specialist

Revision/Rescission of Grading Reports: 10/08/94

T.H. Chaney, Quality Assurance Manager


1.D. T.H. Chaney, Quality Assurance Manager 09/22/94
L.R. Hayes, Technical Project Officer

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/31/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/21/94
Date

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

CAR NO. _____
PAGE: _____ OF _____
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

2 For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

1A. Revision/rescission of grading reports and initiation of scientific notebooks or use of technical procedures to be initiated:

T.H. Chaney, Quality Assurance Manager

L.R. Hayes, Chief, Yucca Mountain Project Branch

Dwight Hoxie, GAC Chairman

Bruce Parks, Acting Chief, Earth Science Investigations Program

January 27, 1995

1D. Preparation of Highlight Sheet

T.H. Chaney

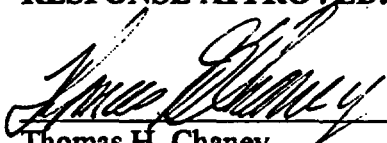
To be distributed by Training Coordinator by January 20, 1995

Distribution of memorandum

T.H. Chaney

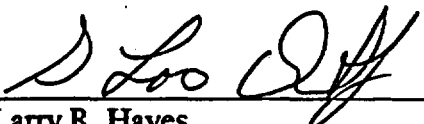
completed December 9, 1994

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

12/14/94
Date



Larry R. Hayes
Chief Yucca Mountain Project Branch

12/14/94
Date