



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

QA: L

SEP 15 1994

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 RESPONSES TO CORRECTIVE ACTION REQUEST
(CAR) YM-94-043, YM-94-048, AND YM-94-049 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 responses to CARs
YM-94-043, YM-94-048, and YM-94-049. The amended responses have
been determined to be satisfactory. Verification of completion
of the corrective actions 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.
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.

Robert B. Constable for

YMQAD:RBC-5079

Richard E. Spence, Acting Director
Yucca Mountain Quality Assurance Division

Enclosure:
CARs YM-94-043, YM-94-048,
and YM-94-049

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PDR WASTE
WM-11 PDR

Larry R. Hayes

-2-

SEP 15 1994

cc w/encl:

~~R. L. Johnson~~ 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

200050

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

8 CAR NO.: YM-94-043
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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 ___ No <u>X</u> If Yes, Circle One: A B C D E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	
9 Response Due Date: 20 Working Days From Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> 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> Date 7-4-94	
15 Response Accepted QAR <i>James Blaylock</i> Date 9/12/94		16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR <i>James Blaylock</i> Date 9/12/94		18 Amended Response Accepted <i>Blaylock for</i> QADD <i>James Blaylock</i> Date 9/12/94	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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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

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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 08/31/94
L.R. Hayes, Technical Project Officer

3. RESPONSE APPROVED:

Thomas H. Chaney

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

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WASHINGTON, D.C.

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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. Hayes to Spence

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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

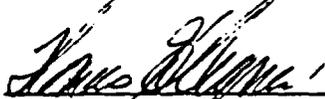
M.H. Mustard, YMP-USGS Quality Assurance Specialist
A.M. Whiteside, YMPB QA Implementation Advisor
T.M. Mendez-Vigo, Quality Assurance Implementation Specialist

Revision/Rescission of Grading Reports: 10/06/94

T.H. Chaney, Quality Assurance Manager

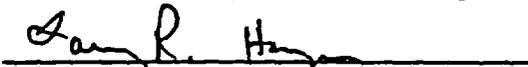
1.D. T.H. Chaney, Quality Assurance Manager 09/22/94
L.R. Hayes, Technical Project Officer

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

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8 CAR NO.: YM-94-048
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CORRECTIVE ACTION REQUEST

1 Controlling Document YMP-USGS-QMP-18.01, Rev. 4		2 Related Report No. YMP-94-06	
3 Responsible Organization USGS		4 Discussed With T. CHANEY	
5 Requirement: YMP-USGS-QMP-8.01, R4 contains the QARD requirements for identification and control of samples.			
6 Adverse Condition: The QMP-8.01, R4 requirements have not been fully incorporated into many of the implementing technical procedures and scientific notebooks. Two examples of procedures not being updated to QMP-8.01, R4 are HP-200, R0 and HP-249, R0.			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C D E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	
		3 Response Due Date: <u>20 WORKING DAYS</u> <u>From ISSUANCE</u>	
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input type="checkbox"/> Root Cause Determination			
12 Recommended Actions: 1. Incorporate the QMP 8.01 requirements in the implementing documents. 2. Review the myriad of sample control procedures to identify interfaces and sequencing. 3. Remove what may be extraneous procedures.			
7 Initiator J. BLAYLOCK <i>C. C. Wilman for</i> 6-30-94		14 Issuance Approved by: QADD <i>R. Blaylock</i> for Date <u>7-4-94</u>	
15 Response Accepted QAR <i>J. Blaylock</i> Date <u>9/1/94</u>		16 Response Accepted QADD Date	
17 Amended Response Accepted QAR <i>J. Blaylock</i> Date <u>9/12/94</u>		18 Amended Response Accepted QADD <i>J. Blaylock</i> Date <u>9/12/94</u>	
19 Corrective Actions Verified QAR Date		20 Closure Approved by: QADD Date	

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94/048

- A. **REMEDIAL ACTION:** The QA Office will provide guidance to the Hydrologic Investigations Program (HIP) and Geologic Studies Program (GSP) Implementation Specialists to identify requirements of QMP-8.01 that must be addressed to technical procedures. This guidance will address the interfaces with other sample management requirements. Within 30 days of receipt of that guidance, the HIP and GSP Chiefs will submit a schedule to the QA Office for the review and revision of active technical procedures that deal with samples. Completion of the schedule will be monitored by the QA Office through the audit and surveillance program.
- B. **EXTENT OF THE DEFICIENCY:** The HIP and GSP Chiefs will submit a list of all active technical procedures that contain requirements for the identification, control, and traceability of samples. At the same time the technical procedure revision schedule is submitted, any procedures not in use and that are not anticipated to be used in the near future will be rescinded by the appropriate Principal Investigator.
- C. **ROOT CAUSE DETERMINATION:** Not required.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Whenever a QMP is revised or modified, QMP-5.03 requires the QA Office to evaluate the need for remedial actions. For each case that affects technical procedures, the QA Office will establish a tracking mechanism with follow-up to assure that the actions are completed in a timely fashion.

QMP-5.01 will be modified to provide for simplified technical procedure revisions when the changes are non-technical in nature.

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. T.H. Chaney, Quality Assurance Manager | 09/15/94 |
| D.H. Appel, Hydrologic Investigations Program Chief | 10/15/94 |
| J.S. Stuckless, Geologic Studies Program Chief | |
| 1.B. D.H. Appel, Hydrologic Investigations Program Chief | 10/15/94 |
| J.S. Stuckless, Geologic Studies Program Chief | |
| 1.D. T.H. Chaney, Quality Assurance Manager | 09/15/94 |

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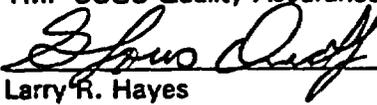
CORRECTIVE ACTION REQUEST (Continuation Page)

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/1/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/1/94
Date

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR NO. YM-94-048

A. REMEDIAL ACTION:

1. The QA Office will provide guidance to the Hydrologic Investigations Program (HIP) and Geologic Studies Program (GSP) Implementation Specialists that identifies the requirements from QMP-8.01 and DOE YAP samples procedures that must be addressed in technical procedures. This guidance will include the interfaces between the sample management procedures.
2. Within 30 days of receipt of that guidance, the HIP and GSP Chiefs will submit a schedule of the QA Office for the review and revision of active technical procedures that deal with samples.
3. A copy of the schedule will be provided to DOE YMQAD.

B. EXTENT OF THE DEFICIENCY: The HIP and GSP Chiefs will submit a list of all active technical procedures that contain requirements for the identification, control, and traceability of samples. At the same time the technical procedure revision schedule is submitted, any procedures not in use and that are not anticipated to be used in the near future will be rescinded by the appropriate Principal Investigator.

C. ROOT CAUSE DETERMINATION: Not required.

D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE: Whenever a QMP is revised or modified, QMP-5.03 requires that QA Office to evaluate the need for remedial actions. For each case that affects technical procedures, the QA Office will establish a tracking mechanism with follow-up to assure that the actions are completed in a timely fashion.

8/23/94 LTR. Hayes to Spence

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WASHINGTON, D.C.

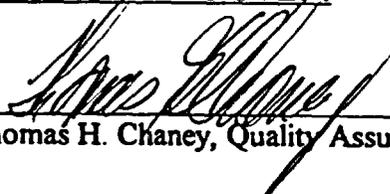
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2. For each action above, identify the name of the individual assigned responsibility for completion of the action and the anticipated (or actual, if complete) completion date.

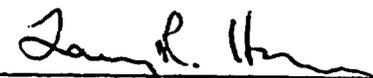
- 1.A. (1) T. H. Chaney, Quality Assurance Manager 09/15/94
(2) D. H. Appel, Hydrologic Investigations Program Chief 10/15/94
J. S. Stuckless, Geologic Studies Program Chief
(3) T. H. Chaney, Quality Assurance Manager *11/01/94
*NOTE: This date represents delivery of the schedule to YMQAD
- 1.B. D. H. Appel, Hydrologic Investigations Program Chief 10/15/94
J. S. Stuckless, Geologic Studies Program Chief
- 1.D. T. H. Chaney, Quality Assurance Manager 09/15/94

3. RESPONSE APPROVED:



Thomas H. Chaney, Quality Assurance Manager

8/16/94
Date



Larry R. Hayes,
Chief, Yucca Mountain Project Branch

8/23/94
Date

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8 CAR NO.: YM-94-049
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CORRECTIVE ACTION REQUEST

1 Controlling Document QARD, Rev. 0	2 Related Report No. YMP-94-06
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3 Responsible Organization USGS	4 Discussed With T. CHANEY
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5 Requirement:
Section 5.2.2.D of the QARD states, in part: "Implementing documents shall include the following information as appropriate to the work to be performed: D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished."

6 Adverse Condition:
QMP 16.03, R3, provides no criteria as to what constitutes a trend, hence the rationale and conclusions of the trend reports for the time periods 10/1/93 - 12/31/93 and 1/1/94 - 3/31/94 are not substantiated by the information provided.

9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes, Circle One: A B C D E	10 Does a stop work condition exist? Yes ___ No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Circle One: A B C	3 Response Due Date: <u>20 WORKING DAYS</u> <u>FROM T.CHANEY</u>
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11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1. Provide qualitative criteria in QMP 16.03.
2. Change the definition of adverse condition to be consistent with the QARD glossary.
3. Substantiate the trend reports for the time frame identified above.

7 Initiator J. BLAYLOCK <i>C.C. Wynn for</i> 6-30-94	14 Issuance Approved by: QADD <i>[Signature]</i> for Date <u>7-A-94</u>
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15 Response Accepted QAR <i>[Signature]</i> 9/12/94 Date <u>9/12/94</u>	16 Response Accepted QADD Date _____
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17 Amended Response Accepted QAR <i>[Signature]</i> Date <u>9/12/94</u>	18 Amended Response Accepted QADD <i>[Signature]</i> 9/12/94 Date <u>9/12/94</u>
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19 Corrective Actions Verified QAR Date _____	20 Closure Approved by: QADD Date _____
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-049

- A. **REMEDIAL ACTION:** The two trend reports generated during the identified time frame will be reviewed. The review will address consistency of the approach for identifying adverse quality trends. The Quality Assurance Management Information Reports will be amended to add any supplemental information required to clarify the qualitative criteria in the trend analysis contained in the reports found.
- B. **EXTENT OF THE DEFICIENCY:** Two quarterly Quality Assurance Management Information Reports were produced during the time frame indicated.
- C. **ROOT CAUSE DETERMINATION:** Not. Required.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** YMP-USGS QMP-16.03, R3 will be modified to include qualitative criteria for trend identification and to change the definition of "condition adverse to quality" to be consistent with the QARD.

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 N.R. Karas, Program Development Coordinator 10/01/94
- 1.D N.R. Karas, Program Development Coordinator 10/01/94

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/1/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/1/94
Date