



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

MAR 24 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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-046 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YMP-94-06 OF U.S. GEOLOGICAL SURVEY (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR YM-94-046 and determined the results to be satisfactory. As a result, the CAR is considered closed.

If you have any questions, please contact either Robert B. Constable at 794-7945 or Stephen R. Maslar at 794-7762.

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2638

Enclosure:
CAR YM-94-046

cc w/encl:

~~A. 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, USGS/SAIC, Golden, CO
D. G. Horton, OQA (RW-3) NV
W. E. Barnes, YMSCO, NV

cc w/o encl:

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

YMP-5

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PDR WASTE
WM-11 PDR

102.7
WM-11
NAD3/1

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

8 CAR NO.: YM-94-046
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QA

CORRECTIVE ACTION REQUEST

1 Controlling Document QARD, Revision 0; YMP-USGS-QMP-16.04, Revision 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:
QARD, Section 16.0 states: "A condition adverse to quality shall be identified when a QARD or implementing document requirement is not met." QMP-16.04, Section 5 states: "The identification of a condition adverse to quality shall be documented by the individual identifying the condition using a Quality Deficiency Report (QDR) or equivalent."

6 Adverse Condition:
Contrary to the above requirements, during a review of USGS internal audit reports 94058-IA and 94031-IA, it appears that of 13 concerns identified, more than half of these concerns met the criteria of the QARD and QMP-16.04 for a conditional adverse to quality without QDRs or equivalent being issued to document these conditions. USGS, per internal memo dated 6/17/94, has defined/interpreted a condition adverse to quality a "a clean or very clear violation of a QMP or technical procedure." This is not in compliance with the QARD or QMP-16.04 definition of a condition adverse to quality in that it does not include noncompliance with quality program requirements other than those specified in procedures.

9 Does a Significant Condition Adverse to Quality exist? Yes <u>X</u> No If Yes, Circle One: A <u>(B)</u> 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: 20 Working Days From Issuance
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11 Required Actions: Remedial Extent of Deficiency Preclude Recurrence Root Cause Determination

12 Recommended Actions:
1) USGS should use the wording in the QARD and QMP-16.04 as the basis for determining conditions adverse to quality.
2) Previously identified and future concerns with the associated recommendation need to be formally tracked to insure acceptable closure to USGS-QA.

7 Initiator S. Maslar <i>C.C. Wanen for</i> 6-30-94	14 Issuance Approved by: <i>[Signature]</i> QADD Date <u>7/5/94</u>
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15 Response Accepted QAR <i>S.R. Maslar</i> Date <u>8/11/94</u>	16 Response Accepted QADD Date
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17 Amended Response Accepted QAR <i>C.C. Wanen for S.R. Maslar</i> Date <u>8-16-94</u>	18 Amended Response Accepted <i>[Signature]</i> QADD Date <u>8/16/94</u>
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19 Corrective Actions Verified QAR <i>S.R. Maslar</i> Date <u>3/22/95</u>	20 Closure Approved by: <i>[Signature]</i> QADD Date <u>3-23-95</u>
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-046

- A. **REMEDIAL ACTION:** The issues, documented as Concerns and Recommendations rather than deficiencies, will be tracked to ensure appropriate resolution of the issues.
- B. **EXTENT OF THE DEFICIENCY:** The approach for using Concerns was initiated as a result of significant revisions to QMP-16.04, Control of QDRs, and QMP-18.01, Audits, which procedurally eliminated the "Observation" as a tool to document weaknesses or recommendations for improvement in the program. The effective date of the QMPs was September 29, 1993. The first of the 73 Concerns was initiated on January 12, 1994. All potential QDR conditions are identified in the Concerns.
- C. **ROOT CAUSE DETERMINATION:** The USGS tries to avoid creating unnecessary paperwork whenever possible by concentrating on documenting those conditions in the program that clearly impact the results of our work. When a condition that may potentially be adverse to quality is identified, the appropriate QA and technical staff members make a determination as to whether a true deficient condition exists and if quality is enhanced by initiating a QDR. As a result, the verification group chose a conservative interpretation of a Condition Adverse to Quality and, to minimize conflict after the loss of the Observation tool, the Verification Group established a means to document potential or difficult quality issues in the form of Concerns and Recommendations, with the understanding that Management would recognize the intent of the identified concern and responsibly initiate corrective action. The Verification Group, clearly understanding what a Condition Adverse to Quality is, proceeded with this alternative approach as a means to attain compliance with the USGS QA Program.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Corrective Actions will consist of two elements:
- First, effective immediately, the Verification Group will utilize a strict interpretation of the QARD definition for Conditions Adverse to Quality to identify deficiencies (QDRs).
- Second, QMPs 16.04 and 18.01 will be changed to include a provision for documenting Concerns that encompass weaknesses and suggestions for improvement.

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.

L.L. McInroy, Verification Supervisor

09/12/94

8/1/94 Ltn. Hayes to Spence
Exhibit QAP-16.1.2
CAR94-46.164

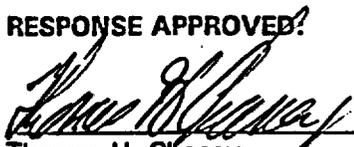
REV. 2/14/94

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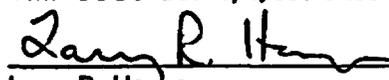
CORRECTIVE ACTION REQUEST (Continuation Page)

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

8/9/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

8/9/94
Date

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

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CORRECTIVE ACTION REQUEST (Continuation Page)

1. AMENDED CORRECTIVE ACTION RESPONSE FOR CAR No. YM-94-046 (Dated 11/30/94)

- A. **REMEDIAL ACTION:** No change. The issues, documented as Concerns and Recommendations rather than deficiencies, will be formally tracked to ensure acceptable resolution of the issues.
- B. **EXTENT OF THE DEFICIENCY:** No change. The approach for using Concerns was initiated as a result of significant revisions to QMP-16.04, Control of QDRs, and QMP-18.01, Audits, which procedurally eliminated the "Observation" as a tool to document weaknesses or recommendations for improvement in the program. The effective date of the QMPs was September 29, 1993. The first of the 73 Concerns was initiated on January 12, 1994. All potential QDR conditions are identified in the Concerns.
- C. **ROOT CAUSE DETERMINATION:** No change. The USGS tries to avoid creating unnecessary paperwork whenever possible by concentrating on documenting those conditions in the program that clearly impact the results of our work. When a condition that may potentially be adverse to quality is identified, the appropriate QA and technical staff members make a determination as to whether a true deficient condition exists and if quality is enhanced by initiating a QDR. As a result, the verification group chose a conservative interpretation of a Condition Adverse to Quality and, to minimize conflict after the loss of the Observation tool, the Verification Group established a means to document potential or difficult quality issues in the form of Concerns and Recommendations, with the understanding that Management would recognize the intent of the identified concern and responsibly initiate corrective action. The Verification Group, clearly understanding what a Condition Adverse to Quality is, proceeded with this alternative approach as a means to attain compliance with the USGS QA Program.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** Added new paragraph: Corrective Actions will consist of two elements:
- (1) Effective immediately, the Verification Group will utilize a strict interpretation of the QARD definition for Conditions Adverse to Quality to identify deficiencies (QDRs).
 - (2) New Paragraph: As committed in 1A., Remedial Action, the Concerns and Recommendations have been tracked and will continue to be tracked with follow through to ensure acceptable resolution of the issues. In cases where further evaluation indicates a deficiency exists, QDRs will be issued. It is not believed, however, that it is necessary to persist in implementing the approach at this time due, principally, to the recent DOE Transition Plan which will soon require all participants to utilize DOE deficiency documents and tracking systems.

It is, therefore, recommended that Corrective Action Item 1.D(2) and responsibility Item 2, 1.D.(2) be deleted.

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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. L.L. McInroy, Verification Supervisor

08/01/94

1.D.(1) L.L. McInroy, Verification Supervisor

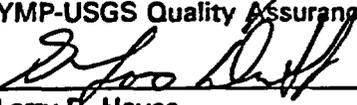
08/01/94

3. RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

11/30/94
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

11/30/94
Date

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RADIOACTIVE WASTE MANAGEMENT
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DATE: 1/24/95
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CORRECTIVE ACTION REQUEST (Continuation Page)

1. SUPPLEMENTAL RESPONSE FOR CAR No. YM-94-046

This supplemental response provides a reassessment of a specific provision for documenting Concerns that encompass weakness and suggestions for improvements.

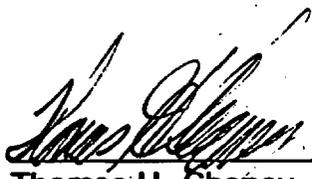
QMP-16.01, R1, will be completed and effective prior to 3/10/95. A review of QMP-18.01, R7, indicates no changes are appropriate for that procedure. It does not discuss deficiencies but only refers the reader to QMP-16.04.

2. RESPONSIBLE INDIVIDUAL:

L.L. McInroy, Verification Supervisor

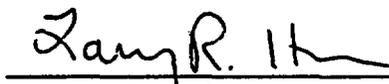
03/10/95

3. SUPPLEMENTAL RESPONSE APPROVED:



Thomas H. Chaney
YMP-USGS Quality Assurance Manager

1/24/95
Date



Larry R. Hayes
Chief, Yucca Mountain Project Branch

1/25/95
Date



YMP-USGS
QUALITY DEFICIENCY REPORT
Continuation Sheet

QA: L
SCP: NA
WBS #: 1.2.11

USGS-QDR- _____

QDR Page ____ of ____

(To be filled out by Responder[s]):

Page 1 of ____

- Response
- Amended/Supplemental Response
- Extension Request
- Notification of Completion of Actions
- QDR Void Request

Submitted by: _____
Signature Date

(To be filled out by QA Office:)

Approved Rejected Basis for Rejection: _____

Amended/Supplemental Response Due Date _____

ATL/STL: _____
Signature Date

QA Manager: _____
Signature Date

VERIFICATION OF CORRECTIVE ACTION FOR CAR YM-94-046

Reviewed revised procedure, QMP-16.04, Revision 1, and found it acceptable. As a result of this verification, CAR YM-94-046 is considered closed.

S. R. Maslar
Stephen R. Maslar, QAR

3/22/95
Date



YMP-USGS
QUALITY ASSURANCE
VERIFICATION

QUALITY CONCERN FORM

Concern No: _____
Page 1 of _____

SECTION 1 - INITIATION

Associated Oversight Number: _____ Issue Date: _____ Due Date: _____

Subject (Include QMP, technical procedure, etc.): _____

SECTION 2 - RESOLUTION AND/OR CLOSURE ACTION

Contacts: _____

Comments: _____

SECTION 3 - FOLLOW-UP RESULTS

Close, based on above comments. Close, based on action(s) taken and verified.

Further follow-up action(s): _____

Follow-up due date: _____

Signature, QA Office

Date

SECTION 4 - CLOSURE APPROVAL

Signature, QA Office

Date

Copy to:

MANAGEMENT PROCEDURES MANUAL

CHAPTER 16 - CORRECTIVE ACTION

**SECTION 4 - CONTROL OF QUALITY DEFICIENCY REPORTS
AND QUALITY CONCERNS**

1. **PURPOSE.** The purpose of this Quality Management Procedure (QMP) is to document a method for reporting, validating, responding to, and verifying conditions or conditions potentially adverse to quality discovered by Yucca Mountain Project - U.S. Geological Survey (YMP-USGS) personnel and support organizations.
2. **SCOPE OF COMPLIANCE.** This procedure is applicable to all conditions or conditions potentially adverse to quality associated with quality-affecting activities performed by YMP-USGS personnel and support organizations unless an alternate method for documenting the control of the condition adverse to quality has been approved by the YMP-USGS Quality Assurance (QA) Manager.

This QMP does not apply to the control of supplier deficiencies as described in QMP-7.01, the control of non-conforming samples as described in QMP-8.01, nor the control of deficient or nonconforming measuring and test equipment as described in QMP-12.01. Quality concerns formally identified prior to the effective date of this procedure and currently awaiting resolution and closure will be assigned a unique identification number and tracked in accordance with this procedure.

3. **DEFINITIONS.** For the purposes of this procedure, the following definitions shall prevail:
 - 3.1 **Actions to Prevent Recurrence:** Actions taken that are intended to preclude repetition of a condition adverse to quality.
 - 3.2 **Condition Adverse to Quality:** A state of noncompliance with quality assurance program requirements.
 - 3.3 **Corrective Action:** Actions taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
 - 3.4 **Investigative Actions:** Actions taken to determine the extent and potential impact of a condition adverse to quality.
 - 3.5 **Quality Deficiency:** A document initiated for purposes of tracking the disposition of a condition adverse to quality.
 - 3.6 **Quality concern:** A condition potentially adverse to quality, including those which may stem from interpretation of governing documents.
 - 3.7 **Remedial Actions:** Actions taken to correct identified conditions adverse to quality.

2/10/95 Chapman & Spence

are of concern to the YMP-USGS and support personnel. These quality concerns shall be documented on the Quality Concern Form (Attachments 3).

5.1 QDR Initiation: The QDR initiator shall complete the Initiation portion, Part I, of the QDR (Attachment 1 or equivalent).

5.1.1 The QDR initiator shall identify how the condition adverse to quality was identified, i.e., audit, surveillance, verification, trending, or other routine operations; and shall identify the associated SCP Activity, if applicable.

5.1.2 The QDR initiator shall specify the requirement violated, state the specific deficiency, and provide other pertinent information and/or recommendations as applicable.

5.1.3 The initiator shall forward the QDR to the QA Manager for validation.

5.2 QDR Validation: The QA Manager shall review Part I of the QDR to ascertain if it is valid and properly documented.

5.2.1 If the QDR is valid and properly documented, the QA Manager checks "Valid" and signs the QDR in Part II.

5.2.2 If the QDR is valid, but not properly documented, the QA Manager shall discuss the QDR with the initiator. Either the initiator or the QA Manager shall make the needed corrections.

5.2.3 If the QDR is not considered valid, the QA Manager shall discuss the QDR with the initiator. After discussion, if the QDR is still not considered valid, the QA Manager checks "Invalid" to document the rejection and signs Part II. Justification of the action and a copy of the invalidated QDR are returned to the initiator.

5.3 QDR Severity Level: The QA Manager, in consultation with the QDR originator, shall assign a severity level based on the following guidelines. Severity levels decrease in significance from 1 to 3. The QA Manager shall check the appropriate boxes in Part II of the QDR to identify necessary parts of a response based upon the following guidance.

5.3.1 Severity level 1 is assigned to significant conditions adverse to quality. Severity level 1 conditions are generally applicable when it is likely that results from an entire SCP Activity would be in jeopardy if the condition is not corrected. An example of a severity level 1 condition would be conducting a data gathering activity without either a technical procedure or scientific notebook, without personnel instruction, and without documentation of personnel qualifications. Responses to severity level 1 deficiencies are required to address impact on data, root cause, action(s) to prevent recurrence, remedial actions, investigative actions, and annotated documents (documents with critical explanations or analysis; commentary). Severity level 1 deficiencies shall be evaluated by the QA Manager to determine if a stop work condition exists in accordance with QMP-16.02, Control of Stop Work Orders. The result of the evaluation shall be documented in Part II of the QDR.

are rejected, the QA Manager shall provide appropriate rationale to support the rejection and a new response due date shall be assigned.

5.8.2 If the proposed response is rejected, the responsible organization shall provide the QA Manager with an amended or supplemental response on a QDR continuation sheet prior to or on the response due date assigned in Para. 5.8.1.

- 5.9 **QDR Amended/Supplemental Response:** If the QDR assigned responder recognizes that a proposed response is no longer correct or appropriate, an amended or supplemental response may be submitted at any time on a QDR continuation sheet. The amended or supplemental response should clearly state what parts of the previous response it is superseding.
- 5.10 **Completion of Actions:** All corrective actions shall be implemented by the responsible organization as committed to in the approved response unless an extension request has been approved (see Para. 5.10.1 below). When the actions are complete, the responsible organization shall notify the QA Office on a QDR continuation sheet that actions are complete.
- 5.10.1 In the event that corrective actions cannot be completed by the scheduled due date, an extension request shall be documented on a QDR continuation sheet and submitted to the YMP-USGS QA Manager no later than the due date for the corrective action. Extension requests shall include a justification for the delay, a statement of progress achieved, and an evaluation of impact due to failure to maintain the approved schedule. Examples of acceptable justifications are unexpected extended absence by key personnel involved with the actions, or rescheduling of anticipated events or actions which impacted the corrective actions and which were beyond the control or influence of the responders.
- 5.10.2 Extension requests shall be evaluated by the Audit Team Leader, Surveillance Team Leader, and/or QA Manager, as applicable, and the acceptance or rejection shall be documented on the continuation sheet. For those extension requests that are rejected, the YMP-USGS QA Manager shall contact appropriate management of the responsible organization to develop an acceptable schedule for completion of the corrective actions.
- 5.11 **Request to Void a QDR:** If, during the course of investigating the deficient condition, it is determined through objective evidence that the condition is not a violation, the responsible person may request that the QA Manager void the QDR. The request to void a QDR should be documented on a QDR continuation sheet. The QA Manager will view the evidence and accept or reject the request. Acceptance will be processed in accordance with Para. 5.13.
- 5.11.1 If the request to void a QDR is rejected, the QA Manager will provide on a QDR continuation sheet appropriate rationale to support the rejection and the request for an amended response.
- 5.12 **QDR Verification:** QDRs are generally closed by verification of corrective actions. See Para. 5.13 for alternate closures.

5.15.1 INITIATION (Section 1 of Attachment 3): When appropriate, the QA Office shall initiate a form for quality concerns that have been identified..

5.15.2 REVIEW, RESOLUTION AND/OR CLOSURE ACTION (Section 2 of Attachment 3): QA Office reviewers shall perform quality Concern Form reviews, document personnel contacts, ensure affected personnel are adequately notified of the concern and its implications and contribute to follow-up actions. Reviews shall be performed by persons or organizations not directly responsible for the quality concern.

5.15.3 FOLLOW-UP RESULTS (Section 3 of Attachment 3): Based on the follow-up results, the QA Office shall recommend closure or further follow-up action(s) and sign and date the form. Further follow-up action(s) are documented on the form continuation sheet(s).

5.15.4 CLOSURE (Section 4 of Attachment 3): After final follow-up action is completed, the QA Manager (or delegate) shall provide closure approval.

5.15.5 DISTRIBUTION: The completed Quality Concern Form shall be distributed to QA Office personnel who were responsible for initiating the quality concern, and affected others.

5.16 Maintenance of Quality Concern Tracking System: The QA Office shall maintain a tracking system for quality concerns in accordance with QMP-16.03. This tracking system will include a status-history of each quality concern, including initiation and closure dates.

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: None.

6.2 Records Center Documents: The following QA records shall be submitted by the QA Manager to the YMP-USGS Local Records Center as complete record packages in accordance with QMP-17.01:

- Completed YMP-USGS Quality Deficiency Reports (or equivalent) and supporting documentation
- Invalidated Quality Deficiency Reports and the justification for invalidation
- Quality Concern form(s) and support documentation

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes YMP-USGS-QMP-16.04, R0, Control of Quality Deficiency Reports and Modifications QMP-16.04,R0-M1, -M3, -M4, and -M5.

7.2 References Cited:

- YMP-USGS-QMP-7.01, Receipt of Purchased Items and/or Services
- YMP-USGS-QMP-8.01, Identification and Control of Samples
- YMP-USGS-QMP-12.01, Instrument Calibration

<u>Revision/ Modification No.</u>	<u>Effective Date</u>	<u>Description of Changes</u>
R0-M4	12/09/94	Procedure modified as a result of corrective actions during DOE Audit YMP-95P-04.
R0-M5	02/21/95	Procedure changed to exclude the use of the QDR process for documenting deficient or nonconforming M&TE.
R1	03/10/95	This revision incorporates all Modifications to R0 and the identification of concerns as committed to in DOE CAR YM-94-046.