



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

FEB 06 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-94-046 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE  
DIVISION'S (YMQAD) AUDIT YMP-94-06 OF THE U.S. GEOLOGICAL SURVEY  
(SCPB: N/A)

The YMQAD staff has evaluated the amended response to CAR YM-94-046. The amended response has been determined to be satisfactory. Please provide YMQAD with copy of revised procedure upon completion. 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 Stephen R. Maslar at 794-7762.

YMQAD:RBC-1973

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

Enclosure:  
CAR YM-94-046

130040

YMP-5

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PDR WASTE  
WM-11 PDR

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102.7  
WM-11

FEB 06 1995

Larry R. Hayes

-2-

cc w/encl:

~~D. 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  
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

**ORIGINAL**  
THIS IS A RED STAMP

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

8 CAR NO.: YM-94-046  
PAGE: 1 OF 1  
QA

**CORRECTIVE ACTION REQUEST**

1 Controlling Document QARD, Revision 0; YMP-USGS-QMP-16.04, Revision 0		2 Related Report No. YMP-94-06	
3 Responsible Organization USGS		4 Discussed With T. Chaney	
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 <u>    </u> If Yes, Circle One: A <u>(B)</u> 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: <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) 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. Wam fu</i> 6-30-94		14 Issuance Approved by: QADD <i>[Signature]</i> Date <u>7/5/94</u>	
15 Response Accepted QAR <i>S.R. Maslar</i> Date <u>8/11/94</u>		16 Response Accepted QADD <i>[Signature]</i> Date <u>    </u>	
17 Amended Response Accepted QAR <i>C.C. Wam fu S.R. Maslar</i> Date <u>8-16-94</u>		18 Amended Response Accepted QADD <i>[Signature]</i> Date <u>8/16/94</u>	
19 Corrective Actions Verified QAR Date <u>    </u>		20 Closure Approved by: QADD Date <u>    </u>	

**ENCLOSURE**

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WASHINGTON, D.C.

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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

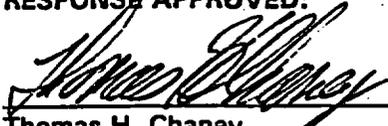
8/1/94 Ltn. Hayes & Spence

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WASHINGTON, D.C.

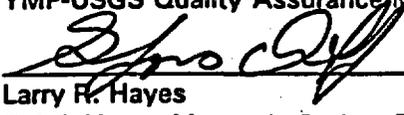
CAR NO. YM-94-046  
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QA

**CORRECTIVE ACTION REQUEST (Continuation Page)**

**3. RESPONSE APPROVED:**

  
\_\_\_\_\_  
Thomas H. Chaney  
YMP-USGS Quality Assurance Manager

8/11/94  
Date

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

8/11/94  
Date

For

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

CAR NO. YM-94-046  
PAGE: 1 OF 2  
QA

**CORRECTIVE ACTION REQUEST (Continuation Page)**

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

- A. **REMEDIAL ACTION:** 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:** 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:
- (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) 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.**

1.A. L.L. McInroy, Verification Supervisor	08/01/94
1.D.(1) L.L. McInroy, Verification Supervisor	08/01/94
1.D.(2) L.L. McInroy, Verification Supervisor	10/01/94

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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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U.S. DEPARTMENT OF ENERGY  
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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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**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.

1.A. L.L. McInroy, Verification Supervisor

08/01/94

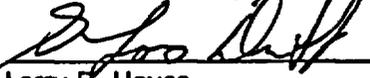
1.D.(1) L.L. McInroy, Verification Supervisor

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

For

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

CAR NO. YM-94046  
 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.

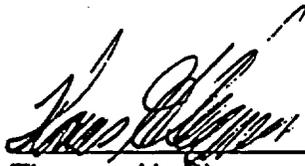
QMP-16.01, R1, will be completed and effective prior to 3/10/95. A review of QMP-18.01, R7, indicates no changes are appropriate for that procedure. It does not discuss deficiencies but only refers the reader to QMP-16.04.

**2. RESPONSIBLE INDIVIDUAL:**

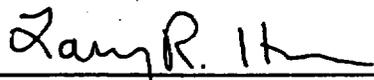
L.L. McInroy, Verification Supervisor

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

1/24/95 Hayes to Spence