



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

AUG 16 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 RESPONSE TO CORRECTIVE ACTION REQUEST  
(CAR) YM-94-046 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-94-046. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after October 1, 1994, after all corrective actions have been implemented. 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.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4685

Enclosure:  
CAR YM-94-046

cc w/encl:

~~R. C. 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  
D. G. Horton, OQA (RW-3) NV  
R. M. Nelson, Jr., 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

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N/A03

<b>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</b>		8 CAR NO.: <u>YM-94-046</u> PAGE: <u>1</u> OF <u>1</u> QA
<b>CORRECTIVE ACTION REQUEST</b>		
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	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) 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. Wan for</i> <i>6-30-94</i>	14 Issuance Approved by: QADD <i>[Signature]</i> Date <i>7/5/94</i>	
15 Response Accepted QAR <i>S.R. Maslar</i> Date <i>8-11-94</i>	16 Response Accepted QADD <i>[Signature]</i> Date <i>    </i>	
17 Amended Response Accepted QAR <i>C.C. Wan for S.R. Maslar</i> Date <i>8-16-94</i>	18 Amended Response Accepted QADD <i>[Signature]</i> Date <i>8/16/94</i>	
19 Corrective Actions Verified QAR <i>    </i> Date <i>    </i>	20 Closure Approved by: QADD <i>    </i> Date <i>    </i>	

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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**

- 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

8/9/94 Lt. N. Hayes & Spence

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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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QA

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  
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CAR NO. YM-94-046  
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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

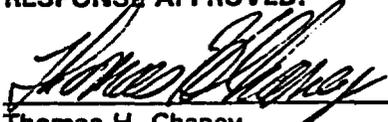
8/1/94 Ltn. Hayes & Spence

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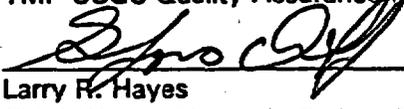
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**CORRECTIVE ACTION REQUEST (Continuation Page)**

**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