



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

JAN 13 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 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
(USGS) (SCPB: N/A)

The YMQAD staff has verified the corrective action to CAR
YM-94-046 and determined the results to be unsatisfactory
because revision of USGS Quality Management Procedures (QMP)
to include documenting concerns has not been accomplished as
specified in the accepted response. In addition, a USGS
amended response to CAR YM-94-046 recommending deletion of the
QMP revisions from the response was rejected by YMQAD on
December 21, 1994.

Provisions for documenting concerns that encompass weaknesses
and suggestions for improvement is an enhancement to the USGS
quality program and is in line with the Office of Civilian
Radioactive Waste Management's approach to the projectwide
corrective action program to be implemented during fiscal year
1995. Therefore, USGS QMP should be revised to address
documentation of concerns as identified in the approved CAR
response.

A response from USGS indicating a new completion date for
revision of procedures is required to be submitted to this
office within ten working days of this letter. Verification of
completion of required corrective action will be performed
after the date provided.

All other corrective actions identified in the response to the
CAR were verified to be satisfactorily completed.

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YMP-5

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PDR WASTE PDR
WM-11

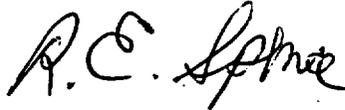
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Larry R. Hayes

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JAN 13 1995

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-1677

Enclosure:
CAR-YM-94-046

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, USGS/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

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

8 CAR NO.: YM-94-046
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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 ___ 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: 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 fur</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 _____ Date _____	
17 Amended Response Accepted QAR <i>C.C. Wam fur 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 _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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CORRECTIVE ACTION REQUEST (Continuation Page)

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

- 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

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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

For

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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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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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- 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).
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