



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

AUG 17 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 RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)
YM-95-042 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION'S (YMQAD) AUDIT YM-ARP-95-09 OF U.S. GEOLOGICAL
SURVEY (USGS) (SCP: N/A)

The YMQAD staff has evaluated the response to CAR YM-95-042. The response has been determined to be unsatisfactory. The response addresses conditions related to the USGS Trend Reports for the first and second quarters for fiscal year 1995. In hindsight, the response to the first quarter report is inadequate since the review performed indicates there is no evidence of a trend and yet YMQAD CAR YM-95-046, issued during the review, indicates additional problems with Quality Management Procedure QMP-3.04. The Trend Report gave the USGS an opportunity to identify and resolve those issues rather than receiving a significant CAR from Yucca Mountain Site Characterization Office. The response is indicative that the trending program is superficial in nature and unable to quantify or identify underlying problems. Consideration of the possible trends needs to be more than a cursory determination that each occurrence is an isolated event. The response is hereby rejected.

An amended response is required to be submitted to this office within ten working days of the date of this letter. Send the original of your response to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109. If an extension to the due date is necessary, it must be requested in writing, with appropriate justification, prior to that date.

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Larry R. Hayes

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AUG 17 1995

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or James Blaylock at (702) 794-7913.



Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

YMQAD:RBC-4266

Enclosure:
CAR YM-95-042

cc w/encl:

~~U. 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

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U.S. DEPARTMENT OF ENERGY
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B. CAR NO. **YM-95-042**
PAGE **1** OF **2**
QA

CORRECTIVE ACTION REQUEST

1. CONTROLLING DOCUMENT: QARD, DOE/RW-0333P	2. RELATED REPORT NO.: YM-ARP-95-09
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3. RESPONSIBLE ORGANIZATION: U. S. Geological Survey (USGS)	4. DISCUSSED WITH: L. McInroy
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5. REQUIREMENT:

- Paragraph 16.2.1: A condition adverse to quality shall be identified when a QARD or an implementing document requirement is not met.
- Paragraph 16.2.5: The Quality Assurance organization shall verify implementation of corrective actions taken for all reported condition adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.
- Paragraph 16.2.6B: Reports of nonconformances and significant conditions adverse to quality shall be evaluated to identify adverse quality trends and to help identify root causes.

6. ADVERSE CONDITION:
Contrary to the cited requirements:

- There is no criteria to evaluate potential conditions adverse to quality relative to quality or non-quality activities. Two USGS Quality Deficiency Reports (QDR), 95002 and 95014, were closed on the basis that the activities were no longer quality related. However, these QDR closures were based solely on statements from the respective Principal Investigators and no other documentation.
- QDRs were being closed prior to completion of corrective actions.
- The Quarterly Quality Assurance Management Report is based on sorting of deficiency documents according to procedure, organization, or SCP activity number. The sort on USGS-QMP-5.01 had two QDRs for lack of technical procedures; there were two additional YMQAD CARs citing the QARD for lack of technical procedures/Scientific Notebooks, that were not included. These four deficiency documents would have constituted a trend in accordance with the USGS procedure.
- The report for January - March 1995 had these USGS QDRs on QMP-2.08, "Non Federal Contractor Personnel Qualifications," and identified this as a trend. No QDR was initiated, nor any discussion of any proposed action.

9. Does a Significant Condition Adverse to Quality exist? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Check One: <input checked="" type="checkbox"/> A <input checked="" type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E	10. Does a stop work condition exist? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No; If Yes, Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	13. 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:

7. Initiator James Blaylock James Blaylock	14. Issuance Approved by [Signature] QADD [Signature] Date 5-17-95
15. Response Accepted James Blaylock QAR [Signature] Date 5/22/95	16. Response Accepted [Signature] QADD [Signature] Date 6-30-95
17. Amended Response Accepted QAR _____ Date _____	18. Amended Response Accepted QADD _____ Date _____
19. Corrective Actions Verified QAR _____ Date _____	20. Closure Approved by QADD _____ Date _____

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U.S. DEPARTMENT OF ENERGY
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8.
CAR NO. YM-95-042
PAGE 2 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

Block 5 continued

4. Paragraph 16.2.6.D: Identified adverse trends shall be reported to the organization responsible for corrective action.

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

CAR NO. YM-95-042
PAGE: 1 OF 4
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

1. CORRECTIVE ACTION RESPONSE FOR CAR No. YM-95-042

ITEM #1

- A. **REMEDIAL ACTION:** QDRs 95004 and 95014 were closed on the basis that the activity had initially been incorrectly identified as quality-affecting. The concern expressed in this CAR is that the re-classification to non-quality affecting was not sufficiently documented. The remedial action is to amend the closed QDRs to add supplemental justification that the activity is non-quality related.
- B. **EXTENT OF THE DEFICIENCY:** Only a very small number of QDRs have been closed on the basis of improper quality classification. However, to ensure that all are identified and evaluated, the deficiency database will be reviewed for deficiencies closed under similar circumstances. Those identified will be evaluated and, if necessary, amended as noted under Remedial Action.
- C. **ROOT CAUSE DETERMINATION:** The criteria in QMP-4.01 for determining if a procurement is quality related is not clear.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** QMP-4.01, Revision 7 has incorporated more detailed criteria for determining if a procurement is quality related.

ITEM #2

- A. **REMEDIAL ACTION:** QDR 95059 was closed prior to the completion of the Corrective Action. The QDR was closed on the basis that the identical Corrective Action (to review various QMPs) were covered under CAR YM-94-050, and that tracking CAR YM-94-050 through closure would adequately monitor the corrective action. The Remedial Action is to finalize the revision of QMPs -4.01, -4.02, and -7.04 in a timely manner, and review the QDR data base to ensure that any reference to CAR YM-95-050 has been properly resolved.
- B. **EXTENT OF THE DEFICIENCY:** It is not believed that additional QDRs were closed on this basis; however, the data base of deficiencies will be reviewed for deficiencies closed under similar circumstances. Those identified will be evaluated and, if necessary, amended as noted under Remedial Action.
- C. **ROOT CAUSE DETERMINATION:** The condition occurred due to a failure to literally follow the QARD requirements, and due to the view that the approach was reasonable. The approach eliminated needless duplicate tracking effort.

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

CAR NO. YM-95-042
PAGE: 2 OF 4
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** The Verification Staff received training on APs - 16.1Q and -16.2Q procedures on 06/12/95. As of July 3 of this year, all deficiencies will be processed in accordance with APs - 16.1Q and 16.2Q. No further Corrective Action is required.

ITEM #3

- A. **REMEDIAL ACTION:** The Quarterly Quality Assurance Management Information Report will be amended to add QMP-5.05, R4 as a fifth QMP that experienced three or more deficiencies during the second quarter of FY95. CARs YM-95-022 and YM-94-043 were deficiencies written against SCP Activities 8.3.1.2.2.9, Unsaturated Zone Modeling and 8.3.1.17.4.12, Tectonic Modeling, respectively. Modeling activities are controlled by the YMP-USGS via scientific notebooks. Scientific notebook requirements are implemented through QMP-5.05.
- B. **EXTENT OF THE DEFICIENCY:** The FY95 first quarter Quality Assurance Management Information Report will be reviewed and amended, if required, to ensure that YMQAD CARs were properly incorporated into the trend analysis.
- C. **ROOT CAUSE DETERMINATION:** The criteria used by the YMP-USGS in identifying trends is to first sort the deficiencies by YMP-USGS Quality Management Procedure violations, i.e., QMP-4.01, QMP-5.01, etc. Whenever there are three or more deficiencies identifying the same QMP it is considered a potential trend and examined in detail to see if the deficiencies document the same procedural requirement violation. If they do, a trend is identified, and if the procedural requirement being violated corresponds to a QARD requirement it is also identified. For this reason the YMQAD CARs cited were not linked to a QMP-5.01 violation and were more appropriately associated with a violation of QMP-5.05 controlling the use of scientific notebooks. This approach was taken because not all YMP-USGS procedural requirements correspond to a QARD requirement and trending at the participant level was used by YMP-USGS management to assess the effectiveness of QMP implementation.
- D. **CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** No specific corrective actions required; trend analysis to transition to the OCRWM OQA at the end of FY95.

ITEM #4

- A. **REMEDIAL ACTION:** No remedial action required. The Quarterly Quality Assurance Management Information Report for the second quarter of FY95, January through March, 1995 states: "In addition to the commitments in the QDRs listed above, the YMP-USGS QA Office will compile an updated list of augmented staff to help ensure that personnel qualifications for contractor personnel are documented as required." This proposed action is in addition to the already accepted planned actions identified in the QDRs cited. The YMP-USGS programmatic requirement to initiate a unique

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

CAR NO. YM-95-042

PAGE: 3 OF 4

QA

CORRECTIVE ACTION REQUEST (Continuation Page)

QDR as a result of an identified trend is implemented "if currently planned actions are not considered adequate as corrective manners." (See QMP-16.03, R3, Para. 5.3.).

- B. EXTENT OF THE DEFICIENCY:** Investigative actions are not required. Identified trends and the necessity for additional actions and/or issuance of a QDR is at the discretion of the QA Manager as described in Para. 5.3 of QMP-16.03, R3. For the trend identified, the corrective actions planned in the cited QDRs were considered adequate and the updated list was an additional tool to facilitate the QA Office in managing personnel qualification documentation requirements.
- C. ROOT CAUSE DETERMINATION:** No root cause determination required. Implementation of QMP-16.03, R3 was properly executed.
- D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE:** No corrective actions required. As written, the Quarterly Quality Assurance Management Information Report for the second quarter of FY95 identifies a trend associated with contractor personnel qualifications and proposes additional management actions in addition to those committed to in the cited QDRs.

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.

ITEM #1 A. L.L. McInroy 07/30/95
B. L.L. McInroy 08/15/95
D. T.H. Chaney (Issue QMP-4.01, R7) 07/15/95

ITEM #2 A. T.H. Chaney (Revise QMPs -4.01, -4.02, -7.04) 07/15/95
B. L.L. McInroy 08/15/95

ITEM #3 A. R. Scavuzzo 07/21/95
B. R. Scavuzzo 08/04/95

ITEM #4 None.

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 U.S. DEPARTMENT OF ENERGY
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CAR NO. YM-95-042
 PAGE: 4 OF 4
 QA

CORRECTIVE ACTION REQUEST (Continuation Page)

3. RESPONSE APPROVED:

Martha H. Mustard

6-15-95

for Thomas H. Chaney
 YMP-USGS Quality Assurance Manager

Date

for Robert W. Craig

6/15/95

Larry R. Hayes
 Chief, Yucca Mountain Project Branch

Date