



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

NOV 02 1994

Les E. Shephard
Technical Project Officer
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Site Characterization Project
Sandia National Laboratories
P.O. Box 5800, Mail Stop 1333
Albuquerque, NM 87185

EVALUATION OF RESPONSE TO CORRECTIVE ACTION REQUEST (CAR)
YM-94-091 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-09 OF SANDIA NATIONAL
LABORATORIES (SNL) (SCPB: N/A)

The YMQAD staff has evaluated the response to CAR YM-94-091.
The response has been determined to be unsatisfactory because
it does not acceptably resolve the noted conditions. The
reasons to support this determination are as follows:

1. Your response indicates that there were no other examples of this type of deficiency found after reviewing 1993 and 1994 CARs. This evaluation apparently was ineffective due to the YMQAD CAR which resulted from the YMQAD Surveillance SR-95-003 which was conducted during the week of October 17, 1994. This CAR identifies an identical condition that was addressed by YMQAD CAR YM-94-091. Please provide the reason for the inadequate evaluation and why the condition that was found during the surveillance was not identified by the SNL Quality Assurance (QA) evaluation.
2. Your response to root cause determination is incomplete. The evaluation of this portion of the SNL response cannot be completed due to the reference made to SNL CAR 94-01, which was not provided as part of the response.
3. Your response indicates that the QA staff will review CARs more stringently in the future to assess whether the reported condition is a "deviation" or an "observation." Your response does not provide any verifiable basis that would prevent this from recurring. Based on the YMQAD surveillance referenced above, the action to prevent recurrence does not assure effective implementation of the corrective action program. Please reevaluate your response in this area and respond accordingly.

YMP-5 080089
9411080240 941102
PDR WASTE
WM-11 PDR

NH03 1/1
102-7
WM-11

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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.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or Richard L. Maudlin at (702) 794-7290.

Catherine Hampton for
Richard E. Spence, Director

Yucca Mountain Quality Assurance Division

YMQAD:RBC-514

Enclosure:
CAR YM-94-091

cc w/encl:

J. H. Hines, OOD, AL

~~U. G. Spraul~~, NRC, Washington, DC

S. W. Zimmerman, NWPO, Carson City, NV

R. R. Richards, SNL, Albuquerque, NM, M/S 1333

M. C. Brady, SNL, Las Vegas, NV

F. J. Schelling, SNL, Las Vegas, 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-94-091
PAGE: 1 OF 1
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document QAIP 16-01, Revision 2, Corrective Action		2 Related Report No. YMP-94-09	
3 Responsible Organization SNL		4 Discussed With R. Richards	
5 Requirement: QAIP 16.01, Section 6.1, Step 1 states in part: "Initiator shall promptly identify deviations...and initiate the corrective action process by completing the Corrective Action Request (CAR)...." (Section 3.1, Defines adverse conditions as deviations, failures, malfunctions, deficiencies, etc.)			
6 Adverse Condition: Contrary to the above, CARs 94-02, 94-04 and 94-05 address an explicit deviation (condition adverse to quality) from specified requirements (i.e., shall); however, this CAR has been classified as an "observation" which is defined in QAIP 16-01, Section 3.4 as an observed and documented potential adverse condition. QAIP 16-01, Section 3.5 further defines that potential adverse conditions are conditions which if left uncorrected, could lead to an adverse condition (i.e., deviation).			
9 Does a Significant Condition Adverse to Quality exist? Yes ___ No <u>X</u> If Yes. Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes ___ No <u>X</u> ; 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			
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: Take action to review all observations. If the observation identifies a departure from an approved procedure, document the deviation in accordance with approved procedures. Include in your response the cause and actions to preclude reoccurrence.			
7 Initiator Richard L. Maudlin <i>R. Maudlin</i> 09/08/94		14 Issuance Approved by: <i>[Signature]</i> for Date 9.12.94 QADD	
15 Response Accepted QAR _____ Date _____		16 Response Accepted QADD _____ Date _____	
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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RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

8 CAR NO YM-94-0
PAGE 1 OF 1
1992 10/11/94 QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

CORRECTIVE ACTION RESPONSE FOR CAR # YM-94-091

A. Remedial

No actions are necessary to correct the identified condition since all three CARs, even though reported as "Observations," addressed "Remedial Actions," "Root Cause," and "Actions to Prevent Recurrence" (see attached copies). These CARs were all issued as a result of SNL YMP Audit CU-A93-1 of the University of Colorado.

It appears the only discrepancy made was marking a box "observation" rather than "deviation" since all other corrective action criteria were met.

B. Extent of Deficiency

No other examples of this type of deficiency were found after reviewing 1993 (CARs after the last YMPSCO Audit) and 1994 CARs. This deficiency has no impact on any SNL YMP work performed. This was documented in the responses to the subject CARs.

C. Root Cause Determination

The following are the results of the investigation to determine causes for the identified deficiency.

CAR 94-02

- 1) The lack of signature by the SNL YMP Manager on the QAIP 2-6 forms was determined to be an isolated instance and therefore was not documented as a deviation (Auditor judgement).
- 2) The lack of updating training assignments to include QAIP 16-1 was issued as an observation since the contract scope of work had not been updated, ^{which} and was identified as a "Deviation" in CAR 94-01 during the same audit. The QAIP had not been imposed on University of Colorado at this point as described in CAR 94-01.

10/13/94 LTR. SHEPARD TO SPENCE

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

8 CAR NO YM-94-
PAGE 2 OF 2
RRL 10/11/94 Q1:

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

CORRECTIVE ACTION RESPONSE FOR CAR #YM-94-091

CAR 94-04

This CAR was issued as an observation since the equipment in question was no longer in use and no further work involving the equipment was planned. As previously stated, a deviation was issued in CAR 94-01 which documented the fact that QAIP 12-1 used for calibration had not been addressed in procurement documents.

CAR 94-05

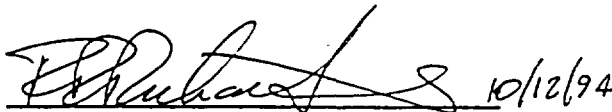
This CAR was issued as an observation since the work in question had been completed. The submittal of Scientific Notebooks for review had not been adequately addressed in procurement documents. Inadequate procurement documents was addressed in CAR 94-01 as a deviation.

D. Corrective Action to Preclude Recurrence

The QA staff will review CARs more stringently in the future to assess whether the reported condition is a "deviation" or an "observation."

Corrective Action Completion Dates:

All actions above are considered complete.


R. R. Richards
QA Department Manager

SNL

YMP

CORRECTIVE ACTION REQUEST

JEP
11/26/94
2

1. CAR No.: 94-02 Date: 11/2/93 Page 1 of 2
2. Initiator and Organization: D. Hawkinson/6319 WBS No.: 124212/124231
3. Responsible Organization-SNL: 6313 or Contractor: _____
4. Discussed With: R. Price/L. Jung Organization: SNL YMP
5. Work Stoppage: ☒ No ☐ Yes
6. Related Report No. Audit Report CU-A93-1
7. Identified During: ☒ Audit ☐ Trend ☐ Mgmt. Assess. ☐ Surveillance ☐ Other _____
8. Requirement (Reference Documents):
QAIP 2-6, Section 4.1, Step 5, Department Manager shall sign certification form to...
QAIP 2-5, Section 5.3, Step 1, SNL YMP Manager shall determine if additional training is required...
9. Deviation ☐ or Observation ☒ (Describe in Detail):
 - CU personnel M. Parashkevova and Y.T. Lin Certification forms have not been approved by SNL YMP Manager.
 - CU personnel (all) training assignment lacks updating to include Procedure 16-1.
10. Significant Condition Adverse to Quality? (SCAQ) ☒ No ☐ Yes (Notify SNL YMP TPO if Yes)
SNL YMP QA Sign/Date: David R. Hawkinson 11/22/93
11. Management Responsible for Developing Response: L.S. Coatin Response Due Date: 12/10/93

Proposed Corrective Actions (12.1 and 12.3 not required for Observation. Use 12.2 to respond to Observations.)

12.1 Root Cause (Mandatory for Significant Conditions and CARs from Audits)

FAILURE OF SNL personnel to assure required documentation & training were complete prior to starting work at CU.

12.2 Remedial Actions (Mandatory for All Deviations) (To be used for Nonconforming Sample Disposition(s))

NO adverse impact on work being performed by CU.
- Complete qualification form for subject personnel.

- ADD QAIP 16-1 to all required CU training.

12.3 Actions to Prevent Recurrence (Mandatory for Significant Conditions and CARs from Audits)

Delegated Rep. will assure any new personnel are qualified and trained prior to starting work and that all required documentation is submitted to the SNL LRC.

12.4 Estimated Corrective Action Completion Date:

1/28/94

12.5 Responsible Management Sign/Date:

L.S. Coatin

12-10-93

12.6 Department Manager or Delegated Authority (For External CARs)

Sign/Date:

N/A

12.7 SNL YMP QA Concurrence With Proposed Corrective Actions (Mandatory for All Deviations.

Optional for Observations) SNL YMP QA Sign/Date:

David R. Hawkinson 12/10/93

13. Corrective Action Completion

Responsible Management Sign/Date:

L.S. Coatin

1-26-94

14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.

SNL YMP QA Sign/Date:

J.C. Friend

(R. Price)

1/26/94

See Attached

HWF 18-1, 1M-2 (11/93)

File Code:

CAR 94-02

Verified that the following actions have been completed and that this CAR can be considered closed:

- 1) Verified that QAIP 2-6 Certificates of Qualification had been completed and were in the SNL YMP Local Records Center for M. Parashkevova and C.T. Lin.
- 2) Verified that training assignment sheets had been generated and reading assignments made for all CU personnel for QAIP 16-1.

Verified by John C. Fuen

Date: 1/26/94

SNL
YMP

CORRECTIVE ACTION REQUEST

1. CAR No.: 94-04 Date: 11/12/93 Page 1 of 2
2. Initiator and Organization: D. Hawkinson/6319 WBS No.: 12.4.2.1.2
3. Responsible Organization-SNL: _____ or Contractor: University of Colorado
4. Discussed With: B. Amadei/S. Sture Organization: University of Colorado
5. Work Stoppage: ☒ No ☐ Yes
6. Related Report No. Audit Report CU-A93-1
7. Identified During: ☒ Audit ☐ Trend ☐ Mgmt. Assess. ☐ Surveillance ☐ Other _____
8. Requirement (Reference Documents):
See Page 2

9. Deviation ☐ or Observation ☒ (Describe in Detail):
See Page 2

10. Significant Condition Adverse to Quality? (SCAQ) ☒ No ☐ Yes (Notify SNL YMP TPO if Yes)
SNL YMP QA Sign/Date: David R. Hawkinson 11/22/93

11. Management Responsible for Developing Response: B. Amadei Response Due Date: 12/10/93

12. Proposed Corrective Actions (12.1 and 12.3 not required for Observation. Use 12.2 to respond to Observations.)

12.1 Root Cause (Mandatory for Significant Conditions and CARs from Audits)

CU and task leaders did not follow the requirements of QAIP 12-1.

12.2 Remedial Actions (Mandatory for All Deviations) [To be used for Nonconforming Sample Disposition(s)]

No further work involving calibration equipment is planned. There is no apparent impact on work performed by CU because of the conditions identified in this CAR

12.3 Actions to Prevent Recurrence (Mandatory for Significant Conditions and CARs from Audits)

If any future work is performed that requires calibrated M & TE then the task leader will assure it is conformed to the requirements of QAIP 12-1.

12.4 Estimated Corrective Action Completion Date:

January 31, 1994

- 12.5 Responsible Management Sign/Date: [Signature] January 28, 1994

12.6 Department Manager or Delegated Authority (For External CARs)

Sign/Date: Ronald H. Prie 1/31/94

- 12.7 SNL YMP QA Concurrence With Proposed Corrective Actions (Mandatory for All Deviations. Optional for Observations) SNL YMP QA Sign/Date: [Signature] 1/31/94

13. Corrective Action Completion

Responsible Management Sign/Date: Ronald H. Prie 1/31/94

14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.
SNL YMP QA Sign/Date: [Signature] 1/31/94

File Code:

Primary 94/1.2.4.2.1.2 / IMP / 1.3 / 94-04 / QA
X-0.0.0.1 X11.0.0.0

NWF 18-1,11-2(11/04/93)

CORRECTIVE ACTION REQUEST

Continuation Sheet

CAR NO.: 94-04

Page 2 of 2

Block 8: REQUIREMENT

QAIP 12-1, Revision 01 and:

- Section 4.2, Step 2, states in part:
 - "All M&TE used by...SNL Contractors in establishing parameters in support of YMP shall be identified and labeled to indicate calibration status...."
 - "M&TE shall be identified and/or labeled to indicate by whom it was calibrated and when the next calibration is due."
- Section 4.2, Step 3, states in part:
 - "M&TE shall be calibrated, adjusted and maintained at prescribed intervals..."
- Section 4.2, Step 4, states in part:
 - "M&TE ... a documented recall system shall be used to ensure that M&TE in expired calibration status are not used."

QAIP 4-1, Revision 03, Section 4.3.2 and Step 5 for QA Program including sub-tier states in part:

- "QA requirements shall be extended to the sub-tier suppliers through either options...supplier's to have an SNL QA approved program that implements YMP QARD requirements prior to start of any work..."

Block 9: DEVIATION

- CU procured the calibration services of MTS Corporation without SNL QA approval of MTS QA Program for compliance to YMP QARD requirements for sub-tier suppliers.
- M&TE had no labels affixed to Load Cells/profilometer to indicate calibration status or when next recalibration was due.
- M&TE was not controlled by a "RECALL" system that identified the required frequency of recalibration and/or due date of next calibration.

Recommended Corrective Actions :

1. CU needs to provide technical justification/evaluate the impact of above conditions upon the credibility of data obtained for Tests 1 and 2.
2. Provide a statement that assures any future sub-tier procurement actions of CU that will be preapproved by SNL PI and M&TE will be controlled in the future to QAIP 12-1.

NWF 16-1.1/1-2(11/04/93)

SNL
YMP

CORRECTIVE ACTION REQUEST

1. CAR No.: 94-05 Date: 11/12/93 Page 1 of 2
2. Initiator and Organization: D. Hawkinson/6319 WBS No.: 12.4.2.1.2
3. Responsible Organization-SNL: 6313 or Contractor: University of Colorado
4. Discussed With: R. Price/B. Amadei Organization: SNL and CU
5. Work Stoppage: ☒ No ☐ Yes
6. Related Report No. Audit Report CU-A93-1
7. Identified During: ☒ Audit ☐ Trend ☐ Mgmt. Assess. ☐ Surveillance ☐ Other _____
8. Requirement (Reference Documents):
See Page 2

9. Deviation ☐ or Observation ☒ (Describe in Detail):
See Page 2

10. Significant Condition Adverse to Quality? (SCAQ) ☒ No ☐ Yes (Notify SNL YMP TPO if Yes)
SNL YMP QA Sign/Date: David R. Hawkinson 11/22/93

11. Management Responsible for Developing Response: B. Amadei
L.S. Coetin Response Due Date: 12/10/93

12. Proposed Corrective Actions (12.1 and 12.3 not required for Observation. Use 12.2 to respond to Observations.)

12.1 Root Cause (Mandatory for Significant Conditions and CARs from Audits)

Failure of task leader to require CU to submit SN's to be reviewed and submitted as QA records.

12.2 Remedial Actions (Mandatory for All Deviations) [To be used for Nonconforming Sample

SN's for EP-44 and EP-45 have been submitted to the task leader for review and submittal to the record center. There is no apparent impact on previous CU work. If the review reveals discrepancies with the SN's, then separate CAR's will be issued to document the conditions.

12.3 Actions to Prevent Recurrence (Mandatory for Significant Conditions and CARs from Audits)

Task leaders will specify in work agreements and/or procurement documents the submittal requirements of QAIP 20-2 if future SN's are to be used. The task leader for CU work will assure that documents assigned to CU are maintained current. Additionally, based on the audit results, the CU personnel are more aware of the importance of document control for YMP work.

12.4 Estimated Corrective Action Completion Date:

January 31, 1994

- 12.5 Responsible Management Sign/Date: [Signature] Jan. 28, 1994

- 12.6 Department Manager or Delegated Authority (For External CARs)
Sign/Date: [Signature] 1/31/94

- 12.7 SNL YMP QA Concurrence With Proposed Corrective Actions (Mandatory for All Deviations.
Optional for Observations) SNL YMP QA Sign/Date: _____

13. Corrective Action Completion
Responsible Management Sign/Date: [Signature] 1/31/94

14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.
SNL YMP QA Sign/Date: [Signature] 1/31/94 See Page 2

File Code: Pumicary 94/1.2.4.2.1.2/IMP/1.3/94-05/QA
111000E

NWF 18-1.1/1-2(11/10/93)

CORRECTIVE ACTION REQUEST
Continuation SheetCAR NO.: 94-05Page 2 of 2**Block 8: REQUIREMENT**

QAIP 20-2, Section 4.1, General Requirements for Scientific Notebooks (SNs) states:

- "SNs shall be reviewed by a competent independent individual to...." Technical reviews may be performed periodically--or as a minimum when the SN is complete.
- Section 5.0, Records Management states in part, "QA Records generated as a result of this procedure shall be prepared and submitted to SNL YMP Records Center in accordance with SNL YMP Procedures 17-1 and 17-2."

Block 9: OBSERVATION

Contrary to the above requirements, the SNs for Tasks 1, 2, and 3, have been reported in SAND Reports; SAND92-1853, SAND92-2247 already published in September 1993 and SAND93-7079 in current 2nd-level of review and need the following retroactive completions for the following:

1. Test logbooks for EP-44 and EP-45 have not received an independent technical review and these tasks have been completed.
2. Test logbooks for Tasks 1, 2, and 3 need to be finalized per QAIP 20-2, Sections 4.1 and 5.0 and submitted to the SNL YMP Local Records Center.

Block 14 Verification

LAB Books for:

- Normal Compression and Shear Test on Rock Joint
- Profilometer on Joint Surfaces
- Rotational Test

were submitted to SNL and reviewed by
R. Price on 12/14/93.

Books were closed and submitted to
FDA's LRC on 12/14/93.

NW 16-1, 1/1-2(11/04/93)