



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

JAN 23 1995

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

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-091 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE DIVISION'S (YMQAD) AUDIT YMP-94-09 OF SANDIA NATIONAL LABORATORIES (SCPb: N/A)

The YMQAD staff has verified the corrective action to CAR YM-94-091 and determined the results to be satisfactory. As a result, the CAR is considered closed.

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

YMQAD:RBC-1799

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

Enclosure:
CAR-YM-94-091

cc w/encl:
J. H. Hines, OGD, AL
~~J. 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

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

270671

YMP-5

9501300311 950123
PDR WASTE
WM-11

PDR

NH03 11
102-7
WM-11

**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
If Yes, Check One: ☐ A ☐ B ☐ C ☐ D ☐ E

10 Does a stop work condition exist?
Yes No; If Yes - Attach copy of SWO
If Yes, Check One: ☐ A ☐ B ☐ C

13 Response Due Date:
20 Working Days
From Issuance

11 Required Actions: ☒ Remedial ☒ Extent of Deficiency ☒ Preclude Recurrence ☒ 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 *R. Maudlin* 09/08/94

14 Issuance Approved by
QADD *R. Maudlin* for Date 9.12.94

15 Response Accepted
QAR *R. Maudlin* 12/20/94 Date 12/20/94

16 Response Accepted
QADD *R. Maudlin* for Date

17 Amended Response Accepted
QAR *R. Maudlin* 12/20/94 Date 12/20/94

18 Amended Response Accepted
QADD *R. Maudlin* for Date 12.23.94

19 Corrective Actions Verified
QAR *R. Maudlin* 1.20.95 Date 1.20.95

20 Closure Approved by
QADD *R. Maudlin* for Date 1.20.95

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WASHINGTON, D.C.

26/02/94 091.
101
B CAR NO YM-94-01
PAGE 1 OF 2
992 10/14/94 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, 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.

PR 12/11/94
8 CAR NO. YM-94-01
PAGE 2 OF 2
PR 12/11/94 QA

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.

 10/12/94

R. R. Richards
QA Department Manager

SNL
YMP

CORRECTIVE ACTION REQUEST

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11/26/94
2

1. CAR No.: 94-02 Date: 11/12/93 Page 1 of 1
2. Initiator and Organization: D. Hawkinson/6319 WBS No.: 1242121242231
3. Responsible Organization-SNL: 6313 or Contractor: _____
4. Discussed With: R. Price/J. 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 10-1.
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. Conlin 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 forms for subject personnel.
- ADD QAIP 161 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. Conlin 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. Conlin 1-26-94

14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.
SNL YMP QA Sign/Date: J.C. Freno 1/26/94
See Attached

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. Amadi/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. Amadi 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
No followup required

WVF 18-1.3/1-2(11/04/93)

File Code:

Primary 94/1.2.4.2.1.2 / IMP/1.3/94-04/QA
X-0000 Y110.000

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 Celle/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 Tasks 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.

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.: 124.2.12
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. Costin 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: Primary 94/1.2.4.2.1.2/IMP/1.3/94-05/QA

CORRECTIVE ACTION REQUEST
Continuation SheetCAR NO.: 94-05Page 2 of 2Block 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 Joints
- 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 & LRC on 12/14/93.

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RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

8 CAR NO.: YM-94-091
PAGE: 1 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

1. CORRECTIVE ACTION AMENDED 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), as a "deviation" would require. These CARs were all issued as a result of SNL YMP Audit CU-A93-1 of the University of Colorado.

B. Extent of Deficiency

A review of 1993 CARs (subsequent to the last YMQAD audit) and 1994 CARs showed a single other apparently similar case ("observation" CAR 94-23). Comparison of that situation with the adverse condition cited on this CAR, however, showed that the cases are only superficially similar: initiators of the CARs are different and the rationale for identifying them as observations differed markedly. In any case, the response to CAR 94-23 specified remedial action, impact, and extent, as a "deviation CAR" would. Therefore, no action concerning the extent of the deficiency is needed.

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 judgment).
- 2) The lack of updating training assignment to include QAIP 16-1 was issued as an observation since the contract scope of work had not been updated to include that procedure in the contract requirements (i.e., no deviation from existing contract requirements had occurred on the part of the contractor, so there was no basis for a "deviation CAR" to be issued to them). The deviation on the part of SNL (in not including that QAIP in the contract requirements) 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, attached.

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WASHINGTON, D.C.

8 CAR NO.: YM-94-091
PAGE: 2 OF 2
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

CAR 94-04

This CAR was issued as an observation since the cited requirements had not been imposed on the contractor (so there was no basis for claiming that a deviation from requirements had occurred on the part of the contractor). Additionally 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, against SNL, which documented the fact that QAIP 12-1, for control of M&TE, 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 and, again, there was no deviation by the contractor. The submittal of Scientific Notebooks for review had not been adequately addressed in procurement documents. As above, inadequate procurement documents were addressed in CAR 94-01 as a deviation on the part of SNL.

D. Corrective Action to Preclude Recurrence

The investigation into the causes of the adverse condition described in block 6, above, shows that there is no clear root cause. In fact, the use of "observation CARs" to point out to a contractor adverse conditions which SNL, rather than the contractor, was responsible for creating, appears to be an appropriate mechanism. However, the existence of observations in the SNL YMP QA corrective action system has created confusion on the part of QA staff, technical staff, and management. Therefore, QAIP 16-1 will be revised to remove "observations" as a mechanism to be documented by means of a Corrective Action Report.

2. Responsible individuals and Anticipated Action Completion Dates:

1D, above. Responsible - John Friend; anticipated completion date - 12/20/94.



L. E. Shephard

12/5/94
Date

SNL
YMP

CORRECTIVE ACTION REQUEST

1. CAR No.: 94-01 Date: 11/2/93 Page 1 of 2
2. Initiator and Organization: D. Hawkins/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):
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. Hawkins 11/22/93
11. Management Responsible for Developing Response: L.S. Costin 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 Delegated Reps. to followup on CURRENT QA requirements.
- 12.2 Remedial Actions (Mandatory for All Deviations) [To be used for Nonconforming Sample Disposition(s)] There has been no adverse impact on work performed by CU. A work agreement or contract revision will be issued to specify current QA requirements.
- 12.3 Actions to Prevent Recurrence (Mandatory for Significant Conditions and CARs from Audits)
Work Agreements will be issued when required to maintain CU work under current QA requirements.
- 12.4 Estimated Corrective Action Completion Date:
1/28/94
- 12.5 Responsible Management Sign/Date: Lesly L 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. Hawkins 12/10/93

13. Corrective Action Completion
Responsible Management Sign/Date: Lesly L 1-28-94
14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.
SNL YMP QA Sign/Date: James 1/28/94 See Attached Work Agreement

File Code:

SNL 16-1, 1/12/94 (10/93)

CORRECTIVE ACTION REQUEST

Continuation Sheet

CAR NO.: 94-01

Page 2 of 2

Block 8: REQUIREMENT

QAIP 1-5, "ESTABLISHING WORK AGREEMENTS"

2.0 Scope, identifies this procedure is applicable for activities subject to the QA Program, where scientific investigation is being conducted without a Technical Procedure (TP). The Work Agreement (WA) shall be used as the required training document.

4.1 Preparing a WA, Note 1 states "Contracts issued to suppliers in accordance with Procedure 4-1 may be used instead of a WA as long as the Contract addresses the 18 WA Elements."

Block 9: DEVIATION

Contrary to the above requirements and the Quality Assurance Grading Report (QAGR) "Rolled-Down" of Procedure 1-5 to both WBS No.'s 1.2.4.2.1.2 and 1.2.4.2.3.1, SNL has not controlled University of Colorado (CU) activities by WAs to either WBS.

The procurement document task descriptions within "Statements-of-Work" (SOWs) do not address required WA Elements (5), (7), (8), (10), (11), (12), (15), (16), (17), and (18), as an acceptable alternative to issuing WAs.

Note: WA-0063 and WA-0070 were issued to SNL Organizations to do work to WBS 1.2.4.2.3.1 but did not consider the same degree of work control for CU.

SNL
YMP

CORRECTIVE ACTION REQUEST

SNL
11/24/93
2

1. CAR No.: 94-02 Date: 11/02/93 Page 1 of 1
2. Initiator and Organization: D. Hawkinson/6319 WBS No.: 124.212/124.231
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. Asses. ☐ 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 10-1.
10. Significant Condition Adverse to Quality? (SCAQ) ☒ No ☐ Yes (Notify SNL YMP TPO if Yes)
SNL YMP QA Sign/Date: David R. Hawkinson 11/24/93
11. Management Responsible for Developing Response: J.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 forms 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: [Signature] 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: [Signature] 1-26-94

14. Verification of Corrective Action Implementation. Include or Reference Documented Objective Evidence.
SNL YMP QA Sign/Date: J.C. Friend [Signature] 1/26/94
See Attached

SNL 16-1.1M-2(11/02/93)

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-I.

Verified by John C. Finner

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.: 124212
3. Responsible Organization-SNL: _____ or Contractor: University of Colorado
4. Discussed With: B. Amadi/S. Sturge 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. Amadi 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

No followup required

File Code:

94/1.2.4.2.1.2 / IMP / 13 / 94-04 / QA

CORRECTIVE ACTION REQUEST

Continuation Sheet

CAR NO.: 94-04Page 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 Tasks 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.

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. Contin 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: Ronald H. Price 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: Ronald H. Price 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: Primary 94/1.2.4.2.1.2/IMP/1.3/94-05/QA

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

NYF 18-1.1/1-2(11/04/93)

VERIFICATION AND CLOSURE STATEMENT

CAR YM-94-091

SANDIA procedure No. QAIP 16-1, Corrective Action, was revised and approved for issue 1/6/95, with an effective date of 1/23/95. The procedure was reviewed by the undersigned and found to be in full compliance with Sandias response commitment and requirements of the QARD. Based on this review , this CAR is considered closed.

Signed Robert R. Cantale 1.17.95