



## Department of Energy

Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office  
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APR 20 1995

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VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF CORRECTIVE ACTION REQUEST (CAR) YM-94-087 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-94-087 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 794-7945 or Richard L. Maudlin at 794-7290.

Richard E. Spence, Director  
Yucca Mountain Quality Assurance Division

YMQAD:RBC-2983

Enclosure:  
CAR YM-94-087

cc w/encl:

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K. L. Boardman, OQD, AL  
S. W. Zimmerman, NWPO, Carson City, NV  
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YMP-5

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PDR WASTE PDR  
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8 CAR NO.: YM-94-087  
PAGE: 1 OF 2  
QA

CORRECTIVE ACTION REQUEST

1 Controlling Document  
QAIP 16-01, Revisions 1, 2 and 3, Corrective Action

2 Related Report No.  
YMP-94-09

3 Responsible Organization  
SNL

4 Discussed With  
J. Voight/C. Jaramillo/D. Hawkinson

5 Requirement:

A. Section 6.1, Step 2 states: SNL YMP QA shall determine if the deviation is a significant condition adverse to quality as defined in Subsection 3.8."

B. Section 6.2, Step 1 states in part: "Responsible Mgt PI/TL shall...identify proposed remedial actions...." (Note: Section 3.6 indicates remedial actions are to include a determination of impact on previously completed work and an investigation into the extent of the adverse condition.)

C. Section 6.4, Step 1 states in part: "...shall verify satisfactory completion of corrective actions and document objective evidence that was used to verify completion and effectiveness of those actions.... Verify all deviation remedial actions were completed as specified...."

6 Adverse Condition:  
Contrary to the above, objective evidence (SNL CARs 93-23, 93-32, 93-36, 93-38, 94-11, 94-12, and 94-25) reviewed reveals that: (1) there was one case noted where determination of significance was not addressed, (2) in all but one case reviewed, remedial actions did not include a determination of impact on previously completed work and an investigation into the extent of the adverse condition, (3) in all but one instance, verifications of corrective action do not detail specific objective evidence that was used to verify completion and effectiveness of those actions, (4) in two instances CARs were closed without verification of completion of all corrective action.

9 Does a Significant Condition Adverse to Quality exist? Yes X No       
If Yes, Check One:  A  B  C  D  E

10 Does a stop work condition exist? Yes      No X; 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:

1. For Item 1 in Block 6, evaluate CAR 93-36 for significance and document results (remedial only).

2. For Item 2 in Block 6, the following is recommended:

A. Determine that extent of this deficiency.

7 Initiator  
Richard L. Maudlin *Maudlin* 09/08/94

14 Issuance Approved by  
QADD *AC Spence* Date: 7/12/94

15 Response Accepted  
QAR \_\_\_\_\_ Date \_\_\_\_\_

16 Response Accepted  
QADD \_\_\_\_\_ Date \_\_\_\_\_

17 Amended Response Accepted  
QAR *Maudlin* Date 12/21/94

18 Amended Response Accepted  
QADD *AC Spence* Date 12/28/94

19 Corrective Actions Verified  
QAR *Maudlin* Date 04/17/95

20 Closure Approved by:  
QADD *AC Spence* Date 4/19/95

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U.S. DEPARTMENT OF ENERGY  
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8 CAR NO.: YM-94-087

PAGE: 2 OF 2  
QA

**CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)**

13 Recommended Action(s) (continued)

- B. Identify the cause of the condition.
  - C. Determine what actions are necessary to preclude reoccurrence.
  - D. Identify the impact on quality due to not implementing this requirement.
3. For Item 3 in Block 6, the following is recommended: (see recommended actions for Item 2 above)
4. For SNL CARs 93-36 and 94-25 in Item 4 of Block 6, take the necessary action to complete verification of ALL items identified in the response to the CARs. Also, evaluate the extent of the identified condition and what actions will be taken to preclude reoccurrence.

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WASHINGTON, D.C.

8 CAR NO.: YM-94-087

PAGE: 21 OF 1

QA  
10/12/94

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

CAR YM-94-087

- A. Remedial Action: For the cited internal SNL YMP CARs, which are all closed, no specific remedial action will be taken, since the situations documented in the CARs have all been overtaken by time and events. Action to preclude recurrence, specified below, will be more significant in correcting this situation.
- B. Extent of the Deficiency: All SNL YMP CARs for FY 94 will be reviewed for evidence of the deficiencies cited in Block 6, above. (Responsible party: J. Voigt; Anticipated Completion Date: October 31, 1994)
- C. Root Cause Determination: The four cited discrepancies can be attributed to a lack of attention to detail on the part of QA personnel involved. Additionally, some of the personnel had not received enough guidance for them to be aware of the specifics that needed to be addressed.
- D. Actions to Preclude Recurrence: All QA personnel involved in CAR verification activities will receive refresher training that will specify each aspect of the corrective action process, so that these types of discrepancies will not occur in the future. (Responsible individual: J. C. Friend; Anticipated Completion Date: November 30, 1994)

for

  
10/12/94  
L. E. Shephard  
SNL YMP Technical Project Officer

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WASHINGTON, D.C.

CAR NO. YM-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

VERIFICATION OF CORRECTIVE ACTION TO CAR YM-94-087

On 04/11-12/95 a follow-up was performed to verify implementation of the corrective actions as provided in the 12/05/94 SNL response to CAR YM-94-087. The results of the verification are as follows. (Please note that the item numbers used to denote the verification relate to those item numbers on the response attached to this verification report)

- (1) Based on the review of Amendment #1 to SNL CAR 93-23 and review of SNL Internal Audit Report A93-1, it was concluded that no incidents of personnel working to outdated procedures was found, so the only problem to be resolved was updates to the applicable QAGRs for WBS 1.2.5.4.6. Implementation satisfactory.
- (2) Based on a review of SNL CAR 93-32 and associated amendments, the impact due to no review of the Scientific Notebook for "Gravity-Driven Instability in a Partially Wetted Fracture Experiment" was considered insignificant. Implementation satisfactory.
- (3) A review of SNL CAR 93-36 indicates correction of the CAR to reflect the status of significance. Also reviewed the letter from ITI, dated 10/22/93, attesting to the completion of corrective action as stated in the response to SNL CAR 93-36. Implementation satisfactory.
- (4) Reviewed page 4 of SNL CAR 93-38 which provides a response to the noted condition. Part of the response indicates a statement related to the integrity of the samples based on the noted condition. This statement is considered acceptable as an impact statement. Implementation satisfactory.
- (5) A review was performed to determine the impact on training and qualification of personnel for National Center for Atmospheric Research (NCAR) and JF Agapito due to the fact that procurement documentation for these contractors did not include training and qualification requirements. The impact, as assessed by SNL, related to inclusion of training and qualification requirements being included in procurement documents. The evaluation was performed to address SNL CARs 94-11, SNL CAR 94-12, and YMQAD CAR YM-93-097. What was not clear in the documentation was an assessment on the work done by these contractors in the absence of contractual requirements for personnel to be trained and qualified to perform quality affecting activities. To attempt to ascertain the answer to this concern the following was noted. NCAR at the time the procurement problem was noted was under a SNL self imposed stop work. A review of SNL Audit Report NCAR-A93-1, dated 10/26-27/93, indicated a Readiness Review of NCAR was being performed as part of the released to return to work. Part of the readiness review was to determine training and qualification requirements of personnel. As a result, there was no apparent impact on the work of NCAR since they were under a stop work. As for JF Agapito, an SNL evaluation, AGA-E93-1, was performed in August 1993. The report for this evaluation reflected inclusion of a review of training and qualification of personnel to SNL procedural requirements. No problems were noted. As a result there is no impact in that it is assumed that JF Agapito personnel were trained and qualified to perform the work.

In addition, a review was conducted of the updates to Purchase Requisitions AH-3870, dated 5/7/94 and AF-9277 to ascertain the

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

CAR NO. Ym-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

inclusion of QA requirements for the qualification and training of personnel. The results reflected an attachment to include these requirements. The update to Purchase Requisition AH-3870 was incorporated into the parent contract via Amendment #1 dated 06/15/94. The update to Purchase Requisition AF-9277 was incorporated into the parent contract as Amendment #8 dated 5/18/94. Implementation satisfactory.

- (6) SNL CAR 95-06 was reviewed and found to re-identify the same problems addressed in SNL CAR 94-25. A review of the response to SNL CAR 95-06 revealed a detailed discussion to resolve the noted conditions. An assessment of the impact on previous work and the extent of the condition were discussed. As of this date, the response has been accepted by SNL. Follow-up to the corrective actions has not yet occurred. Implementation satisfactory.
- (7) Response acceptable as written. No verification required.
- (8) A sample of six SNL CARs, 94-09, 94-14, 94-24, 94-33, 94-47, and 94-52, were selected to validate the review and conclusions that were documented in the review that J. Voiet performed on 10/31/94. The evaluation and associated notes appeared to be accurate and true. SNL CARs 94-67 and 94-76 were reviewed and found to adequately address extent and impact as appropriate. Also, a review was conducted of the documented evidence of the screening process of procurement documents that was performed and documented on 02/10/95. Reviewed SNL CAR 95-11 which documented additional problems as noted in SNL CAR 94-21. Implementation satisfactory.
- (9) A review of the correction to SNL CAR 94-08 was conducted. The review revealed that the correction was as stated in the SNL response to this CAR (YM-94-087).
- (10) A review of SNL CAR 94-13 was conducted and it was noted that a verification statement had been added to reflect verification of training on Eaton. Implementation satisfactory.
- (11) A review of SNL Procedure QAIP 16-1, R5 revealed that a set of instructions are attached which provide guidance on completion of corrective action requests. Included were requirements to address impact and extent of condition by the resondee. Also reviewed the "CAR Checklist for QA" which identifies instructions for QA personnel on completing the CAR form. An evaluation of a sampling of current SNL CARs was performed to determine the effectiveness of the corrective action taken to preclude recurrence. The SNL CARs selected are as follows.

<u>SNL CAR No.</u>	<u>Status</u>
95-04	Closed
95-13	Closed
95-17	Closed
95-14	Open

Two primary issues were evaluated. First, did the CAR documentation include an impact and extent evaluation and second, was there detailed documentation related to the verification. The results of the review indicated a marked improvement over past work. Some minor points related

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CAR NO. 92-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

to the evaluation were discussed with SNL personnel. It is recommended that SNL QA Management continue to strengthen and improve the process as deemed necessary. Implementation satisfactory.

Although, SNL has made significant strides in improving documentation related to the corrective action process, future audits and surveillances of SNL should include evaluations to assure continued effective implementation of the corrective action process.

Based on the above evaluation, this CAR is considered closed.

  
R.L. Maudlin

09/17/95  
Date

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8 CAR NO YH-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

revisions to the identified contracts. These amendments were verified. No further remedial actions required.

- ⑥ **CAR 94-25** To address the numerous shortcomings in the content of, processing of, response to, follow-up of, and close-out of this CAR, another CAR (95-06) has been initiated. The new CAR includes the adverse conditions documented on CAR 94-25, plus additional, related adverse conditions that have been identified since CAR 94-25 was initiated (e.g., failure to apply remedial actions to all noncompliance cases, ineffectiveness of corrective actions, sign-off for closure of the CAR without verifying all actions as complete, etc.). This will cause the initial adverse conditions, as well as the additional conditions, to be resolved in a comprehensive, integrated, and adequate manner.

B. Extent of the Deficiency:

All SNL YMP CARs for FY94 have been reviewed for evidence of the deficiencies cited in Block 6, above. The matrix for the review is attached. An analysis of that review has revealed the following information with regard to the four items as cited in Block 6.

- ⑦ **Item #1:** *"determination of significance not given"* There were no further occurrences of the deficiency in CAR's 94-01 to 94-76. There is no further action required.
- ⑧ **Item #2:** *"remedial actions did not include a determination of impact on previously completed work and an investigation into the extent of the adverse condition"* The review showed there were 34 cases of statements that were unclear or not explicit, of statements that were misplaced on the form, or of actions that made the statements not applicable. Each of those cases were reviewed a second time to determine if the deficiency warranted further investigative action. In all of those cases, the issue had been addressed in another manner, by later investigative actions related to another CAR or because the evidenced CAR had been generated as a result of a comprehensive screening of a previous CAR. CAR's 94-67 to 94-76 all showed that the impact and extent statements were included in the remedial action response. This is due an increased awareness on the part of the QA staff. In addition, the review revealed one case, CAR 94-21, where there was no impact or extent statement and the statement was not covered by any later action. For this case, impact and extent will be determined by screening of procurement documentation for appropriate proposal evaluation planning and execution. A new SNL CAR will be written if other occurrences are discovered.
- ⑨ **Item #3:** *"verifications..do not detail specific objective evidence"* The review revealed that there were 11 cases of evidence not detailed, no statement of effectiveness, or

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<sup>B</sup> CAR NO YM-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

AMENDED RESPONSE

1. Corrective Action Response for CAR YM-94-087

A. Remedial Actions

- ① **CAR 93-23** The extent and impact of the deficiency were not documented in the remedial action statement. However, examination of the situation showed that all QAGRs were effected, but there was no impact because, regardless of the out-of-date status of the QAGR's, the personnel involved were actually working to the current procedures. The remedial action statement in CAR 93-23 has been revised to include an impact and extent statement and resubmitted to the LRC. Copy is attached.
- ② **CAR 93-32** The extent and impact of the deficiency were documented in the investigation done by Jim Voigt, page 5 of the CAR. The Objective Evidence has been corrected on the CAR and has been resubmitted to the LRC. Copy is attached. The verification was completed at the time of the CAR.
- ③ **CAR 93-36** The significance has been documented and submitted to the LRC. Copy is attached. The extent of the deficiency was implied under "Actions to Prevent Recurrence". The responsible person stated that once remedial actions had taken place, "all files will be photocopied and dual storage maintained." The impact of the deficiency was indeterminate. The objective evidence was cited at the bottom of the CAR. The verification was based on the acceptance of a completed ITC surveillance and a completed and closed ITC CAR. ITC, at the time of the deviation and subsequent corrective action, had their own QA program, including an independent verification function. The contract then expired, precluding the possibility of a verification visit to the contractor. SNL QA accepted the documented evidence under those conditions. No further verification action is required or feasible.
- ④ **CAR 93-38** The remedial action involved moving all samples and reviewing the activities in the core library. The responsible person described his evaluation of impact in his response and stated "sample integrity has not been compromised." This illustrates that impact and extent were addressed through those actions. The objective evidence was a statement of results of QA verification (examination of the storage area) documented on the CAR form. No remedial actions are required.
- ⑤ **CAR 94-11 & 94-12** These CARs were written to track the corrective actions which resulted from a comprehensive screening done for CAR YM-93-97 to determine extent and impact. The remedial action while not stating the impact and extent are addressed under "Actions to Prevent Recurrence". The objective evidence was stated as the

12/5/94

LTR. SHEPARD TO SPENCE

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8 CAR NO YM-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

objective evidence not apparent. Each case was reviewed a second time to determine if the deficiency warranted further verification. One case, CAR 94-08 required further actions on the part of SNL YMP QA. CAR 94-08 needed an additional statement to void an action listed in 12.3 (a). CAR 94-08 has been corrected to include required detail.

- ⑩ Item #4: "CARs were closed without verification" The review revealed that there were 11 cases of CARs closed without a complete verification. Each case was reviewed a second time to determine if the deficiency warranted further verification. In all cases but one, the verification had not been completed with relation to "Actions to Preclude Recurrence", showing a consistent problem in that area. That is, responses were accepted by SNL QA that were stated in such a manner there was not a specific point in time for verification, or the action was too broad to verify. In the other case, CAR 94-13 was missing statement of verification of training on Eaton. This was verified and the CAR was closed.

As a result of the comprehensive review, it was decided that, while there were multiple examples of the items cited Block 6, in most cases, when an in depth review was done of the CAR, the Corrective Action had been completed. The instances that required further documentation were quickly resolved. Based on this in depth review, it was not evident that a similar investigation of FY93 CAR's is warranted. Additionally, we are concerned with identifying and correcting problems in deviation-reporting/corrective-action-processing that currently exist. FY94 CARs provide a large enough sample to do so without highlighting problems that may have existed 1 1/2 to 2 years ago but that have not existed more recently or presently.

C. Root Cause Determination:

The two reviews of all of FY 94 CARs have revealed the following:

Personnel responsible for preparing responses to CARs were not enabled to prepare those responses with thorough, appropriate, and comprehensive content because they have not received sufficient guidance from SNL QA Staff in order to allow them to prepare responses containing adequate and verifiable content. Instructions for completing CARs were not always enclosed with the CAR when delivered, and the instructions that were provided were not entirely clear.

There was not a consistent "quality control" mechanism in place for the review of the CAR for adequacy of the response or during verification for closure to assure that all actions were verified and that a consistent level of documentation was obtained as objective evidence.

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WASHINGTON, D.C.

8 CAR NO YM-94-087  
PAGE \_\_\_\_\_ OF \_\_\_\_\_  
QA

CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

D. Actions to Preclude Recurrence:

11

To address the root cause concerning preparation of adequate CAR responses, an improved set of instructions focused on the content of CAR responses will be developed, for distribution with newly-initiated CARs. (The objective evidence for completion of this action will consist of a copy of the new instructions.)

To address the root cause concerning less-than-effective CAR-response review and verification actions by QA staff, a "CAR Checklist for QA" will be developed, and its use will be required for SNL YMP QA staff.

2. Responsible Individuals and Anticipated Completion Dates:

Remedial actions are all complete.

Investigation to determine extent of deficiency - These actions have all been completed except for the investigation of extent and impact for the situation exemplified by CAR 94-21, as specified in B, Item#2, above: Responsible Person: D. Hawkinson.  
Anticipated Completion Date: 01/27/95.

Actions to preclude recurrence - Responsible Person: R. R. Richards. Anticipated completion date: 01/20/95

 12/2/94  
L. E. Shephard