

MANAGEMENT PROCEDURES MANUAL

CHAPTER 16 - CORRECTIVE ACTION

SECTION 1 - CONTROL OF CORRECTIVE ACTION REPORTS

1. PURPOSE. To establish a system for identifying, determining the cause, and providing corrective action for significant or recurring conditions adverse to quality, or potentially adverse to quality, that include but are not limited to a breakdown of the USGS QA Program and repetitive nonconformances.
2. SCOPE OF COMPLIANCE. This procedure is applicable to all USGS personnel and USGS contractors involved in Yucca Mountain Project (YMP) activities that affect quality.
3. DEFINITIONS.
 - 3.1 Condition Adverse to Quality: An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability.
 - 3.2 Corrective Action: Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude repetition.
4. RESPONSIBILITIES.
 - 4.1 USGS personnel and USGS contractor personnel assigned to a QA Level I or II project or task are responsible for identifying any significant or recurring discrepancies which need correction and filing a Corrective Action Report (CAR), when necessary. USGS personnel and USGS contractor personnel are also responsible for implementing assigned corrective actions.
 - 4.2 The Chief, Branch of YMP, or delegate is responsible for assigning corrective action responsibility to USGS and USGS contractor personnel if the action involves technical activities. He is also a permanent member of the Corrective Action Review Board.
 - 4.3 The Quality Assurance Manager or delegate is responsible for assigning corrective action responsibility to QA and Records personnel if the action involves QA or Records matters, determines whether a Corrective Action Review Board action is needed, and is responsible for corrective action verification.
 - 4.4 A Corrective Action Review Board consisting of two permanent members and additional members appointed as necessary, shall either approve the proposed corrective action or provide an alternative corrective action

statement. The two permanent members of the Board are the Chief, Branch of YMP and the QA Manager or their delegates. The appointed members are added to the Board as needed by the permanent members for their technical assistance or expertise.

5. PROCEDURE. For significant conditions adverse to quality, or potentially adverse to quality, the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate and upper levels of management for review and assessment.

5.1 Implementation of a Corrective Action Report:

5.1.1 Any USGS personnel or USGS contractor personnel that observe a condition adverse to quality, or potentially adverse to quality, are responsible for initiating a Corrective Action Report (CAR) (Attachment 1).

5.1.1.1 The initiator shall complete parts 1 through 5 of the CAR, including assignment of a CAR number.

5.1.1.2 All CARs are assigned a unique number in the following format: YMP-USGS-CAR-XX-YY, where the 'X's are the fiscal year and the 'Y's are a sequential number starting with 01. CAR numbers are assigned by the USGS QA Office where the numbers are tracked in the USGS CAR Status Log (Attachment 2).

5.1.2 The CAR shall then be sent the QA Office for review and approval (part 6) and entry into the USGS CAR Status Log (Attachment 2).

5.1.3 The CAR shall then be forwarded to the responsible PI or delegate who is to provide a proposed corrective action (part 7) or a plan describing future actions to resolve the CAR, and signs and dates the report (part 8).

5.1.4 The CAR shall then be sent to the QA Manager for review of the proposed corrective action.

5.1.4.1 The QA Manager shall review the CAR and decide, based on direct influence of all Level I and II activities, recurrences, etc., if Corrective Action Review Board action is necessary.

5.1.4.2 If Corrective Action Review Board review is required the Board shall either approve the proposed corrective action or provide an alternative corrective action statement (part 9). Board approval is documented by signing and dating the CAR (part 10).

5.1.4.3 If the QA Manager determines that Corrective Action Review Board action is not necessary, the CAR shall be approved and dated by the QA Manager (part 10). The remaining Corrective Action Review Board blocks shall be marked N/A.

5.1.5 The CAR shall be distributed by the QA Office to the Corrective Action Implementor, the Chief, Branch of YMP, the YMPO and SAIC/T&MSS, and the responsible Branch Chief.

5.1.6 The designated Corrective Action Implementor, upon receipt of the CAR, shall ensure the QA Manager's signature appears in part 10 prior to implementing the corrective action. The organization/individual responsible for implementing the corrective action shall assure that the corrective action is completed in a timely manner.

5.1.7 After the corrective action has been completed, the CAR shall be signed and dated by the Corrective Action Implementor (part 11).

5.1.8 The CAR shall be returned to the QA Office for verification of corrective action and closure of the CAR.

5.1.8.1 Verification of the corrective action shall be accomplished by audit, surveillance, or management review of the affected activity.

5.1.8.2 Should verification of corrective action prove unsatisfactory, it shall be so noted on the original CAR and a new CAR shall be generated to describe the continued unacceptable condition. The new CAR shall have the same number as the superseded CAR but with the next higher revision number and shall be processed in the same manner as the superseded CAR.

5.1.9 The QA Manager shall review the CAR for completeness and effectiveness of corrective action, sign and date the report (part 13), and be responsible for distribution, logging and filing of the report with the USGS Records Processing Center in accordance with YMP-USGS-QMP-17.01.

5.1.10 The closed CAR shall be distributed by the USGS QA Office to the Chief, Branch of YMP, the YMPO and SAIC/T&MSS, and the responsible Branch Chief.

5.2 Revision of a CAR:

5.2.1 If revision to a CAR is necessary at any time during the process, a new CAR shall be initiated and marked with the appropriate revision number. The revised CAR shall be processed as was the original. The QA Office shall keep an historical file of all revisions.

5.3 CAR Status Log:

5.3.1 The QA Office shall assign CAR numbers in sequential order in the following format: YMP-USGS-CAR-XX-YY, where the 'X's are the fiscal year and the 'Y's are a sequential number starting with 01.

5.3.2 The CAR numbers shall be entered into the USGS CAR Status Log (Attachment 2).

5.3.3 The USGS CAR Status Log shall show the following as a minimum:

- o The CAR number
- o A brief description of the deficient condition
- o The person or organization responsible for determining and carrying out the corrective action
- o The status of each CAR
- o The date the CAR was closed

5.3.4 The CAR shall also be entered into the QA Tracking System in accordance with YMP-USGS-QMP-16.03, "Trending", for the purpose of monitoring trends.

5.3.5 When repetitive or recurring corrective actions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition of existing CARs (QMP-16.03).

6. RECORDS MANAGEMENT.

6.1 Controlled Documents: None.

6.2 Records Center Documents: Completed Corrective Action Report forms, CAR Status Log pages for closed CARs, and all transmittal memos and letters concerning CARs shall be submitted to the Records Center in accordance with YMP-USGS-QMP-17.01.

7. RELATED DOCUMENTS.

7.1 Superseded Documents: This QMP supersedes NNWSI-USGS-QMP-16.01, R1, Control for Corrective Action Procedure.

7.2 References Cited:

YMP-USGS-QAPP-01, QA Program Plan

YMP-USGS-QMP-16.03, Trend Analysis

YMP-USGS-QMP-17.01, Records Management

8. ATTACHMENTS.

Attachment 1: Corrective Action Report Form

Attachment 2: USGS CAR Status Log

9. APPROVALS AND EFFECTIVE DATE.

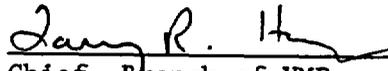
EFFECTIVE DATE: Upon approval.



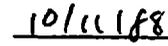
YMP-USGS Quality Assurance Manager



Date



Chief, Branch of YMP



Date

CORRECTIVE ACTION REPORT

IDENTIFICATION OF CORRECTIVE NEED

Source: 1. NCR #: _____ 2. Audit #: _____ 3. Other: _____

4. Description _____

5. _____
Originator Date 6. _____
QA Approval Date

CORRECTIVE ACTION

7. Proposed corrective action: _____

8. _____
Principal Investigator Date

9. Corrective action statement: _____

10. Review Board Approval:

Project Coordinator Date QA Manager Date Other Date

Implementation: 11. _____
Completed Date

VERIFICATION OF CORRECTIVE ACTION

12. _____
Verification-QA Approval Date 13. _____
Final QA Approval Date

14. Comments: _____

15. Distribution: DOE/YMPO Chief, Branch of NNWSI
SAIC/T&MSS USGS QA Office

CORRECTIVE ACTION REPORT

Instructions for Completion

- 1a. CAR #
 1. NCR number(s) which require corrective action, if applicable.
 2. Audit number(s) which require corrective action, if applicable.
 3. Other reason for corrective action.
 4. Description and cause of the item or event requiring corrective action.
 5. Signature of Originator and date the CAR was originated.
 6. Signature and date of Quality Assurance approval of the CAR.
 7. Proposed corrective action, to be inserted by the Principle Investigator.
 8. Signature and date by the PI before forwarding for determination of need of Corrective Action Review Board action.
 9. Corrective Action Statement may be provided by Corrective Action Review Board.
 10. Signature and date of Corrective Action Review Board approval.
 11. Signature and date of completion of implementation.
 12. Signature and date of QA verification that corrective action was accomplished.
 13. Signature and date of QA Manager denoting final approval of the CAR.
 14. Comments.
 15. Distribution.

USGS CAR STATUS LOG

CAR #	DATE INITIATED	DESCRIPTION OF CAR	RESPONSIBLE PERSON/ ORGANIZATION	DISPOSITION ACTIONS AND DUE DATES	CLOSED DATE