

UNCONTROLLED COPY



OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

CORRECTIVE ACTION

Procedure No.:

QAAP 16.1

Revision:

4

Date:

11/12/91

Page

1 of 20

Concurrence

Date:

10/25/91

Approval

Date:

10/29/91

1.0 PURPOSE

This procedure establishes the responsibilities and methods to ensure that conditions adverse to quality are promptly identified and corrected.

2.0 SCOPE

This procedure applies to conditions adverse to quality identified in activities subject to quality assurance (QA) program controls. Item related conditions adverse to quality are identified and controlled in accordance with QMP-15-01, *Control of Nonconformances*. However, repetitive or significant item related conditions adverse to quality shall also be processed in accordance with this procedure.

This procedure shall be used by the Office of Civilian Radioactive Waste Management (OCRWM) and direct-support contractor personnel for identifying, evaluating and correcting conditions adverse to quality.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document (QARD)*, DOE/RW-0214

3.1.2 *Quality Assurance Program Description Document (QAPD)*, DOE/RW-0215

3.1.3 QAAP 16.2, *Stop Work*

3.1.4 QAAP 2.9, *Quality Assurance Program Trend Evaluation and Reporting*

3.2 DEFINITIONS

3.2.1 Conditions Adverse to Quality - An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items and nonconformances.



- 3.2.2 Quality Assurance Representative - An individual representing the OCRWM Office of Quality Assurance.
- 3.2.3 Responsible Manager - The OCRWM Division, Associate, or Office Director, or the Civilian Radioactive Waste Management (CRWM) Technical Project Officer or Project Manager having functional responsibility for the item or activity that is the subject of a Corrective Action Request.
- 3.2.4 Root Cause - The basic cause for a specific condition adverse to quality which, if corrected, will preclude recurrence of the same or similar significant condition adverse to quality.
- 3.2.5 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for preparing and maintaining this procedure.

4.2 RESPONSIBLE MANAGER

The Responsible Manager is responsible for:

- 4.2.1 Controlling activities and/or the use of items identified as having conditions adverse to quality until resolution is reached;
- 4.2.2 Taking immediate action to correct conditions adverse to quality where threat of degradation or irretrievable loss to the PROGRAM exists;
- 4.2.3 Taking remedial action to correct identified conditions adverse to quality;
- 4.2.4 Investigating significant conditions adverse to quality to determine the overall extent of the problem and root cause; and
- 4.2.5 Implementing measures to preclude recurrence of significant conditions adverse to quality.

4.3 OCRWM PERSONNEL

OCRWM personnel (including direct-support contractor personnel) are responsible for:



- 4.3.1 Identifying and reporting conditions adverse to quality observed in the conduct of PROGRAM activities or in the characteristics of PROGRAM products;
- 4.3.2 Initiating a Corrective Action Request (CAR) as necessary; and
- 4.3.3 Providing support in resolving conditions adverse to quality.

4.4 DIVISION DIRECTORS, OFFICE OF QUALITY ASSURANCE

The Headquarters Quality Assurance Division Director (HQ QADD) and the Yucca Mountain Quality Assurance Division Director (YM QADD) are responsible for:

- 4.4.1 The overall implementation of this procedure;
- 4.4.2 Reviewing and approving the issuance and closure of CARs; and
- 4.4.3 Ensuring that the Director, OQA is copied on the issuance and closure of all CARs pertaining to OQA and any CARs identifying significant conditions adverse to quality.

4.5 QUALITY ASSURANCE REPRESENTATIVE (QAR)

The QAR is responsible for:

- 4.5.1 Reviewing CARs to determine if the condition is a significant condition adverse to quality;
- 4.5.2 Reviewing CARs to determine if the CAR identifies a stop work condition;
- 4.5.3 Establishing response due dates and recommending the CAR for issuance;
- 4.5.4 Reviewing and accepting the response and verifying and documenting implementation of corrective actions; and
- 4.5.5 Forwarding copies of correspondence related to CARs to the CAR Coordinator.

4.6 CAR COORDINATOR

The CAR Coordinator is responsible for:

- 4.6.1 Assigning unique CAR numbers;
- 4.6.2 Maintaining working files for open CARs;
- 4.6.3 Maintaining and logging correspondence on the CAR Summary Sheet;



- 4.6.4 Tracking the status of CARs;
- 4.6.5 Entering closed CARs into the QA Records System; and
- 4.6.6 Issuing periodic status reports of open CARs.

5.0 GENERAL

5.1 VALIDITY OF CARs

CARs shall be evaluated to determine validity. A CAR is considered valid if it identifies a condition adverse to quality based upon the following criteria:

- a) Activities affecting quality are being performed without appropriate QA Program controls.
- b) Activities affecting quality are not in compliance with an existing QA program-implementing document requirement.
- c) A nonconforming condition exists that has the potential to impact multiple items or related activities.

5.2 LOGGING AND NUMBERING OF CARs

A CAR log (which may be a computerized data base) is maintained by the CAR Coordinator for tracking the progress and status of CARs. The CAR log shall identify, as a minimum, the unique CAR number, the assigned QAR, the organization responsible for responding to the CAR, the dates of issuance, response and closure, whether the CAR identifies a significant condition adverse to quality, and whether a stop work condition was identified. CAR numbers will be assigned as follows:

XX-YY-NNN, where:

- XX = Acronym for the QA Division issuing the CAR (i.e., HQ-Headquarters, YM-Yucca Mountain).
- YY = the last two digits of the fiscal year that the CAR is initiated.
- NNN = the next sequential number, beginning with "001" for each fiscal year.

5.3 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

CARs shall be evaluated in accordance with the following criteria to determine if the identified condition is a significant condition adverse to quality:



- a) A condition determined to be repetitive in nature relative to the condition being evaluated.
- b) A condition indicating a QA Program breakdown, for example:
 - o A deficiency in the production of the waste form or damage to the waste form that degrades the waste form's ability to perform its intended function.
 - o A deficiency in the high-level nuclear waste transportation process or transport casks that would seriously impact its intended function of assuring public health and safety.
 - o A deficiency in design as approved for fabrication or construction such that the design deviates extensively from design criteria and basis.
 - o A deficiency in the fabrication or construction of or significant damage to barriers, structures, systems or components that requires extensive evaluation, redesign, or repair in order to establish the adequacy of the barrier, structure, system, or component to perform its intended function of assuring public health and safety.
 - o A deviation from performance specifications that will require extensive evaluation, redesign or repair to establish the adequacy of a structure, system, or component to perform its intended function.
 - o An error in a computer program used to support activities affecting quality after it has been released for use.
 - o Loss of essential data required for activities affecting quality.
- c) A condition that, were it to remain uncorrected, could have an adverse impact on waste form production, high-level nuclear waste transport, safety or waste isolation.

5.4 DETERMINATION OF STOP WORK CONDITIONS

CARs that identify significant conditions adverse to quality shall be evaluated to determine whether a stop work condition exists in accordance with the following criteria:

- a) Repetitive deficiencies affecting items or activities important to radiological safety, storage, transport, or disposal of high-level nuclear waste when previous corrective actions have not precluded recurrences.



- b) Significant deficiencies that could affect activities important to radiological safety aspects of storage, transport, or disposal of high-level nuclear waste.
- c) Activities affecting quality are being performed without approved procedures or by unqualified personnel.
- d) Other significant conditions determined by the Director, OQA to have major impacts on the overall QA Program or quality of items and related activities.

5.5 TREND EVALUATION AND REPORTING

Conditions reported by CARs are subject to trend evaluation in accordance with QAAP 2.9, *Quality Assurance Program Trend Evaluation and Reporting*.

5.6 DISPUTE RESOLUTION

Disputes that arise during the implementation of this procedure shall be directed to the attention of appropriate management for resolution and, if not resolved, elevated to progressively higher levels of management including, if necessary, the Director, OCRWM.

6.0 PROCEDURE

6.1 INITIATION AND ISSUANCE

- 6.1.1 Upon discovering a potential condition adverse to quality, OCRWM personnel shall initiate a CAR by completing the initiator actions in accordance with Attachment I.
- 6.1.2 The initiator shall forward the CAR to the YM QADD or HQ QADD, as applicable. The QADD shall evaluate the CAR for the validity of the identified condition, based upon the criteria in Subsection 5.1.
 - 6.1.2.1 If the CAR is determined to be valid, the QADD shall assign a QAR and forward the CAR to the CAR Coordinator for processing in accordance with Paragraph 6.1.3.
 - 6.1.2.2 If the CAR is determined to be invalid, then the QADD shall document the justification and return the CAR to the initiator for concurrence. If the initiator does not agree that the CAR is invalid, the matter shall be elevated to the Director, OQA for resolution. No further action is required if all parties agree that the CAR is not valid.



- 6.1.3 The CAR Coordinator shall assign a unique CAR number and enter the CAR in a log in accordance with Subsection 5.2.
- 6.1.4 After the CAR number is assigned and logged, the CAR Coordinator shall forward the original CAR to the assigned QAR for processing. The QAR completes the required actions as identified in Attachment I and as detailed below.
- 6.1.5 The QAR shall determine if the condition is a significant condition adverse to quality, based upon the criteria in Subsection 5.3.
- 6.1.5.1 If it is determined that the CAR does not represent a significant condition adverse to quality, the QAR continues processing the CAR in accordance with Paragraph 6.1.7.
- 6.1.5.2 If it is determined that the CAR does represent a significant condition adverse to quality, the QAR continues processing the CAR in accordance with Paragraph 6.1.6.
- 6.1.6 The QAR shall determine whether a stop work condition exists based on the criteria in Subsection 5.4 for a CAR that identifies a significant condition adverse to quality.
- 6.1.6.1 If it is determined that a stop work condition does exist, then the QAR shall:
- a) immediately provide verbal notification to the Director, OQA that a stop work condition has been identified;
 - b) initiate a Stop Work Order in accordance with QAAP 16.2, *Stop Work*; and
 - c) continue processing the CAR in accordance with Paragraph 6.1.7.
- 6.1.6.2 If it is determined that a stop work condition does not exist, the QAR then continues processing the CAR in accordance with Paragraph 6.1.7.
- 6.1.7 The QAR shall determine the types of corrective action required for resolution of the condition adverse to quality and indicate these actions on the CAR. For all CARs, action required shall include, as a minimum, remedial action to correct the identified condition. In addition, for significant conditions adverse to quality, required actions shall include investigative action to determine extent, investigative action to determine root cause,



and corrective action to preclude recurrence. The QAR may also indicate any additional recommended actions on the CAR.

- 6.1.8 The QAR shall identify the response due date and forward the CAR to the QADD for approval.
- 6.1.9 When the CAR is ready for approval, the QADD shall sign and date the CAR, then forward a copy of the CAR to the Responsible Manager by memorandum or letter.
- 6.1.10 The original of the CAR form and a copy of the transmittal letter or memo are forwarded to the CAR Coordinator. Throughout the remaining processing of the CAR, the QADD and the QAR shall ensure that the CAR Coordinator is notified of all CAR status changes and is provided copies of all correspondence relative to the CAR.
- 6.1.11 The CAR Coordinator shall maintain the original CAR and copies of transmittal memorandums or letters. The CAR Coordinator shall update the log as changes occur and record all relevant correspondence on the CAR Summary Sheet (Attachment II).
- 6.1.12 The QADD shall ensure that copies of the CAR and the transmittal letter or memo are forwarded to the Director, OQA for all CARs issued to a Responsible Manager within the areas of responsibility of OQA.
- 6.1.13 If the CAR identifies a significant condition adverse to quality, the QADD shall ensure that copies of the CAR and the transmittal letter or memo are forwarded to the Director, OQA. In addition, if the Responsible Manager to whom the CAR is issued is not an OCRWM Associate or Office Director, copies of the CAR and the transmittal letter or memo shall be forwarded to the OCRWM Associate or Office Director having line responsibility for the activities of the Responsible Manager.

6.2 CORRECTIVE ACTION RESPONSE

- 6.2.1 The Responsible Manager shall determine the corrective actions required and develop a corrective action response. The format for documenting CAR responses is shown in Attachment III. The Responsible Manager shall sign and date the response to indicate approval. The response shall be submitted to the applicable QADD. Guidelines for root cause determination are presented in Attachment IV.
- 6.2.2 If the requested response due date cannot be met, the Responsible Manager shall submit a written request for extension to the applicable QADD prior to the due date. The request for extension shall include appropriate justification for the delay.



6.2.3 Upon receipt of a request for extension of the response due date, the QADD shall evaluate the extension request and issue a letter or memorandum notifying the Responsible Manager of the approval or disapproval of the request.

6.3 RESPONSE EVALUATION

6.3.1 Upon receipt of a CAR response, the QAR shall evaluate the response to ensure that it addresses the required elements and that the proposed actions will sufficiently resolve the adverse condition.

6.3.1.1 If the response is acceptable, then the QAR indicates acceptance by signing and dating the original CAR form. The CAR is then forwarded to the applicable QADD for approval and subsequent issuance of a letter or memorandum notifying the Responsible Manager of response acceptance.

6.3.1.2 If the response is unacceptable, the QADD shall issue a letter or memorandum requesting an amended response to the Responsible Manager. This request shall include specific identification of portions of the response determined unacceptable and reasons or justification for the determination.

6.3.2 The Responsible Manager shall notify OQA if a previously submitted CAR response needs to be changed and submit an amended response in accordance with Paragraph 6.2.1.

6.3.3 Amended responses to CARs shall be reviewed and processed in accordance with this subsection.

6.4 VERIFICATION OF CORRECTIVE ACTION

6.4.1 Upon completion of the required corrective actions, the QAR shall verify that the accepted actions identified in the response have been satisfactorily implemented. The QAR shall document the verification on a CAR Continuation Sheet (Attachment I) identifying the objective evidence reviewed.

6.4.1.1 If the implementation is found to be complete and acceptable, the QAR shall sign the CAR indicating satisfactory verification and forward the CAR to the QADD for closure in accordance with Subsection 6.5.

6.4.1.2 If the implementation is found incomplete, unacceptable, or cannot be verified, then the QAR shall initiate a letter or memorandum delineating specific details of the corrective actions found to be satisfactory and unsatisfactory, providing



recommendations for corrections for those portions found unsatisfactory, and requesting an amended response. The letter or memorandum shall be signed by the QADD and issued to the Responsible Manager.

- 6.4.2 Amended responses submitted as a result of unsatisfactory verification shall be processed in accordance with Subsection 6.3.

6.5 CAR CLOSURE

6.5.1 When the CAR is ready for closure, the QADD shall sign and date the CAR and issue a letter or memorandum notifying the Responsible Manager that the CAR is closed.

6.5.2 The CAR Coordinator shall update the CAR log and process the completed CAR package for submittal to the QRC or LRC, as described in Section 7.0.

6.6 CHANGING CARs

6.6.1 The QAR shall document changes required to a previously issued CAR on a CAR Continuation Sheet providing justification for the changes.

6.6.2 Changes that indicate an increase in the scope of the previously reported condition shall be reevaluated in accordance with Subsection 6.1.

6.6.3 If extensive changes warrant superseding a previously issued CAR with a new CAR, the superseded CAR shall be voided in accordance with Subsection 6.7.

6.7 VOIDING CARs

6.7.1 When it is determined that an issued CAR is potentially invalid, the QADD shall discuss the condition with the initiator and the assigned QAR.

6.7.2 If it is agreed that the CAR is invalid, the QADD shall ensure that the complete justification is documented with signatures and dates of those involved in the decision and close the CAR in accordance with Subsection 6.5.

6.7.3 If all individuals involved do not agree that the CAR is invalid, the matter shall be elevated to the Director, OQA for resolution.



6.8 **STATUS**

- 6.8.1 The CAR Coordinator shall provide periodic status reports to the Director, OQA and the applicable QA Division Director. The reports shall provide a status of open CARs issued by the Division.
- 6.8.2 The CAR Coordinator shall periodically review the CAR Log and identify those CARs that have not been responded to by the response due date. The QAR shall be notified for resolution.
- 6.8.3 Should violation of established due dates persist or if unsatisfactory responses continue, the QADD shall direct the matter to the attention of appropriate management as described in Subsection 5.6.

7.0 **RECORDS**

Record files for open CARs shall be maintained by the CAR Coordinator. Closed CARs shall be assembled by the CAR Coordinator and processed in accordance with QAAP 17.1, *QA Records Management* or QMP-17-01, *Records Management: Record Source Implementation*. Completed CARs and CAR continuation sheets (including CARs voided after issuance), CAR Responses, CAR Summary Sheets, and relevant correspondence listed on CAR Summary Sheets are considered QA Records. QA Records required as a result of implementing QAAP 16.2, *Stop Work*, shall be filed in the Quality Records Package for the associated CAR.

8.0 **ATTACHMENTS**

- 8.1 Attachment I - Corrective Action Request
- 8.2 Attachment II - CAR Summary Sheet
- 8.3 Attachment III - Format for Corrective Action Response
- 8.4 Attachment IV - Guidelines for Root Cause Determination
- 8.5 Attachment V - QAAP 16.1 Flowchart



ATTACHMENT I (Continued)

Instructions for Completing Corrective Action Requests

Initiator

1. Enter the document and revision which has been violated.
2. Enter the number of the report that resulted in identifying the adverse condition (e.g., Audit Report Number, Surveillance Report Number, Nonconformance Report Number, Quality Concerns Identification Number). Enter N/A if there is not a related report.
3. Enter the organization responsible for the adverse condition (e.g., RW-40).
4. Enter the name of the individual(s) with whom the adverse condition was discussed.
5. State the requirement in narrative, concise form including specific reference (paragraph/section number) to the controlling document.
6. Describe the adverse condition found, in concise narrative form including references to examples discovered. (Use and refer to continuation sheet, if needed).
7. Sign and date the CAR.

CAR Coordinator

8. Enter the CAR number and the date the number is assigned.

QAR

9. Check "Yes" or "No" as applicable indicating whether the condition is a significant condition adverse to quality. Circle A, B, or C identifying the applicable criterion of Subsection 5.3.
10. Check "Yes" or "No" as applicable indicating whether a stop work condition exists. Circle A, B, C, or D identifying the applicable criterion of Subsection 5.4. Attach a copy of any Stop Work Order issued.
11. Enter the response due date.
12. Check the applicable blocks based upon the following:
Condition Adverse to Quality - at a minimum, remedial action is required
Significant Condition Adverse to Quality - all four actions are required
13. (Optional) Provide a recommended action that would be acceptable.
- 15, 17, and 19 Sign and date the CAR when and if applicable.

QADD

- 14, 16, 18, and 20 Sign and date the CAR when and if applicable



ATTACHMENT I (continued)

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

CAR NO. _____
DATE: _____
PAGE: _____ OF _____
QA

CORRECTIVE ACTION REQUEST (Continuation Page)

REV. 08/91



ATTACHMENT II (Example)

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

CAR NO. _____
DATE: _____
PAGE: _____ OF _____
QA

CAR SUMMARY SHEET

	<u>Date</u>	<u>Letter Reference</u>
<u>Issuance Letter/Memo</u>	_____	_____
<u>Response Extension Request</u>	_____	_____
Acceptance	_____	_____
<u>Response Received</u>	_____	_____
Acceptance	_____	_____
<u>Request Amended Response</u>	_____	_____
Response	_____	_____
Acceptance	_____	_____
<u>Request Amended Response</u>	_____	_____
Response	_____	_____
Acceptance	_____	_____
<u>C/A Extension Request</u>	_____	_____
Acceptance	_____	_____
<u>C/A Extension Request</u>	_____	_____
Acceptance	_____	_____
<u>Unsatisfactory Verification</u>	_____	_____
Response	_____	_____
Acceptance	_____	_____
<u>Closure Letter</u>	_____	_____
Other _____	_____	_____
_____	_____	_____
_____	_____	_____

REV. 08/91



ATTACHMENT III

Format for Corrective Action Response

The CAR response shall include the following information:

1. Corrective Action Response for CAR # _____
 - A. Remedial Action - Actions taken to correct specific deficiencies noted.
(Required for all CARs)
 - B. Investigative Action - Actions taken to determine the extent of the condition.
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
 - C. Root Cause Determination - Identification of the root cause of the condition.
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
 - D. Corrective Action to Preclude Recurrence - Actions taken to address the root cause and preclude recurrence of the condition.
(Required for all significant conditions adverse to quality or any Condition Adverse to Quality if requested by OQA)
2. For each action above, identify the name of the individual assigned responsibility for completion and the anticipated (or actual, if complete) completion date.
3. Response Approved: _____ Date: _____
Responsible Manager



ATTACHMENT IV

Guidelines for Root Cause Determination

GUIDELINES

When it is established that an investigation to determine root cause is required, the guidelines consist of the following steps:

- 1) Define the specific condition. Pertinent questions must be asked and answered as accurately as possible.
 - a) What happened?
 - b) Where did the condition occur?
 - c) When did the condition occur?
 - d) What was the extent of the condition?
 - e) Who was involved?
 - f) How did it happen?
 - g) Why did it happen?
- 2) Obtain information which is related to the identified condition using the listed methods.
 - a) Investigation of the specific condition adverse to quality.
 - b) Personnel interviews
 - c) Review of pertinent documents
 - d) Use of quality tools (cause & effect diagrams, comparative analysis, etc.)
 - e) Collection of data

There are ten apparent cause categories; each of these apparent causes require questions to be answered in arriving at cause determination. The following is a checklist of the ten categories:

- a) Procedures
 - b) Personnel
 - c) Management system
 - d) Immediate supervision
 - e) Training
 - f) Communications
 - g) Scientific investigation/design
 - h) Human factors
 - i) Unexpected failure
 - j) Reliability system
- 3) Develop a list of potential causes using the above methods.
 - 4) Continue to keep asking the "Why" question. When there is confidence that the answer to "Why" will preclude recurrence, the root cause has been determined.
 - 5) Confirm the accuracy of your conclusions:
 - a) Review the cause against facts, opinions, and time sequence.
 - b) Ask "How would this apply to similar conditions?".
 - c) Obtain more information to test the root cause, if necessary.



ATTACHMENT IV
(continued)

EXAMPLE QUESTIONS

The following is a checklist of the ten categories and related questions:

1. Procedures

- a) Was the procedure not used?
- b) Was there an error in following procedure?
- c) Was the procedure wrong or inadequate?

2. Personnel

- a) Was there lack of attention given to a task?
- b) Was there lack of personnel qualification?

3. Management System

- a) Were there standards, policies, and administrative controls in place?
- b) Were audits and evaluations inadequate?
- c) Was there lack of corrective action?

4. Immediate Supervision

- a) Was preparation/planning by supervisor adequate?
- b) Was there no supervision or inadequate supervision?

5. Training

- a) Was there no training?
- b) Were there inadequate training methods?

6. Communications

- a) Was there a verbal misunderstanding?
- b) Was there no communication or was the communication not timely?

7. Scientific Investigation/Design

- a) Do scientific investigation or design documents exist?
- b) Were there no design or technical reviews performed?
- c) Were there no computer software controls in place?

8. Human Factors

- a) Was there proper man-machine interface?
- b) Was the work environment inadequate?
- c) Was the system too complex?
- d) Was there a no fault tolerant system?



ATTACHMENT IV
(continued)

9. Unexpected Failure

- a) Was the failure unforeseen?
- b) Was the risk known and assumed?
- c) Was material or equipment inadequate?
- d) Was the calibration program inadequate?

10. Reliability System

- a) Was there inadequate preventive maintenance?
- b) Was the equipment unreliable?
- c) Was there an error in fabrication?
- d) Was there installation error?



ATTACHMENT V
QAAP 16.1 FLOWCHART

