



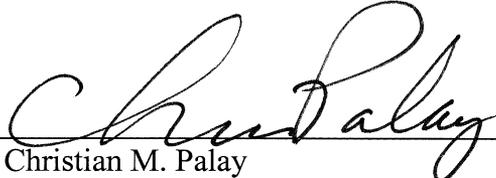
Office of Environmental Management

Administrative Procedure

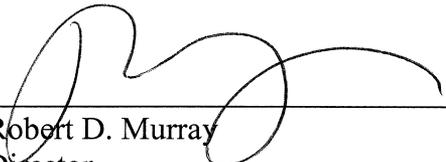
Corrective Action

AP-16.1Q, Revision 2

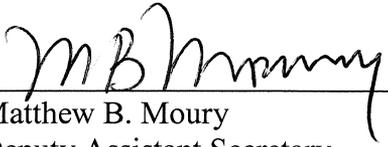
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1.0 PURPOSE

The purpose of this procedure is to establish responsibilities and processes for Conditions Adverse to Quality (CAQs) indentified in activities related to the High-Level Waste (HLW) and Used Nuclear Fuel (UNF) Oversight Program. This procedure also establishes the processes for evaluating and verifying corrective actions plans.

2.0 SCOPE

The scope of this procedure is to identify and process to closure CAQs associated with the HLW and UNF Oversight Program. The Office of Environmental Management (EM) is responsible for developing and fostering an environment in which continuous improvement is a fundamental and integral part of the mission and daily conduct. Management at all levels shall foster a “No Fault” attitude to encourage the identification of conditions adverse to quality.

3.0 APPLICABILITY

This procedure applies to Environmental Management (EM) personnel and contractors that participate in activities associated with the HLW and UNF Oversight Program.

4.0 REQUIREMENTS and REFERENCES

4.1 Requirements

4.1.1 *Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20*

4.1.2 EM-QA-002, *Quality Assurance Program Plan (QAPP)*

4.2 References

4.2.1 AP-2.1Q, *Qualification of Personnel*

5.0 DEFINITIONS

N/A

6.0 RESPONSIBILITIES

- 6.1 Deputy Assistant Secretary (DAS), Safety, Security, and Quality Programs
 - 6.1.1 Responsible for issuance of the Corrective Action Reports (CARs).
 - 6.1.2 Responsible for the approval of the corrective action plan and closure for CARs
- 6.2 Director, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for the preparation, change, and approval of this procedure.
- 6.3 QA Lead for the HLW and UNF Oversight Program
 - 6.3.1 Responsible for assignment of the Quality Assurance Representative (QAR).
 - 6.3.2 Responsible for numbering CARs.
 - 6.3.3 Responsible for receiving and processing CARs and ensuring compliance with this procedure.
 - 6.3.4 Responsible for CAR trending.
- 6.4 QAR
 - 6.4.1 Responsible for recommendation of issuance of CARs
 - 6.4.2 Responsible for the determination of CAR significance.
 - 6.4.3 Responsible for the determination if a Stop Work Order (SWO) is required.
 - 6.4.4 Responsible for evaluating and verifying completion and effective implementation of corrective actions for CARs.
- 6.5 Initiator
 - 6.5.1 Individuals working on HLW or UNF activities responsible for identifying and reporting conditions that could affect quality.
- 6.6 Responsible Manager
 - 6.6.1 Individuals who coordinate the development and completion of corrective action plans for CARs.

6.7 Environmental Management Consolidated Business Center (EMCBC)
Coordinator, Office of Technical Support and Asset Management

6.7.1 Responsible for maintaining QA Records associated with this procedure.

7.0 CORRECTIVE ACTION REPORT (CAR) PROCESS

7.1 This procedure describes the following corrective action process:

Step 1 – Initiation and issuance of a Corrective Action Report – Part I

Step 2 – Response to a Corrective Action Report – Part II

Step 3 – Response Evaluation of a Corrective Action Report – Part III

Step 4 – Verification and Closure of a Corrective Action Report – Part III

Step 5 – Trending

7.2 CAQ and SCAQ are documented and reported to the appropriate level of management responsible for the condition. Phases of the CAR process are documented using the following forms:

<u>CAR Phase</u>	<u>CAR Form Name</u>
Initiation	Form 16.1-1, <i>Corrective Action Report – Part I</i>
Response	Form 16.1-2, <i>Corrective Action Report – Part II</i>
Verification	Form 16.1-3, <i>Corrective Action Report – Part III</i>

8.0 PROCEDURE

8.1 Initiation and issuance of a Corrective Action Report – Part I

- 8.1.1 The Initiator should begin the CAR process as soon as practical once a CAQ is identified and begin documentation of the CAR Part I (Form 16.1-1).
- 8.1.2 The Initiator shall contact the QA Lead to obtain a CAR number using the instruction for Form 16.1-1.
- 8.1.3 The QA Lead shall assign a QAR and a number to the CAR and communicate that information to the initiator to be included on Form 16.1-1.
- 8.1.4 The QAR shall be qualified as an auditor per AP-2.1Q, *Qualification of Personnel*.
- 8.1.5 The initiator shall identify and describe the CAQ in detail, outlining out how the CAQ fails to conform to procedures, test plans, etc. This includes the identification of the responsible manager that was notified of the CAR, the Responsible Organization.
- 8.1.6 The Initiator shall print name, sign and date Form 16.1-1.
- 8.1.7 The Initiator shall forward the CAR to the QAR.
- 8.1.8 The QAR shall determine if the adverse condition meets the definition of 5.2 of this procedure to consider categorizing it as a SCAQ. In addition, The QAR shall determine whether or not the SCAQ warrants issuance of a Stop Work Order (SWO).
- 8.1.9 If a SWO is necessary, the QAR shall contact the local DOE Responsible Manager to initiate the SWO using site procedures.
- 8.1.10 The QAR shall assign the Response Due Date.
- 8.1.11 The QAR shall review CAR form for correctness and completeness and sign and date Form 16.1-1.
- 8.1.12 The QAR shall forward the CAR to the DAS for issuance to the Responsible Manager.

8.2 Response to a Corrective Action Report – Part II

- 8.2.1 The Responsible Manager shall record the CAR Number on the top of the Form 16.1-2, *Corrective Action Report (CAR) Part II*.
- 8.2.2 The Responsible Manager documents the extent and impact of the CAQ.
- 8.2.3 If the condition is an SCAQ, the Responsible Manager shall document the root cause of the condition using the condition codes provided in Form 16.1-2. Evidence of the root cause, analysis method used, and qualifications and the training of the individual(s) who performed the root cause analysis shall be attached to the form.
- 8.2.4 The Responsible Manager shall then document the Proposed Remedial Action(s), Person(s) Responsible to Complete, and Proposed Completion Date.
- 8.2.5 The Responsible Manager shall then document the Action(s) to Prevent Recurrence, Person(s) Responsible to Complete, and Proposed Completion Date.
- 8.2.6 The Responsible Manager shall sign and date the CAR then submit the form to the QA Lead.
- 8.2.7 If the Responsible Manager cannot complete the corrective actions as planned by the due date, then the Responsible Manager shall provide an Extension Request in writing to the QA Lead prior to the due date of the corrective actions.

8.3 Response Evaluation of a Corrective Action Report – Part III

- 8.3.1 The QA Lead shall forward a copy of the CAR Part II (Form 16.1-2) to the QAR for evaluation.
- 8.3.2 The QAR shall document the evaluation of the proposed response and determine if the proposed response is adequate to resolve the CAQ. If any of the proposed corrective actions listed on the CAR Part II are unacceptable to the QAR, the QAR shall document the proposed response as “rejected” and provide justification on the CAR Part III (Form 16.1-3).
- 8.3.3 The QAR shall sign and date the CAR Part III (Form 16.1-3) and forward it to the DAS for distribution back to the Responsible Manager.
- 8.3.4 For rejected CAR Part IIs, the Responsible Manager shall address the justification for rejection on a new CAR Part II (Form 16.1-2) in accordance with section 8.2 of this procedure.

8.4 Verification and Closure of a Corrective Action Report – Part III

- 8.4.1 When all approved corrective actions have been completed, the Responsible Manager shall notify the QAR that corrective action verification is needed.
- 8.4.2 The QAR shall evaluate and verify completion and effective implementation of the corrective actions for the CAR. The QAR shall document this verification on Form 16.1-3. If results of the verification are unsatisfactory, the QAR shall document the reasons for the unsatisfactory verification on Form 16.1-3.
- 8.4.3 For satisfactory verification, the QAR shall sign and date Form 16.1-3 and forward the form to the DAS. The DAS shall approve CAR closure and notify the Responsible Manager. For unsatisfactory verification, the DAS shall distribute the unsatisfactory results as documented on Form 16.1-3 to the Responsible Manager.
- 8.4.4 For unsatisfactory verification, of corrected action(s), the Responsible Manager shall address the reason(s) for rejection as documented on Form 16.1-3 and the start the process of re-verification starting at section 8.4.

8.5 Trending

- 8.5.1 The QA Lead shall evaluate CARs and other reports of noncompliance and identify adverse trends at a frequency that provides for identification of adverse quality trends.
- 8.5.2 The QA Lead shall distribute trend evaluations to the appropriate management for review and appropriate action.

9.0 RECORDS

9.1 The following records, generated resulting from this procedure, shall be prepared and submitted to the EMCBC Coordinator in accordance with AP-17.1Q, *Quality Assurance Records*.

9.1.1 The following are considered Lifetime QA Records:

9.1.2.1 For each CAR package, as applicable:

9.1.1.1.1 Form 16.1-1, *Corrective Action Report – Part I*

9.1.1.1.2 Form 16.1-2, *Corrective Action Report – Part II*

9.1.1.1.3 Form 16.1-3, *Corrective Action Report – Part III*

9.1.1.1.4 Extension Requests

9.1.1.1.5 Supporting Documentation (e.g., Root Cause Documentation)

9.1.2 The following are considered Nonpermanent QA Records:

9.1.2.1 Trend Analysis Report

9.1.3 The following are not considered QA Records:

9.1.2.1 Correspondence transmitting CARs, their evaluations, and their closures between the DAS and the Responsible Manager.

10.0 FORMS USED

Form 16.1-1, *Corrective Action Report – Part I*

Form 16.1-2, *Corrective Action Report – Part II*

Form 16.1-3, *Corrective Action Report – Part III*

Corrective Action Report (CAR) Part I

Form Number 16.1-1
Page ____ of ____
(EMCBC USE ONLY)

1. CAR Number:	2. Audit/Surveillance No.:
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3. Name of Responsible Manager Notified:	4. Responsible Organization:
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5. Requirement or Basis for Unsatisfactory Condition:

6. Condition Description:

7. Initiator

_____	_____	_____
Print Name	Signature	Date

8. Significant Condition: <input type="checkbox"/> Yes <input type="checkbox"/> No	9. Stop Work Order Required: <input type="checkbox"/> Yes <input type="checkbox"/> No	10. Response Due Date:
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11. QAR Recommendation for Issuance:

_____	_____	_____
Print Name	Signature	Date

12. DAS Approval for Issuance

_____	_____	_____
Print Name	Signature	Date

Form Number 16.1-1, CAR Part I, Instructions

1. The Initiator contacts the QA Lead to obtain the CAR number (Block 1) via the following naming convention:
 - a. Last two digits of the current fiscal year, (e.g., 11-, 12-, 13-, etc.)
 - b. Adverse condition designator:
 - CAQ for a Condition Adverse to Quality, (e.g., CAQ-)
 - SCAQ for a Significant Condition Adverse to Quality, (e.g., SCAQ-)
 - c. Sequential number based on fiscal year and starting with the number one (e.g. 12-SCAQ-001).
2. The Initiator identifies the Audit or Surveillance Number associated with the CAR. If the CAR was not identified as the result of an Audit of Surveillance, mark "N/A" as appropriate.
3. The Initiator identifies the manager responsible for ensuring that corrective actions are planned and implemented before requesting verification for closure.
4. The Initiator identifies the organization responsible for planning and implementing the corrective actions.
5. The Initiator identifies the requirement (e.g., QARD, implementing document) or basis for unsatisfactory condition in sufficient detail to be traceable.
6. The Initiator describes the adverse condition in sufficient detail to be understood by the QAR. If the adverse condition addresses multiple adverse conditions, provide a summary statement. Supporting observations or discussions should provide sufficient detail to allow identification of the affected work.
7. The Initiator prints name, signs and dates.
8. The QAR determines and identifies if the condition adverse to quality is significant.
9. If the condition adverse to quality is significant, the QAR determines and identifies if a Stop Word Order (SWO) is required.
10. The QAR specifies the due date for the response (i.e., the corrective action plan).
11. The QAR reviews the CAR, prints name, signs and dates signifying recommendation for issuance of the CAR
12. The DAS reviews and approves the CAR by printing name, signing and dating this block.

NOTE: Page numbers are assigned by the EMCBC Coordinator after submission of the entire CAR Records Package.

Corrective Action Report (CAR) Part II

Form Number 16.1-1
Page ____ of ____
(EMCBC USE ONLY)

13. CAR Number:

14. Extent of Condition(s):

15. Impact(s):

16. Cause(s):

17. Proposed Remedial Action:

18. Action(s) to Prevent Recurrence:

19. Proposed Completion Date:

20. Responsible Manager:

Print Name

Signature

Date

CAR Part II Instructions

13. The Responsible Manager copies the CAR Number from the form of the CAR Part I.
14. The Responsible Manager evaluates and identifies the extent of the CAQ.
15. The Responsible Manager identifies the impact of the CAQ on completed or ongoing work activities or products.
16. For SCAQs, the Responsible Manager identifies the root cause using causal codes attached from DOE G 231.1-2. Individuals performing root cause analysis shall be trained and qualified in the method used for the analysis. Root cause analysis documentation will include identifying the method used, analysis, results, names, and signatures of individuals who performed the analysis and submitted the response. The analysis will clearly describe the significant condition adverse to quality and will adequately describe the root causes to support the identification of the correction action. Attach the root cause documentation to the response. This is not optional for SCAQs.
For CAQs and at the discretion of the Responsible Manager, the Responsible Manager describes the apparent cause for the adverse condition (i.e., Inadequate training of personnel, Procedures were inadequate, Assumptions were invalid, etc.). No further documentation is required.
17. Responsible Manager identifies the proposed remedial actions.
18. Responsible Manager documents actions to prevent recurrence of the identified causes for the adverse condition. This is not optional for SCAQs.
19. Responsible Manager identifies the proposed completion date for the remedial actions and actions to preclude recurrence.
20. Responsible Manager prints name, signs, and dates and forwards response to the QAR.

CAR Part II Causal Codes

A1 Design/Engineering Problem

- B1 DESIGN INPUT Less Than Adequate (LTA)
- B2 DESIGNOUTPUT LTA
- B3 DESIGN/DOCUMENTATION LTA
- B4 DESIGN/INSTALLATION VERIFICATION LTA
- B5 OPERABILITY OF DESIGN/ENVIRONMENT LTA

A2 Equipment/Material Problem

- B1 CALIBRATION FOR INSTRUMENTS LTA
- B2 PERIODIC/CORRECTIVE MAINTENANCE LTA
- B3 INSPECTION/TESTING LTA
- B4 MATERIAL CONTROL LTA
- B5 PROCUREMENT CONTROL LTA
- B6 DEFECTIVE, FAILED OR CONTAMINATED

A3 Human Performance LTA

- B1 SKILL BASED ERROR
- B2 RULE BASED ERROR
- B3 KNOWLEDGE BASED ERROR
- B4 WORK PRACTICES LTA

A4 Management Problem

- B1 MANAGEMENT METHODS LTA
- B2 RESOURCE MANAGEMENT LTA
- B3 WORK ORGANIZATION & PLANNING LTA
- B4 SUPERVISORY METHODS LTA
- B5 CHANGE MANAGEMENT LTA

A5 Communications LTA

- B1 WRITTEN COMMUNICATIONS METHOD OF PRESENTATION
- B2 WRITTEN COMMUNICATION CONTENT LTA
- B3 WRITTEN COMMUNICATION NOT USED
- B4 VERBAL COMMUNICATION LTA

A6 Training Deficiency

- B1 NO TRAINING PROVIDED
- B2 TRAINING METHODS LTA
- B3 TRAINING MATERIAL LTA

A7 Other Problem

- B1 EXTERNAL PHENOMENA
- B2 RADIOLOGICAL/HAZARDOUS MATERIAL PROBLEM

From

DOE O 232.2, Occurrence Reporting and Processing of Operations Information

	<h2 style="margin: 0;">Corrective Action Report (CAR)</h2> <h3 style="margin: 0;">Part III</h3>	Form Number: 16.1-3 Page ____ of ____ (EMCBC USE ONLY)
21. CAR Number:		
22. Response Evaluation:		
23. Date Response Received:	24. Date Evaluated:	25. Accept or Reject
26. Comments if Rejected:		
27. QAR Recommendation for CAR Part II Disposition (see block 25):		
_____ Print Name	_____ Signature	_____ Date
28. Results of Verification:		
29. QAR Recommendation for CAR Disposition (see block 28):		
_____ Print Name	_____ Signature	_____ Date
30. DAS Approval for Disposition :		
_____ Print Name	_____ Signature	_____ Date

CAR Part III Instructions

21. The QAR copies the CAR Number from the form of the CAR Part I.
22. The QAR documents the evaluation of the response.
23. The QAR records the date the response was received by the QA Lead from the Responsible Manager.
24. The QAR records the date the completion of the response evaluation.
25. The QAR documents acceptance or rejection of the response by printing either “Accept” or “Reject”.
26. If the action is rejected, the QAR documents the justification for rejecting the response.
27. The QAR then prints name, signs, and dates the evaluation.
28. The QAR documents the results for the verification of the closure package for the CAR. The QAR indicates whether the CAR is ready for closure or the reasons why it must remain open.
29. The QAR prints, signs, dates to recommend the disposition of the CAR.
30. The DAS prints name, signs, and dates to approve the disposition of the CAR.

Form 5.1-1 – Record of Revision

DOCUMENT: AP-16.1Q, *Corrective Action*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Original	All	04/27/2011
1	Extension revision to forms and process	All	04/15/2011
<u>2</u>	General Revision	All	12/14/2012