



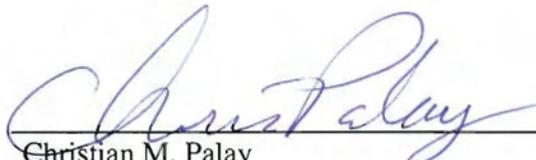
Office of Environmental Management (EM)

Subject: Corrective Action

Administrative Procedure

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Preparer:

  
Christian M. Palay  
Office of Standards and Quality Assurance

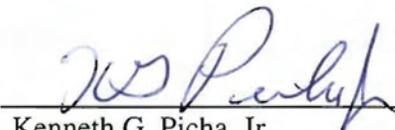
July 1, 2011  
Date

Approval:

 for R. Murray  
Robert D. Murray  
Director  
Office of Standards and Quality Assurance

7-1-11  
Date

Concurrence:

  
Kenneth G. Picha, Jr.  
Acting Deputy Assistant Secretary  
Safety and Security Program

7-1-11  
Date

## 1.0 PURPOSE

This procedure establishes the responsibilities and process to ensure that Conditions Adverse to Quality (CAQs) identified during Environmental Management (EM) Headquarters' oversight of High Level Waste (HLW) and Used Nuclear Fuel (UNF) programs, including those conditions considered significant, are promptly identified and corrected as soon as practical. This procedure also establishes the responsibilities and process for issuing a Quality Assurance Management Stop Work Order to HLW and UNF programs.

## 2.0 SCOPE

This procedure prescribes the process for identifying, documenting, evaluating, preventing, controlling, and correcting conditions adverse to quality, and for ensuring continuous improvement.

All personnel are responsible for detecting and preventing conditions adverse to quality, and for promoting continuous improvements of the processes and activities. Management 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 CAQs identified as a result of the EM Headquarters' oversight of activities subject to the Quality Assurance Requirements and Description (QARD), DOE/RW-0333P. This procedure applies to all individuals within EM who identify, investigate, evaluate, correct, or verify corrective action for a CAQ or associated Stop Work Order.

## 4.0 REQUIREMENTS

- 4.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20
- 4.2 EM-QA-002, Quality Assurance Program Plan (QAPP)
- 4.3 AP-1.1Q, High Level Waste (HLW) and Used Nuclear Fuel (UNF) Independent Oversight Program Description
- 4.4 AP-2.2Q, Surveillances

4.5 AP-17.1Q, Quality Assurance Records

4.6 AP-18.1Q, Audits

## 5.0 DEFINITIONS

5.1 Condition Adverse to Quality (CAQ) – A CAQ is a deviation from a requirement, a deficiency, or some other condition that adversely impacts the quality of a process or product including failures, malfunctions and technical inadequacies.

5.2 Significant Condition Adverse to Quality (SCAQ) – An SCAQ is a condition that, if uncorrected, could have a serious impact on public or personnel health and safety, waste acceptance, the environment, facility operations, or the effective implementation of the quality assurance program. A SCAQ may typically warrant a Stop Work Order (SWO).

5.3 Corrected During Audit (CDA) – A Condition Adverse to Quality that is discovered during an audit or surveillance and in which the corrective action is completed and verified before the completion of the audit or surveillance.

5.4 Stop Work Order (SWO) – A Stop Work Order is an order providing direction to stop activities because of an SCAQ with the potential for imminent and irreparable damage to the QA Program. Anyone performing work on the HLW/UNF Program can initiate a SWO. A SWO direction to the contractor should be in accordance with local DOE site procedures.

## 6.0 RESPONSIBILITIES

6.1 Director, Office of Standards and Quality Assurance

6.1.1 Responsible for the preparation, change, and approval of this procedure.

6.2 QA Lead, Office of Standards and Quality Assurance

6.2.1 Responsible for assignment of the Quality Assurance Representative (QAR).

6.2.2 Responsible for approval of the Corrective Action Report (CAR) closure.

6.3 Quality Assurance Representative (QAR)

6.3.1 Responsible for evaluating and verifying completion and effective implementation of corrective action for a CAR.

6.3.2 Responsible for the determination of CAQ significance.

6.4 Initiator

6.4.1 Individuals working on HLW or UNF activities responsible for identifying and reporting conditions that could affect quality.

6.5 Environmental Management Consolidated Business Center (EMCBC), Office of Logistics Management

6.5.1 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 of a Corrective Action Report – Part I

Step 2 – Conditions Corrected During Audit or Surveillance

Step 3 – Response to a Corrective Action Report – Part II

Step 4 – Response Evaluation of a Corrective Action Report – Part III

Step 5 – Verification and Closure of a Corrective Action Report – Part III

Step 6 – 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, Corrective Action Report – Part I
Response	Form 16.1-2, Corrective Action Report – Part II
Verification	Form 16.1-3, Corrective Action Report – Part III

## 8.0 PROCEDURE

### 8.1 Initiation 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 using Form 16.1-1 as follows.
- 8.1.2 The Initiator shall contact the QA Lead to obtain a CAR number.
- 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 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, and Response Due Date (usually 10 days after receipt of the CAR unless otherwise specified).
- 8.1.5 The initiator shall document the Immediate Corrective Action(s) taken and shall sign and date the form.
- 8.1.6 The Initiator shall forward the CAR to the QAR.
- 8.1.7 The QAR shall determine if the adverse condition appears serious enough 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).
- 8.1.8 If a SWO is necessary, The QAR shall contact the local DOE Responsible Manager to initiate the SWO using site procedures.
- 8.1.9 The QAR shall review the form for correctness and completeness and sign and date Form 16.1-1.
- 8.1.10 For audits or surveillances, the QAR shall forward the completed Form 16.1-1 to the team leader for inclusion into the audit or surveillance report. For other activities, the QAR shall forward the completed Form 16.1-1 to the QA Lead for distribution to the responsible manager.

8.2 Conditions Corrected During Audit or Surveillance

8.2.1 If the condition was Corrected During the Audit (CDA) and the corrective action is verified by the Initiator (or auditor), the Initiator completes the form as the Initiator, Responsible Manager, and QAR and signs as the Initiator and QAR verifying that the condition was corrected.

8.2.2 Completion of Parts II and III are not necessary for CDAs and the Initiator shall record "N/A" for all blocks determined to be not applicable.

8.2.3 If the CAQ was discovered and corrected during an audit or surveillance, then the QAR shall include the CAR as part of the Audit or Surveillance Report.

8.3 Response to a Corrective Action Report – Part II

8.3.1 The Responsible Manager shall record the CAR Number on the top of the Form 16.1-2, Corrective Action Report (CAR) Part II.

8.3.2 The Responsible Manager documents the extent and impact of the CAQ.

8.3.3 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.

8.3.4 The Responsible Manager shall then document the Proposed Remedial Action(s), Person(s) Responsible to Complete, and Proposed Completion Date.

8.3.5 The Responsible Manager shall then document the Action(s) to Prevent Recurrence, Person(s) Responsible to Complete, and Proposed Completion Date.

8.3.6 The Responsible Manager shall sign and date the CAR then submit the form to the QA Lead.

8.3.7 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.

8.4 Response Evaluation of a Corrective Action Report – Part III

8.4.1 The QAR shall sign and date Form 16.1-3 and forward the form to the QA Lead for distribution back to the Responsible Manager.

8.4.2 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 are unacceptable to the QAR, the QAR shall document the proposed response as “rejected” and provide justification on Form 16.1-3.

8.4.3 The QAR shall sign and date the CAR and forward a copy of the CAR to the Responsible Manager and the original to the QA Lead.

8.4.4 For rejected CAR Part IIs, the Responsible Manager shall address the justification for rejection on a new Form 16.1-2 in accordance with 8.3.

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

8.5.1 When all approved corrective actions have been completed, the Responsible Manager shall notify the QAR that corrective action verification is needed.

8.5.2 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.

8.5.3 The QAR shall sign and date Form 16.1-3 and forward the form to the QA Lead. For satisfactory verification, the QA Lead shall approve CAR closure and notify the Responsible Manager. For unsatisfactory verification, the QA Lead shall distribute the unsatisfactory results as documented on Form 16.1-3 to the Responsible Manager.

8.5.4 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 8.5.1.

8.6 Trending

8.6.1 The QA Lead shall perform trending of CAQ.

8.6.2 The QA Lead shall evaluate reports of non-conformance and CAQ to identify adverse trends at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause.

8.6.3 The QA Lead shall distribute trend evaluations promptly to contractor management and to the Director of the Office of Standards and Quality Assurance for review and appropriate action.

## 9.0 RECORDS

The following QA Records, generated as a result of this procedure, shall be prepared and submitted to the EMCBC Records Center in accordance with AP-17.1Q, Quality Assurance Records.

### 9.1 QA Records

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

Extension Requests

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

Recurring Condition Evaluation

Trend Analysis Report

## 10.0 FORMS USED

Form 5.1-1, Record of Revision

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

	<b>Corrective Action Report (CAR) Part I</b>	Form Number 16.1-1 Page ____ of ____ (EMCBC USE ONLY)
1. CAR No.:		2. Audit/Surveillance No.:
3. Name of Responsible Manager Notified:		4. Responsible Organization:
5. Response Due Date:		
6. Describe Requirement:		
7. Describe Condition Adverse to Quality:		
8. Initiator		
_____	_____	_____
Print/Type Name	Signature	Date
9. Condition Corrected During Audit (Yes or No)		
10. Condition is Significant (Yes or No):		11. Stop Work Order Required (Yes of No):
12. Describe Immediate Corrective Action(s) Taken:		
13. QAR Approval for Issuance:		
_____	_____	_____
Print/Type Name	Signature	Date

### **CAR Part I Instructions**

1. The Initiator contacts the QA Lead to obtain a CAR number (Block 1) as follows:
  - a. Last two digits of the current fiscal year, (e.g., 11-, 12-, 13-, etc.)
  - b. Responsible organization unique identifier, (e.g., SRS-, ID, HANF-, NSNF, etc.)
  - c. Audit/ surveillance designator (use report number if available), AU-00- or S-00-
  - d. Adverse condition designator:
    - CAQ for a Condition Adverse to Quality, (e.g., CAQ-)
    - SCAQ for a Significant Condition Adverse to Quality, (e.g., SCAQ-)
  - e. Sequential number starting with the number one for each category (e.g., CAQ -001, CAQ -002, or SCAQ -001, SCAQ -002)
  - f. For external assessment reports or discovered conditions adverse to quality that are not associated with the report, list the date of issue of the report or discovery ((e.g., 11-NSNF-06/07/11-CAQ-001 and 11-NSNF-06/07/11-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" (Block 2).
3. The Initiator identifies the responsible manager that was notified (Block 3).
4. The Initiator identifies the responsible organization (Block 4).
5. The Initiator identifies the response due date (Block 5).
6. The Initiator identifies the QARD section/ paragraph requirement violated with identification of supporting procedures and instructions as applicable under "Describe Requirement" (Block 6).
7. The Initiator identifies the Condition Adverse to Quality beginning with a single statement in Block 7. 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.
8. The Initiator prints/ types name signs and dates Block 8.
9. The Initiator identifies if the Condition Adverse to Quality was resolved during the Audit or Surveillance. If the condition was resolved, then the auditor completes the form and signs as both the Initiator and QAR validating closure.
10. The QAR determines and identifies if the condition adverse to quality is significant according to (Block 10).
11. If Block 10 is "Yes," the QAR determines and identifies if a Stop Word Order (SWO) is justified according this procedure. If Block 10 is "No" mark Block 11 "No".
12. The Initiator identifies any immediate corrective actions that were verified (Block 12). For conditions adverse to quality that are corrected during the audit or surveillance identify the measures taken to prevent recurrence.
13. The QAR reviews the CAR, prints/ types name, signs and dates Block 13 signifying approval of the CAR for issuance.

	<b>Corrective Action Report (CAR) Part II</b>	<b>Form Number:</b> 16.1-2 <b>Page</b> ____ <b>of</b> ____ <b>(EMCBC USE ONLY)</b>
14. CAR No:		
15. Extent of Adverse Condition(s):		
16. Impact of Adverse Condition(s)		
17. If Root Cause then List the Root Cause:		
18. Proposed Remedial Action:		
19. Proposed Completion Date:	20. Person Responsible to Complete:	
21. Action to Prevent Recurrence:		
22. Proposed Completion Date:	23. Person Responsible to Complete:	
24. Responsible Manager:		
_____	_____	_____
Print/Type Name	Signature	Date

### **CAR Part II Instructions**

14. Responsible Manager copies the CAR No. from Part I of the CAR form into Block 14.
15. Responsible Manager evaluates and identifies in Block 15 the extent of the CAQ.
16. Responsible Manager identifies in Block 16 the impact of the CAQ on completed and ongoing work activities; QA requirements, and implementing documents.
17. If there is a root cause associated with the CAQ or SCAQ, the Responsible Manager identifies the root cause in Block 17 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 all documentation to the response.
18. Responsible Manager identifies the proposed remedial actions and documents the actions in Block 18. Conditions adverse to quality require remedial action to address: the identified deficiency; the condition on QA requirements, implementing documents or both. Significant conditions adverse to quality require a root cause established using a formal root cause analysis method.
19. Responsible Manager identifies the proposed completion date (Block 19).
20. Responsible Manager Identifies the responsible person/ organization to complete remedial actions (Block 20). If there are multiple actions, identify each action with a proposed completion date and responsible person (include their organization) to complete the remedial actions. The responsible organization is advised to prioritize the actions commensurate with the impact to planned and ongoing work.
21. Responsible Manager documents actions to prevent recurrence in Block 21.
22. Responsible Manager identifies proposed completion date in Block 22.
23. Responsible Manager identifies the responsible person in Block 23. Where there are multiple actions to be performed, list them and their associated proposed completion dates, and the responsible person and organization. The responsible manager is advised to prioritize the actions commensurate with safety significance and the impact to planned and ongoing work.
24. Responsible Manager prints/ types name, signs, and dates Block 24 and forwards response to the responsible QAR. Notify the responsible QAR by E-mail or other correspondence that the committed actions are complete. If the response is not submitted by the due date or if corrective action completion dates are not met, the Responsible Manager must submit an extension request with justification for the delay in responding or completing corrective action to the responsible QAR.

**CAR Part II  
Causal Codes**

**A1 Design/Engineering Problem**

- B1 DESIGN INPUT 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 G 231.1-2, *Occurrence Reporting Causal Analysis Guide*  
Approved 08-20-03

	<b>Corrective Action Report (CAR) Part III</b>	<b>Form Number:</b> 16.1-3 <b>Page</b> ____ <b>of</b> ____ <b>(EMCBC USE ONLY)</b>
25. CAR No:		
26. Response Evaluation:		
Date Response Received:	Date Evaluated:	Accept or Reject
27. Comments if Rejected:		
QAR: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> <span>Print/Type Name</span> <span>Signature</span> <span>Date</span> </div>		
28. Results of Action Verification and Recommendation for Closure:		
QAR: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> <span>Print/Type Name</span> <span>Signature</span> <span>Date</span> </div>		
Audit/Surveillance No.: _____		
QA Lead: _____ <div style="display: flex; justify-content: space-between; width: 100%;"> <span>Print/Type Name</span> <span>Signature</span> <span>Date</span> </div>		

### **CAR Part III Instructions**

25. QAR copies the CAR No from Part I of the CAR form into Block 25.
26. QAR documents the evaluation of the response in Block 26. QAR considers the adequacy of the response in addressing the cause of the CAQ and the action to prevent recurrence. QAR records the date the response was received and the date the response was evaluated. The QAR documents acceptance or rejection of the response by circling either "Accept" or "Reject".
27. If the action is rejected, the QAR documents the justification for rejecting the response in Block 27. The QAR then prints/ types name, signs, and dates the evaluation.
28. The QAR documents the results of the verification of completion of actions to prevent recurrence in Block 28. If applicable, the QAR prints/ types name, sign, dates, and records the audit/ surveillance number, or enters "review" for verification by document review. A copy of the document or pertinent excerpts from the document will be attached to the CAR. The QA Lead prints/ types name, signs, and dates to approve/ close the CAR.

**RECORD OF REVISION**

**DOCUMENT: AP-16.1Q, Corrective Action**

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

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<b><u>Rev. No.</u></b>	<b><u>Description of Changes</u></b>	<b><u>Revision on Pages</u></b>	<b><u>Date</u></b>
0	Original	All	04/27/2011
1	Extensive revision to forms and process.	All	07/15/2011