

Management System: Quality Assurance and Oversight

Subject Area: Issues Management, Performance Trending and Improvement
--

Procedure: Corrective Action

Issue Date and Revision Number: 04/15/2015 2	Lead Subject Matter Expert: Ken Armstrong	Management System Owner: John Sattler
---	---	---

1.0 Applicability

The purpose of this procedure is to provide direction and guidance to Environmental Management Consolidated Business Center (EMCBC) and participating Small Site Federal Project Directors (FPD). This is achieved through effectively managing issues or findings identified through the U.S. Department of Energy (DOE) oversight activities; describing the processes required to ensure issues (Significant Deficiencies, Deficiencies, or Observations) are adequately analyzed to determine level of significance and underlying causes; developing preventive and corrective actions and successfully implementing them in order to resolve the issues and prevent recurrence.

This procedure applies to all Independent Assessment, Management Assessment and Facility Representative Oversight activities performed by the EMCBC and Participating Small Sites. This procedure meets the requirements of EM-QA-001 *EM Quality Assurance Program (QAP) Rev. 1*; DOE Order 414.1D, *Quality Assurance Criteria 3, Management/Quality Improvement*; DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*; and DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*. This procedure also uses guidance and expectations provided in DOE P 226.1B, *Department of Energy Oversight Policy*; DOE G 414.1-1C, *Management Assessment and Independent Assessment Guide*; and DOE G 414.1-2B, Change 1, *Quality Assurance Program Guide*.

This procedure is consistent with DOE requirements and expectations for conducting causal analyses, developing and implementing corrective actions, and tracking issues or findings and preventive and corrective actions to closure from all oversight sources. However, it does not address tracking occurrences identified and tracked through Contractor Systems or the following DOE systems: Occurrence Reporting System (ORPS), Non-Compliance Tracking System (NTS), Departmental Audit Response Tracking System (DARTS), Safeguards and Security Information Management System (SSIMS), the cyber security Plan of Actions and Milestones (POA&M) process, or the Employee Concerns Program. The reporting, concurrence, and approval of preventive and corrective actions for the above systems are governed by DOE requirements addressed in other management systems.

2.0 Required Procedure

MANAGING ISSUES IDENTIFIED IN OVERSIGHT ACTIVITIES	
Step 1	The EMCBC Office of Technical Support and Asset Management and Participating Small Sites shall identify a Corrective Action Coordinator (CAC) for their site. The EMCBC or Small Site CAC is responsible for managing Corrective Actions, tracking issues to resolution and documenting the closure of Issues using the Corrective Action Closure Form.
Step 2	Issues identified during oversight activities conducted by DOE Headquarters (HQ) or Field Offices shall be categorized as a Significant Deficiency, Deficiency, or Observation or Comment (Reference: SAD-OTSAM-414C, Subject Area: Quality Oversight and Assessment). When these priority categories are not provided by the auditing agency, the CAC shall review the issue and assign the appropriate priority category
Step 3	<p>For each issue, the CAC works with the responsible manager to resolve the issue as follows:</p> <ul style="list-style-type: none"> a. For Significant Deficiencies, the CAC: <ul style="list-style-type: none"> i. Ensures root cause and any contributing causes are identified consistent with Steps 4-9, <i>Performing Causal Analysis</i> ii. Ensures corrective actions are developed and documented consistent with the requirements in Steps 10-14, <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i>. b. For Deficiencies, the CAC: <ul style="list-style-type: none"> i. When appropriate, ensures the identification of the apparent cause and determines the root cause consistent with Steps 4-9, <i>Performing Causal Analysis</i> ii. Ensures corrective actions are developed and documented consistent with the requirements in Steps 10-14, <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i>. c. For Observations and Comments the CAC: <ul style="list-style-type: none"> i. Reviews the Observation or Comment to determine if a potential non-conformance could result if the Observation is not addressed. If preventative actions are taken to prevent a non-conformance, the preventive actions are, for all practical purposes, a corrective action and are therefore managed and tracked as a corrective action.
PERFORMING CAUSAL ANALYSIS	
Step 4	The CAC works with the responsible manager to perform causal analysis of Significant Deficiencies and when appropriate for Deficiencies.

Step 5	The CAC leads the collection, organization, and review of data to understand the issues and impacts.
Step 6	The CAC works with the responsible manager to select the appropriate causal analyses methodology and conducts the analysis (i.e., Event and Causal Factor Charting, Change Analysis, Barrier Analysis, and Human Performance Evaluations). NOTE: The DOE O 232.2, <i>Occurrence Reporting and Processing of Operations Information</i> , is the preferred method in DOE for identifying causal factor codes.
Step 7	The CAC works with the responsible manager to identify the root cause and ensures the root causes meet the following criteria: <ul style="list-style-type: none"> a. The issue would not exist if the root cause(s) were not present, b. The issue will not recur if the root cause(s) are corrected and eliminated, and c. Correction of the root cause(s) will prevent recurrence of similar conditions.
Step 8	The CAC works with the responsible manager to document the results of causal analyses and provides at a minimum: <ul style="list-style-type: none"> a. For Significant Deficiencies, the CAC provides the root cause(s) and any contributing cause(s). b. For Deficiencies, the CAC provides the apparent cause(s) and when appropriate, the root cause cause(s).
Step 9	The CAC provides the results of the causal analysis to the responsible manager for development of corrective actions per steps 10-14, <i>Developing, Approving, Implementing, and Verifying Preventative and Corrective Actions</i> and for the generation of Lessons Learned. NOTE: See EMCBC Corporate Operating Experience/Lessons Learned Procedure for more information.
DEVELOPING, APPROVING, IMPLEMENTING, AND VERIFYING PREVENTATIVE AND CORRECTIVE ACTIONS	
Step 10	The Responsible Manager ensures corrective actions for Significant Deficiencies and Deficiencies and preventive actions identified from the analysis of Observations. NOTE: The extent of condition must be considered in the development of the resolution of Significant Deficiencies. NOTE: DOE G 414.1-2B, Change 1, Quality Assurance Program Guide, provides additional guidance in the development of corrective action
Step 11	The Responsible Manager documents and approves preventive and corrective actions identified as discrete tasks.
Step 12	The Responsible Manager or equivalent management level that approved the

	initial actions and commitments shall approve requested changes to corrective actions.
Step 13	<p>The CAC ensures an effectiveness review is conducted for Significant Deficiencies and other issues as appropriate.</p> <p>NOTE: For additional guidance on effectiveness reviews, see DOE G 414.1-2B, Change 1, <i>Quality Assurance Program Guide</i>.</p>
Step 14	The effectiveness reviewer documents the results of the effectiveness review, updates the tracking system, and advises management whether corrective actions can be closed.
TRACKINGS ISSUES, AND PREVENTATIVE AND CORRECTIVE ACTIONS	
Step 15	<p>The Responsible Manager ensures issues and associated corrective actions and preventive actions are entered into a formal tracking system and documented in the associated Corrective Action Closure Form to be tracked to closure.</p> <p>NOTE: EMCBC and Participating Small Site issues and their associated corrective actions and preventive actions are tracked to closure and retained for auditability and trending purposes. DOE provides oversight of contractor issues identified by DOE. The contractor is expected to have its own mechanism for tracking and auditability of contractor issues and associated corrective actions and for trending and analysis.</p>
Step 16	The CAC ensures that deliverables identified as objective evidence for corrective action implementation are documented and maintained.
Step 17	The CAC assigns ISMS functional area codes to issues in the tracking system for ease of binning and trending.
Step 18	<p>The Responsible Manager ensures:</p> <ul style="list-style-type: none"> • Changes to corrective action commitments and justification for the changes are approved by the appropriate approving authority and entered into the tracking system. • Corrective action commitments are monitored and completed on schedule. • Objective evidence supports the closure of corrective action and can be readily retrieved. • The tracking system documents the disposition of issues from EMCBC or Small Site Significant Deficiencies and Deficiencies. • The integrity of the data entered in the tracking system.
Step 19	<p>The CAC tracks to closure all Significant Deficiencies and Deficiencies and ensures issues are trended in order to identify precursor conditions that could signify repeat problem areas, processes or system weaknesses, or other vulnerabilities prior to these conditions initiating a reportable event.</p> <p>NOTE: In order to be effective, trend codes should be consistently applied, and the number of trend codes should be limited.</p>

3.0 References – Forms/Attachments/Exhibits

3.1 References

- SAD-OTSAM-414C, Subject Area: Quality Oversight and Assessment
- DOE O 232.2, Occurrence Reporting and Processing of Operations Information
- DOE O 414.1D Admin Change 1, Quality Assurance
- DOE O 226.1B, Implementation of Department of Energy Oversight Policy
- DOE G 414.1-1C, Management Assessment and Independent Assessment Guide
- DOE G 414.1-2B, Change 1, Quality Assurance Program Guide

3.2 Forms

- FM-OTSAM-414B-01-F1, EMCBC Corrective Action Closure Form

4.0 Records Generation

Records generated through implementation of this procedure are identified as follows, and are maintained by the Office of the Technical Support and Asset Management in accordance with the EMCBC Organizational File Plan:

RECORDS TABLE

Records Category Code	Records Title	Responsible Organization	QA Classification (Lifetime or Non-Permanent)
ENV 01-B-04-B	Corrective Action Closure Form	Office of Technical Support and Asset Management or applicable Field Office	Non-Permanent maintained as QA record for one year after fiscal year the Corrective Actions are closed.

EMCBC RECORD OF REVISION

DOCUMENT TITLE: Corrective Action

If there are changes to the controlled document before the two-year review cycle, the revision number stays the same; one of the following will indicate the change:

I Placing a vertical black line in the left margin adjacent to sentence or paragraph that was revised; or

I Placing the words GENERAL REVISION at the beginning of the text. This statement is used when entire sections of the document are revised.

If changes and updates occur at the two-year review cycle, the revision number increases by one.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Initial Document		11/27/12
1	Add reference to Corrective Action Form and correct Grammatical errors.	Multiple	04/01/13
2	Biannual update to capture DOE order updates, and other minor updates.	All	04/14/15