

Management System: Quality Assurance and Oversight

Subject Area: Oversight and Assessments

Procedure: Independent Assessment

Issue Date:
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1.0 Applicability

This procedure applies to all independent oversight activities performed by the EMCBC and participating Small Sites. This procedure meets the requirements of EM-QA-001 *EM Quality Assurance Program (QAP)* and DOE Order 414.1D, *Quality Assurance Criteria 10, Independent Assessments*. Independent assessments also use guidance provided in DOE G 414.1 1B, *Management Assessment and Independent Assessment Guide*. Independent oversight is not limited to Quality Assurance and this procedure can be used for Independent Oversight of other EMCBC Small Site programs, including Conduct of Operations, Integrated Safety Management, Environmental Management, Safety Culture, and other requirements. Independent assessments shall be performed by personnel knowledgeable in the subject area and trained in assessment techniques. Results of independent assessments/audits are documented and deficiencies verified. These deficiencies are graded based on their significance as follows:

Significant Deficiencies: Deficiencies that if uncorrected, could have a serious effect on the environment, safety, health, security, or operational integrity. This includes Significant Conditions Adverse to Quality. An “Extent of Condition” determination should be considered. Significant Deficiencies shall be tracked, corrective action plans reviewed and corrective actions verified.

Deficiencies: Non-compliances with procedural, contractual or regulatory requirements identified during an assessment. This includes Conditions Adverse to Quality. They are used to indicate inadequacies or safety issues that warrant management attention. Deficiencies shall be tracked, corrective action plans reviewed and corrective actions verified.

Observation: A condition (either positive or negative) that should be brought to the attention of Line Management but does not meet the definition of a deficiency (e.g., a noteworthy practice that may serve as a model for other organizations or an opportunity for improvement).

2.0 Required Procedure

ASSESSMENT PLANNING	
Step 1	<p>Assessment Team Leader: Conducts assessment-scoping activities with the management of the organization subject to assessment and determines the scope of the assessment such as:</p> <ul style="list-style-type: none"> • Applicable programmatic elements to be evaluated • Work activities and critical processes (including timing) subject to requirements. • Key personnel to be interviewed during the assessment. • Documents that must be available prior to or during the assessment
Step 2	<p>Assessment Team Leader: Selects an appropriate number of potential Assessment Team Members who collectively have experience or training commensurate with the scope, complexity, or special nature of the work requiring assessment.</p>
Step 3	<p>Assessment Team Leader: If the assessment is performance based ensure that the following is accomplished:</p> <ul style="list-style-type: none"> • Select one or more technical specialists to assist in assessing the adequacy of technical processes. • Ensure indoctrination of selected technical specialist(s) is accomplished in accordance with the procedure <i>Qualification of Assessment Personnel</i>.
Step 4	<p>Assessment Team Leader: Ensures qualification records for each assigned Assessment Team Member, including technical specialist(s), are complete and that each individual is qualified in accordance with procedure <i>Qualification of Assessment Personnel</i>.</p>
Step 5	<p>Assessment Team Leader: Develops an Assessment Plan that identifies, as a minimum:</p> <p>Cover page including Assessment Plan Title, Date, Organization Assessed, and Signature Block</p> <ol style="list-style-type: none"> 1.0 Assessment Scope 2.0 Requirements For Performing The Assessment 3.0 Assessment Personnel 4.0 Work/Area of Assessment 5.0 Organization to be Notified 6.0 Applicable Documents/Criteria 7.0 Assessment Schedule <p>Note: See sample Recommended Independent Assessment Plan Format</p>
Step 6	<p>Assessment Team Leader: Signs and dates the Assessment Plan and forwards to the organization being assessed.</p>
Step 7	<p>Assessment Team Leader: Assigns required reading to Assessment Team Members.</p>

Step 8	<p>Assessment Team Members: Prepare sections 1 through 3 of the Criteria Review and Approach Document (CRAD) which includes:</p> <ol style="list-style-type: none"> 1.0 Number and Title: (Example: CRAD-3 Quality Assurance) 2.0 Objective: 3.0 Criteria: (Example: Lines of Inquiry or a Checklist) 4.0 Records Reviewed: (Example: Number, Issue, and Title) 5.0 Interviews: (Example: Date and Title) 6.0 Field and/or Work Activities Reviewed: (Example: Date and Activity) 7.0 Discussion of Results: (Provide details related to the conclusion) 8.0 The objectives were “Met” or “Not Met”. 9.0 Conclusion: (including Significant Deficiencies, Deficiencies, Observations) <p>Note: See sample Recommended (CRAD) Format</p>
Step 9	Assessment Team Members: Forwards the CRAD to the Assessment Team Leader.
ASSESSMENT PERFORMANCE	
Step 10	Assessment Team Leader: Conducts a pre-assessment meeting with the assessment team, appropriate management and staff of the Organization Assessed, to review the scope and the status of the related program and work activities planned to be reviewed/assessed.
Step 11	Assessment Team Leader: Documents the pre-assessment meeting attendance on an attendance sheet.
Step 12	Assessment Team: Selects pertinent processes or work activities for observation, personnel for interviews and documents for review as needed to complete each checklist item.
Step 13	<p>Assessment Team: Examines objective evidence in depth and determines if elements are effectively implemented.</p> <p>Note: Notify the Assessment Team Leader of any Significant Deficiencies found during the assessment.</p>
Step 14	Assessment Team: Completes the CRAD information as they conduct the assessment including documentation of potential deficiencies and observations.
Step 15	Assessment Team Leader: Conduct daily caucus with the Assessment Team Members to discuss progress in the planned assessment activities, and any potential areas for improvement or deficiencies.
Step 16	<p>Assessment Team Leader: Conduct daily meetings with the management of Organization Assessed to report progress, emerging issues, status of the assessment, and to coordinate required support for the assessment.</p> <p>Note: Immediately notify the management of the audited organization of any Significant Deficiencies found during the assessment.</p>
Step 17	Assessment Team Leader: Conducts a post-assessment meeting to present the preliminary assessment results to appropriate organizational management.
Step 18	<p>Assessment Team Leader: Documents meeting attendance on an attendance sheet.</p> <p>Note: See Recommended Attendance Sheet Format</p>

POST ASSESSMENT ACTIVITIES

Step 19	Assessment Team: Provides the completed CRAD information to the Assessment Team Leader.
Step 20	<p>Assessment Team Leader: Prepares an Assessment Report using inputs from the Team Members for their respective areas of assessment. The report should identify:</p> <p>Cover page including Assessment Report Title, Date, Organization Assessed and Signature Block</p> <ul style="list-style-type: none">1.0 Executive Summary2.0 Introduction3.0 Verification Approach4.0 Team Organization, Composition, And Qualifications5.0 Team Preparation6.0 Site Coordination And Support7.0 Schedule8.0 Results9.0 Conclusions10.0 Lessons Learned11.0 Corrective Action Plan Requirements12.0 References13.0 Attachment A: Team Leader Letter Of Appointment14.0 Attachment B: Criteria Review And Approach Documents15.0 Attachment C: Team Assignments, Qualifications And Concurrence <p>Note: See sample Recommended Assessment Report Format</p>
Step 21	Assessment Team Leader: Provides a copy of the report to the Organization Assessed for factual accuracy review.
Step 22	Assessment Team Leader: Resolves any factual accuracy issues with the Organization Assessed and complete the Final Report.
Step 23	Assessment Team Leader: Provides a copy of the final report to the Organization Assessed.
Step 24	Assessment Team Leader: Assembles an Assessment Case File containing the final Report and supporting documentation.

3.0 Records Generation

The records table identifies those records generated during the work process described in this procedure that document activities or preserve historically valuable information after the work process is completed.

In accordance with EMCBC IP-414-04, Quality Assurance Records or applicable site specific Quality Assurance Procedure , determine if the record(s) meet the definition of quality assurance records; if deemed quality assurance records, further classify the records as “lifetime” or “non-permanent”.

RECORDS TABLE

Records Category Code	Records Title	Responsible Organization	QA Classification (Lifetime or Non-Permanent)
ENV 01-B-04-B	Assessment Case File	Office of Technical Support and Asset Management or applicable Field Office	Life of the Contract