

Management System: Quality Assurance and Oversight

Subject Area: Oversight and Assessments

Procedure: Independent Assessment

**Issue Date and
Revision Number:**
08/11/15 3

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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 SAP-OTSAM-414 414.1D, *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, trained in assessment techniques and by personnel who do not have responsibility for performing the activities being audited. The scope and duration of the assessment determines the composition of the Independent Assessment Team. Assessment Teams may be as small as one Lead Assessor or as large as a Lead Assessor and a Team of Assessors.

2.0 Required Procedure

ASSESSMENT PLANNING	
Step 1	Lead Assessor: Conducts assessment-scoping activities with the management of the organization subject to assessment and determines the scope of the assessment such as: <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	Lead Assessor: If necessary, selects an appropriate number of Assessment Team Members who collectively have experience or training commensurate with the scope, complexity, or special nature of the work requiring assessment.

Step 3	Lead Assessor: If the assessment is performance based, selects one or more technical specialists to assist in assessing the adequacy of technical processes.
Step 4	Lead Assessor: Ensures qualification records for any additional Assessment Team Members, including technical specialist(s), are complete and that each individual is qualified in accordance with procedure <i>Qualification of Assessment Personnel</i> .
Step 5	<p>Lead Assessor: 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	Lead Assessor: Signs and dates the Assessment. Plan and forwards to the organization subject to assessment.
Step 7	Lead Assessor: Assigns required reading to Assessment Team Members, if necessary.
Step 8	<p>Lead Assessor and any additional 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	Lead Assessor: Compiles CRADs for use during the assessment.
ASSESSMENT PERFORMANCE	
Step 10	Lead Assessor: Conducts a pre-assessment meeting with the Assessment Team Members, 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	Lead Assessor: Documents the pre-assessment meeting attendance on an attendance sheet.
Step 12	Lead Assessor and any additional Assessment Team Members: Selects pertinent processes or work activities for observation, personnel for interviews and documents for review as needed to complete each checklist item.
Step 13	Lead Assessor and any additional Assessment Team Members: Examines objective evidence in depth and determines if elements are effectively implemented. Note: Notify the Lead assessor of any Significant Deficiencies found during the assessment.
Step 14	Lead Assessor and any additional Assessment Team Members: Completes the CRAD information as they conduct the assessment including documentation of potential deficiencies and observations. Team Members identify issues that represent potential safety or quality concerns, process improvement opportunities, deviations from requirements, or any other issues worthy of management attention. Issues should be graded as Significant Deficiency, Deficiency, Observation or Comment as defined in the Subject Area: Quality Oversight and Assessment.
Step 15	Lead Assessor: 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	Lead Assessor: 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. Note: Immediately notify the management of the audited organization of any Significant Deficiencies found during the assessment.
Step 17	Lead Assessor: Conducts a post-assessment meeting to present the preliminary assessment results to appropriate organizational management.
Step 18	Lead Assessor: Documents meeting attendance on an attendance sheet.
POST ASSESSMENT ACTIVITIES	
Step 19	Lead Assessor and any additional Assessment Team Members: Completes CRAD information for use in the Assessment Report.
Step 20	Lead Assessor: Prepares an Assessment Report using inputs from the Team Members for their respective areas of assessment. The report should identify:

	<p>Cover page including Assessment Report Title, Date, Organization Assessed and Signature Block</p> <ul style="list-style-type: none"> 1.0 Executive Summary 2.0 Introduction 3.0 Verification Approach 4.0 Team Organization, Composition, And Qualifications 5.0 Team Preparation 6.0 Site Coordination And Support 7.0 Schedule 8.0 Results 9.0 Conclusions 10.0 Lessons Learned 11.0 Corrective Action Plan Requirements (Including how follow-up actions will be verified accomplished as scheduled) 12.0 References 13.0 Attachment A: Team Leader Letter Of Appointment (if applicable) 14.0 Attachment B: Criteria Review And Approach Documents 15.0 Attachment C: Team Assignments, Qualifications And Concurrence (if applicable) <p>Note: See sample Recommended Assessment Report Format</p>
<p>Step 21</p>	<p>Lead Assessor: Provides a copy of the report to the Organization Assessed for factual accuracy review.</p>
<p>Step 22</p>	<p>Lead Assessor: Resolves any factual accuracy issues with the Organization Assessed and completes the Final Report.</p>
<p>Step 23</p>	<p>Lead Assessor: Provides a copy of the Final Report to the Organization Assessed.</p>
<p>Step 24</p>	<p>Lead Assessor: Assembles an Assessment Case File containing the Final Report and supporting documentation. Audit Case File records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.</p>

3. References – Forms/Attachments/Exhibits

Exhibits:

- 1. Independent Assessment Review Plan Format
- 2. CRAD Format
 - 2A. Samples - SCI CRAD Used for Assessments
 - 2B. Sample Contractor Assurance CRAD
 - 2C. Sample Work Planning Control CRAD
 - 2D. Sample Radiological Controls CRAD
 - 2E. Sample Environmental Management CRAD

- 2F. Sample SCWE CRAD
- 3. Independent Assessment Final Report Format

4.0 Records Generation

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

RECORDS TABLE

Records Category Code	Records Title	Responsible Organization	QA Classification (Lifetime, Non-Permanent, or N/A)
ADM 22-02-B1	*Assessment Case File – Quality Assessment Case Files	Office of Technical Support and Asset Management or applicable Field Office	Non-Permanent – maintained as a QA Record for one year after fiscal year the Corrective Actions are closed.

*Contact the EMCBC Records Management Field Officer for the appropriate Record Category Code for Assessment Case Files other than Quality Assessments.

EMCBC RECORD OF REVISION

DOCUMENT TITLE: **Independent Assessment**

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 Procedure		07/31/12
1	Add statement about Independence of assessors, add "comments" to definition of Observation, change term "ATL" to "LA", delete attendance sheet, And other minor changes.	All	10/23/13
2	Moved Issues Grading from this procedure to Oversight and Assessment SAD.	All	3/13/15
3	Added definition of records To be maintained in the Audit Case File and minor corrections.	All	8/11/15