

Management System Description:

Quality Assurance and Oversight

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1.0 Purpose

The purpose of the Quality Assurance (QA) and Oversight Management System is to provide a consistent approach to effectively and efficiently implement the Department's QA and oversight policies/requirements throughout the EMCBC. This QA and Oversight Management System Description (MSD) outlines the processes and procedures required for EMCBC Federal employees to implement the EMCBC's QA and oversight responsibilities, it does not replace, or replicate, the U.S. Department of Energy (DOE) Directives on Quality Assurance and DOE Directive on Implementation of DOE Oversight Policy. The EMCBC QA and Oversight MSD, and its associated subject areas (SAs) and procedures, supports the [EM Quality Assurance Plan \(EM-QA-0001\)](#), developed to address the DOE QA Directive; the DOE Oversight Directive, and the Equivalency Authorization that substitutes the [H Clause, Quality Assurance \(QA\) Work Affecting Nuclear Safety](#), for the [Contractor Requirements Document \(CRD\) of DOE O 226.1B, Implementation of DOE Oversight Policy](#). The QA and Oversight Management System establishes the consistent EMCBC-wide approach to implementing the Department's oversight policies and directives, and provides the discipline specific criteria against which various activities, functions, or processes are evaluated when performing oversight.

2.0 Responsibilities

The table below represents roles and responsibilities specific to this Management System. For a detailed description of EMCBC roles and responsibilities, please see the [EMCBC Functions, Responsibilities, and Authorities \(FRA\)](#).

Roles	Responsibilities
EMCBC Director and Deputy Director	Exercising authorities delegated from EM-1, the Director and Deputy Director of the EMCBC are the EM Line Managers responsible and accountable to EM-1 for the quality of the work of Federal employees under the EMCBC and Small Sites and for the quality of operations (i.e., facility and infrastructure operations and

	<p>maintenance, protection of the health and safety of the public and workers, environmental protection, emergency management, safeguards and security, information management, cyber security, business management) at the EMCBC and Small Sites, regardless of whether the work is performed by Federal employees, contractors, or subcontractors. The Director of the EMCBC is also responsible and accountable to EM-1 for ensuring that effective oversight of work performance is implemented. The primary QA and oversight responsibilities/authorities of the Director of the EMCBC are:</p> <ul style="list-style-type: none"> • Ensure implementation of the QA and Oversight programs and procedures, throughout the EMCBC and Small Sites. • Serve as the senior DOE line management owner of the EMCBC quality assurance process. • Approve EMCBC Federal Project QAPs (if authority not delegated to FPDs). • Designate an EMCBC Operating Experience Program Coordinator and ensure effective lessons learned management at all EMCBC sites. • Ensure that oversight personnel are afforded unfettered access to information, facilities, and personnel necessary to conduct effective oversight.
Assistant Directors (ADs) EMCBC	<p>Exercising authorities delegated by the Director of the EMCBC, the Assistant Directors for the EMCBC are the EMCBC Line Managers responsible and accountable for the quality of the work of Federal employees assigned to them, and those that perform work for their programs through contracts and/or grants. The primary QA and oversight responsibilities/authorities of the ADs are:</p> <ul style="list-style-type: none"> • Ensure implementation of the EMCBC QA and Oversight Program • Provide input on program office oversight/assessment activities for the EMCBC Integrated Assessment Schedule (IAS). • Perform self-assessments of the performance against the goals and objectives contained in the EMCBC Strategic Plan.

<p>Assistant Directors (AD) The Office of Technical Support and Asset Management</p>	<p>In addition to the AD responsibilities listed above, the Assistant Director of the Office of Technical Support and Asset Management is the Quality Assurance Line Manager responsible and accountable for the Quality Assurance and Oversight Programs and Procedures at the EMCBC. The primary QA and oversight responsibilities/authorities of the AD of Technical Support and Asset Management are:</p> <ul style="list-style-type: none"> • Ensure implementation of the QA and Oversight programs and procedures, throughout the EMCBC and Small Sites. • Develop appropriate QA and oversight related expectations, and performance objectives and measures, for the EMCBC and Small Sites. • Approve the EMCBC Integrated Assessment Schedule (IAS). • Provide input on Small Site oversight/assessment activities for the EM IAS.
<p>Division Director Safety and Quality</p>	<p>The Division Director of the Safety and Quality Group has Line Manager responsibility for the EMCBC personnel who function as Subject Matter Experts in the areas of Environmental, Safety, Health, Quality and Performance Assurance. The primary QA and oversight responsibilities/authorities of the Division Director of the Safety and Quality Group are:</p> <ul style="list-style-type: none"> • Ensure implementation of the QA and Oversight programs and procedures, throughout the EMCBC and Small Sites. • Establish skills and initial and continuing training necessary for the Group. • Ensures that its oversight personnel have the skill set and training needed to perform effective oversight and assessments.
<p>Safety and Quality Division Staff</p>	<p>Safety and Quality Division Staff are responsible for implementing the Quality Assurance and Oversight policies and procedures for the EMCBC and Small Sites. The primary QA and oversight responsibilities/authorities</p>

	<p>of the Safety and Quality Staff are:</p> <ul style="list-style-type: none"> • Ensure that QA and oversight requirements are followed by EMCBC personnel; • Ensure that QA and oversight requirements and expectations are formulated and placed into contracts; • Perform oversight of contractor work to evaluate its adequacy; and • Integrate and implement feedback and improvement mechanisms into the work to attain a culture of continuous improvement.
<p>Small Site Federal Project Directors (FPDs)</p>	<p>The FPDs are responsible and accountable for the quality of the work of Federal employees assigned to them, and for the quality of operations at their site regardless of whether the work is performed by Federal employees, contractors, or subcontractors. FPDs are also responsible and accountable for ensuring that effective oversight of work performance is implemented. The primary QA and oversight responsibilities/authorities of the FPDs are:</p> <ul style="list-style-type: none"> • Assign the responsibility, authority, and accountability to develop and direct the implementation of the Site specific Quality Assurance Plan and Quality Assurance Implementation Plan (QIP). • Ensure that all Small Site personnel implement the Site Specific QAP and QIP. • Annually prepare the Site QA Declaration and submit it to the DAS for review. • Provide input on EMCBC oversight/assessment activities for the IAS. • Review and approve their contractor's QAP, and subsequent annual revisions of the QAP. • Review and approve the Contractor's initial Assurance System Description. • Ensure that oversight personnel are adequately qualified, and have unambiguous lines of authority and responsibility for oversight. • Plan and perform sufficient line management oversight, independent of contractor oversight activities, to evaluate the effectiveness of implementation of the contractor's QAP and

	<p>Assurance System, and to assess the contractor’s performance regarding to the QA and oversight related goals, objectives, and measures of the contract. Adjust the level and/or mix of Site Office oversight of contractor activities commensurate with the effectiveness of the Contractor Assurance System.</p> <ul style="list-style-type: none"> • Coordinate with the EMCBC to obtain QA and/or oversight/assessment support, as needed. • Ensure that Corrective Action Plans (CAPs) are prepared and implemented. Conduct follow-up reviews to evaluate the effectiveness of CAP implementation. • Designate a Site Office Operating Experience Program Coordinator as required by the DOE Operating Experience Directive; ensure the Site implements effective lessons learned management. • Support oversight efforts by ensuring that personnel are afforded access to the site, facilities, operations, personnel, documents, and records; and by ensuring responsiveness to independent oversight reports.
Contracting Officer	Responsible for including the applicable QA clauses and requirements in contracts.

3.0 Management System Operation

3.1 Overview

The EMCBC implements QA to attain and maintain confidence that QA requirements and expectations have been achieved. The DOE QA Directive is applicable to all aspects of the EMCBC’s work, including the work performed on behalf of the EMCBC by contractors. Quality improvement, which includes the use of lessons learned, is one of the Department’s QA criteria in the DOE QA Directive. DOE has issued the DOE Operating Experience Directive to address the management of lessons learned specific to the topic of ES&H protection. In addition to using Operating Experience for ES&H, EMCBC management uses lessons learned and trending as tools to facilitate continuous improvement in all areas of EMCBC operations.

EMCBC implements oversight to maintain sufficient awareness of the status and adequacy of the work performed by EMCBC staff and contractors. The level and/or mix of EMCBC line management oversight of contractor activities may be adjusted commensurate with the

effectiveness of the contractor's assurance system. The DOE Oversight Directive applies to the operations subjects of ES&H, safeguards and security, cyber security, and emergency management. The oversight applied to those aspects of operations is conducted in accordance with a formalized structured program.

Oversight activities are also applied to all other aspects of EMCBC work, including business management functions; project management; facilities and infrastructure operations and maintenance; and scientific research.

Operational awareness functions are used to manage how EMCBC Line Management maintains awareness of the adequacy of operations at its sites. This is accomplished through routine monitoring activities which include facility tours and walkthroughs, work observations, document and records reviews, meeting attendance and participation, and continual interactions with contractor workers, support staff, and management.

Issues management functions manage how EMCBC captures the program and performance issues into a system for effective causal analysis, corrective and preventive action identification, and tracking to resolution.

Criteria and Review Approach Documents, or Lines of Inquiry documents are tools that can aid in assessing specific areas of Contractor QA Program and Assurance System implementation effectiveness, as well as DOE EMCBC Management (self) Assessments. Information on the effectiveness of Contractor QAP and Assurance System implementation are sent up the EMCBC line management chain and to HS-1.

3.2 Key Functions and Processes

3.2.1 Federal Quality Assurance and Oversight

3.2.1.1 Quality Assurance

The *EMCBC Quality Assurance Plan (QAP) and Quality Assurance Implementation Plan (QIP)* delineate the EMCBC-wide program for implementing requirements set forth in the DOE QA Directive and the EM-QA-001 Quality Assurance Plan. The DOE QA Directive requires that each Small Site Federal Project Director develop and maintain a QAP specific to that Site or adopt the DOE EM QAP with implantation matrix. The Site QAP must comply with the Quality Assurance rule, DOE Directive and the [*EM-QA-001 Quality Assurance Plan*](#).

3.2.1.2 Oversight

EMCBC line management establishes its oversight goals and objectives in an IAP. Annually the AD for Technical Support and Asset Management approves the IAP. Each Federal Project Director may establish additional oversight and either maintain a Site IAP or coordinate additional oversight into the EMCBC IAP. Annually, each EMCBC AD self-assesses their organizations performance against the goals and objectives contained in its EMCBC Strategic Plan.

3.2.2 Contractor Quality Assurance and Oversight

3.2.2.1 Quality Assurance

EMCBC Line Management is responsible for ensuring contracts contain DOE EM standard QA clauses and the appropriate QA rules, regulations, DOE Directives, and national/international QA consensus standards. The Small Site contractors develop, maintain, and implement QAPs that satisfy applicable QA contract requirements. The EMCBC may be requested to assist the Federal Project Director in reviewing the contractor's QAP. The EMCBC and Federal Project Directors are responsible for ensuring that contracted work is planned and executed in accordance with the contractor's QAP and that the contractor developed and implemented effective QA, oversight, and assurance programs, including issues management and lessons learned systems.

3.2.2.2 Oversight

The EMCBC Line Management must maintain awareness, of sufficient depth and breadth, of EMCBC Small Site activities to understand the adequacy of the work. Such awareness is obtained through a suite of oversight activities. The level and/or mix of EMCBC oversight of contractor activities is commensurate with the Site hazards, contractor performance, annual declaration needs, and the level of oversight provided by the DOE Site Staff. The EMCBC and/or FPDs may choose to conduct some oversight/assessment activities jointly with the site contractor. However, the EMCBC and DOE Site Staff must perform a sufficient number of assessments independent of those performed by the contractor in order to maintain an objective and unbiased awareness of the adequacy of the contractor's performance.

The EMCBC utilizes an IAS to plan, schedule, and assign resources to formal oversight/assessment activities. The schedule is established on a one year cycle and is updated monthly. Each FPD plans and schedules oversight activities to assess the adequacy and effectiveness of the Site contractor's performance in all areas of responsibility. The IAS provides EMCBC management with a consolidated, comprehensive view of assessment activities and their corresponding resource requirements.

4.0 Requirements

4.1 Primary Responsibility

This Management System has primary responsibility for ("owns") the following requirements:

Document	Title
10 CFR 830, Subpart A	Quality Assurance Requirements
DOE O 210.2A	DOE Corporate Operating Experience Program

DOE O 226.1B	Implementation Of Department Of Energy Oversight Policy
DOE P 226.1B	Department Of Energy Oversight Policy
DOE O 227.1	Independent Oversight Program
DOE O 414.1D	Quality Assurance
EM-QA-001	EM Quality Assurance Program (QAP)
NQA-1 2008 with Addenda thru 2009	ASME NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications, and addenda through 2009
ISO 9001:2008	Quality Management System - Requirements
H Clause	Quality Assurance (QA) Work Affecting Nuclear Safety

5.0 Subject Areas, Program Descriptions, and Guidance Documents

The following Subject Areas are maintained by this Management System:

- [Quality Organization \(Subject Area\)](#)
 - [EMCBC Quality Organization Chart](#)
 - [PL-414-04, Quality Assurance Implementation Plan](#)
 - [PD-411-01, EMCBC Functions, Responsibilities, and Authorities \(FRA\)](#)
- [Training and Qualification \(Subject Area\)](#)
 - [Training Matrix for QA Personnel](#)
 - [IP-414-02, Training and Qualification](#)
 - [PD-361-03, Technical Qualification Program](#)
- [Oversight and Assessments \(Subject Area\)](#)
 - [Management Assessment Schedule](#)
 - [IP-414-09, Management Assessment](#)
 - [PD-361-02, Facility Representative Program](#)
 - [Independent Assessment Schedule](#)
 - [IP-414-10, Independent Assessment](#)
 - [Criteria Review and Approach Documents](#)
 - [New Procedure, Document Review](#)
 - [New Procedure, Stop Work Orders](#)
- [Issues Management, Performance Trending and Improvement \(Subject Area\)](#)
 - [IP-414-03 – EMCBC Corrective Action](#)
 - [New Guide, Establishing and Implementing a Performance Trending Process](#)
 - [New Guide, Analyzing, Charting, and Reviewing Performance Trends](#)

- [IP-230-01, Operating Experience/Lessons Learned](#)
- [QA Records](#)
 - [IP-414-04, Quality Records](#)
- [EM High Level Waste / Used Nuclear Fuel Support](#)
 - [DOE/RW-0333P, \(QARD\), Revision 20](#)
 - [EM-QA-002, Quality Assurance Program Plan \(QAPP\)](#)
 - [QARD Requirements Matrix](#)
 - [AP-1.1Q, HLW and UNF Independent Oversight Program Description](#)
 - [AP-2.1Q, Qualification of Audit Personnel](#)
 - [AP-2.2Q, Surveillances](#)
 - [AP-5.1Q, Preparing Implementing Documents](#)
 - [AP-5.2Q, Developing Forms](#)
 - [AP-6.1Q, Document Review](#)
 - [AP-6.2Q, Document Control](#)
 - [AP-16.1Q, Corrective Action, Rev 1](#)
 - [AP-17.1Q, Quality Assurance Records](#)
 - [AP-18.1Q, Audits](#)
 - [Forms](#)
 - [QARD Audit Checklist](#)
 - [FY 2012 Annual Audit and Surveillance Schedule \(FY2011\)](#)

6.0 References

- [DOE O 413.3B](#), *Program and Project Management for the Acquisition of Capital Assets*
- [DOE G 414.1-1B](#), *Management Assessment and Independent Assessment Guide for use with 10 CFR 830, Subpart A, and DOE O 414.1C, "Quality Assurance;" DOE M 450.4, "Integrated Safety Management System Manual;" and DOE O 226.1A, "Implementation of Department of Energy Oversight Policy"*
- [DOE G 414.1-2B, Admin. Chg. 1](#), *Quality Assurance Program Guide*
- [DOE G 414.1-4](#), *Safety Software Guide for Use with 10 CFR 830, Subpart A, "Quality Assurance Requirements," and DOE O 414.1C, "Quality Assurance"*
- [DOE-STD-1150-2002](#), *Quality Assurance Functional Area Qualification Standard, DOE Defense Nuclear Facilities Technical Personnel*
- [DOE-STD-1172-2011](#), *Safety Software Quality Assurance Functional Area Qualification Standard*
- [DOE-STD-7501-99](#), *The DOE Corporate Lessons Learned Program*