

Management System: Quality Assurance and Oversight

Subject Area: Issues Management, Performance Trending and Improvement

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1.0 Introduction

This Subject Area describes how the EMCBC organization and management meets the requirements of EM-QA-001 Criterion 3 – Management/Quality Improvement.

Criterion 3 – Management/Quality Improvement

In order for quality improvement to occur, it is necessary to have systems that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, inspection rejects, or audits, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations, nonconforming items, or inconsistencies with a requirement, or failures to meet customer, or management expectation. The insights and results provided by the contractor assurance system (CAS) should be leveraged to the extent possible to facilitate continuous quality improvement. EMCBC Management Expectations associated with Quality Improvement consist of:

- Management sets performance goals and standards and establishes metrics that monitor project/program performance to identify Quality Assurance (QA) processes needing improvement.
- Corrective actions are developed and implemented for problems/ findings related to item characteristics, products, process implementation, or services.
- Proposed corrective actions are peer reviewed to ensure they will effectively address the underlying QA performance issues.
- Corrective Action Programs utilize and are consistent with:
 - DOE O 226.1b, Implementation of Department of Energy Oversight Policy;
 - DOE O 227.1, Independent Oversight Program;
 - DOE O 210.2, DOE Corporate Operating Experience Program and
 - DOE G 414.1-2b, Quality Assurance Program Guide.
- A process to determine the significance of identified problems/findings is developed.
- In the case of significant conditions adverse to quality, causes of problems are identified, and include prevention of recurrence as a part of corrective action planning.

- Management identifies the causes of problems and takes corrective actions to address the problems. Formal root cause analysis should be considered based on the complexity of the identified significant issue. Root causes should be identified and documented using an authoritative methodology for root cause identification and be performed by root cause analysis-trained personnel. Significant conditions adverse to quality include prevention of recurrence as a part of the corrective action planning. An “Extent of Condition” determination is considered for significant conditions adverse to quality.
- Completed corrective actions are independently verified for implementation and closure consistent with the graded approach approved in the Quality Assurance Plan/Quality Improvement Plan (QAP/QIP).

Problems with potential programmatic or safety significance or that are widespread, continuing, multiple, or repetitive in nature (i.e., significant conditions adverse to quality) should be afforded special attention. Such problems are entered into a tracking system and identified to management for proper attention.

The DOE Corporate Operating Experience Program order institutes Corporate Operating Experience / Lessons Learned (COE/LL) requirements for the Department of Energy (DOE). The EMCBC procedure provides information for the management of corporate operating experience to prevent adverse operating incidents and to expand the sharing of good work practices, the systematic review, identification, collection, screening, evaluation, and dissemination of operating experience from U.S. and foreign government agencies and industry, professional societies, trade associations, national academies, universities, and DOE and its contractors and to reinforce the core functions and guiding principles of DOE’s Integrated Safety Management System (ISMS) to enhance mission safety and reliability. The document further provides mutual integration with the lessons learned requirements in other DOE directives by using the EMCBC form IP-230-1-F1. *EMCBC and Small Site Corporate Operating Experience/Lessons Learned Input.*

2.0 Contents

Procedures	Procedure Content
1. PS-414-03, EMCBC Corrective Action	<ul style="list-style-type: none"> • Defines the root cause identification and Corrective Action Tracking process • Defines the tailored approach to root cause identification, tracking and trending Corrective Actions
2. IP-230-01, Operating Experience/Lessons Learned	<ul style="list-style-type: none"> • Defines the process for documenting and reporting Lessons Learned at the EMCBC
3. Procedure 1, Trend Evaluation Process	<ul style="list-style-type: none"> • Describes the process for evaluating trends resulting from DOE and contractor assessments in order to identify excellent performance and opportunities for improvement.

Procedures	Procedure Content
4. Procedure 2, Root Cause Analysis	<ul style="list-style-type: none"> • Describes the methods and analytical tools to be used to conduct Root Cause Analyses and validate associated corrective actions.

3.0 Exhibits/Forms

[IP-230-01-F1](#), *EMCBC and Small Site Corporate Operating Experience/Lessons Learned Input*

4.0 Related Information

None

5.0 Requirements

[10 CFR 830, Subpart A](#), *Quality Assurance Requirements*

[DOE O 414.1D](#), *Quality Assurance*

[EM-QA-001](#), *EM Quality Assurance Program (QAP)*

[DOE O 210.2](#), *DOE Corporate Operating Experience Program*

[DOE O 226.1B](#), *Implementation of Department of Energy Oversight Policy*

6.0 Definitions

See Implementing Procedures.