U. S. Department Of Energy (DOE) Office Of Environmental Management (EM) Standing Operating Policies and Procedures (SOPP)		
Title: EM-23 Quality Assurance (QA) Oversight		
EM ORG: EM-23 SOPP #: 43	Revision #: 4	Effective Date: March 29, 2010

1. POLICY: The Office of Environmental Management (EM) Quality Assurance program requirements and expectations are documented in the EM Quality Assurance Program (QAP), EM-QA-001, dated October 2008. The QAP is the EM management system to ensure that all EM organizations "do work correctly." The QAP meets the requirements of DOE O 414.1C, *Quality Assurance*, and 10 CFR 830 Subpart A "*Quality Assurance Requirements*." The QAP demonstrates how QA and the Integrated Safety Management System (ISMS) are fully integrated in EM.

The QAP also provides consistent QA implementation across EM while allowing both for grading based on importance to the EM mission and safety, and for site-specific requirements to be addressed (e.g., DOE/RW-0333P, *Quality Assurance Requirements and Description*; Environmental Protection Agency (EPA) requirements; state permit requirements; etc.).

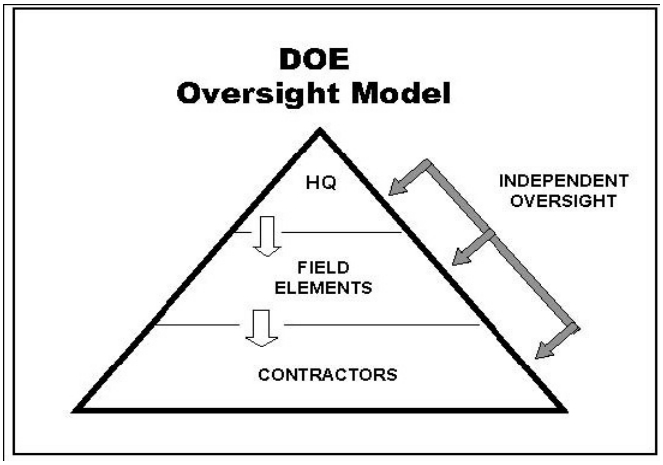
The objective of this Standing Operating Policies and Procedures (SOPP) is to describe the process that will be utilized by the Office of Standards and Quality Assurance (EM-23) within the Office of Safety & Security Programs (EM-20), to guide its activities related to EM Headquarter (HQ) oversight and audit of the EM Field/site, project, and vender QA programs.

The SOPP is consistent with the requirements of DOE Policy 226.1A, *Department of Energy Oversight Policy*, and DOE Order 226.1A, *Implementation of Department of Energy Oversight Policy*, by implementing a quality assurance (QA) oversight process that ensures compliance with applicable requirements, pursues excellence through continuous improvement, provides for timely identification and correction of deficient conditions, and verifies the effectiveness of completed corrective actions.

2. OBJECTIVES:

a. Establish a consistent and integrated process to perform EM-HQ EM-23 QA audit and oversight of EM field, sites, and projects. The SOPP provides a consistent technical basis and approach to assess EM organizations in meeting the requirements and expectations of the EM Corporate QAP.

b. Protect the public, workers, environment, and national security assets through a QA oversight process consistent with the DOE Oversight Model (See Figure 1).



3. **CANCELLATIONS:** This SOPP does not cancel any previous SOPPs.

4. **APPLICABILITY:** This procedure applies to all EM personnel (HQ or Field) serving on EM-HQ led QA audit teams.

5. **REFERENCES:**

a. EM Quality Assurance Program, dated 10/20/08
b. ASME NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications, and addenda through 2007
c. 10 CFR 830, Subpart A, "Quality Assurance Requirements" (i.e., QA Rule)
d. DOE Policy 226.1A, *Department of Energy Oversight Policy*
e. DOE Order 226.1A, *Implementation of Department of Energy Oversight Policy*
f. DOE Order 414.1C, *Quality Assurance*
g. DOE Guide 414.1-1B, *Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance;*
h. *DOE M 450.4-1, Integrated Safety Management System Manual; and DOE O 226.1A, Implementation of Department of Energy Oversight Policy*
i. DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*
j. DOE/RW-0333P, *Quality Assurance Requirements and Description*
k. DOE G 414.1-3, *Suspect/Counterfeit Items Guide*
l. DOE G 414.1-4, *Safety Software Guide*
m. DOE Guide 414.1-5, *Corrective Action Program Guide*
n. Office of Environmental Management Integrated Safety Management system Description (ISMSD), dated April 2007
o. Office of Environmental Management and Energy Contractors Group Quality Assurance Improvement Project Plan, Task #5.8, CD Tables w/Requirements and Performance Objectives, Measures & Commitments

6. **CONTACT:** Robert Murray, Acting Director, Office of Standards and Quality Assurance, EM-23, 202-586-7267, Robert.Murray@em.doe.gov.

7. **DEFINITIONS**: Specific terms used in this procedure are defined as used in DOE Policy 226.1A, DOE O 226.1A, and DOE O 414.1C. Please see Appendix B for Listing and Definition of Most Frequently Used Audit Terms.

8. **REQUIREMENTS**:

a. For EM HQ, Field and Project Offices, EM-23:
   i. Ensures compliance with EM Corporate QAP requirements. EM-23 must periodically examine QA programs and their implementation at the work-activity level to assess that those EM QAP and any applicable external regulatory requirements documented in approved site-specific Quality Assurance Implementation Program (QIP) are met effectively. Deficiencies brought to the attention of management that require a corrective action plan (CAP) must be addressed in a timely manner.
   ii. Ensures EM-HQ compliance with the requirements of the EM QAP. EM-23 must establish and implement oversight processes for monitoring EM-HQ's internal operations.
b. To promote efficiency, EM field organizations perform the majority of onsite operational awareness and day-to-day QA assessment activities. However, EM-23, in coordination with other EM HQ and Field line management may conduct independent QA reviews.

c. EM-23, in coordination with EM HQ line management, must regularly review the results of EM Field organization QA oversight and other information to maintain awareness of site conditions and trends, implementation of the QA program, as well as the effectiveness of Field line management QA oversight activities.

d. EM-23 coordinates its QA oversight activities with site assurance system activities to promote efficient use of resources and to avoid duplication of efforts. EM-23 may conduct some assessments jointly with other EM HQ line management, the Field, or contractor organizations.

e. EM-23 works with EM line management and the EM Field organizations to implement a baseline QA oversight program that focuses resources on selected assessments, operational awareness activities, performance measure monitoring and improvement, and assessment of assurance systems.

9. **ROLES & RESPONSIBILITIES**: EM-23 is responsible for developing and maintaining the EM Corporate QAP. Verification of the implementation of this program is accomplished through this SOPP. Each EM organization (HQ/Field) and contractor is required to develop and maintain a QAP and an approved (QIP) consistent with the requirements of the EM Corporate QAP.

10. **PROCEDURES**: EM-23 implements the following QA oversight and audit processes consistent with ASME NQA-1 Requirement 18, Audits.

a. Elements of EM-23 QA Oversight. EM-23 QA oversight includes maintaining a central clearing house for assessing the adequacy and achievement of quality goals, coordinating quality improvement initiatives among EM Field elements, supplying a source of on-demand QA assessment expertise, reviewing and approving field element documentation, setting goals for efficiencies and defining metrics to measure program effectiveness, and assisting EM Field elements in implementing their QA programs. Key elements of EM-23 oversight include:

i. QA Oversight and Audit Program Plan: EM-23 QA Oversight Program Plans identify the program areas to be reviewed, periodicity of reviews, reviews necessary to maintain the baseline oversight program, qualifications of review personnel, and the source of review criteria. Program plans describe the various oversight methods used, how they are used, and how the results of the various methods are integrated and considered as a whole to give an accurate oversight picture. Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program. Consistent with NQA-1 Requirement 18-Subpart 100: "..*These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated".* Appendix A provides the template for scheduling of planned EM-23 QA oversight and audits. EM-23 shall publish and share the oversight/audit schedule with a affected organizations at least 30 days in advance of planned site visit.

ii. Continuous Improvement: EM-23 oversight identifies ways to make programs more effective and efficient through improved performance and reports such opportunities to EM line managers for their consideration.

iii. Communication: EM-23 has effective processes for communicating QA issues (including corrective action plans) across EM organizations and the management chain to senior management using a graded approach that considers hazards and risks. The processes must provide sufficient technical basis to allow managers to make informed decisions. Processes for resolving disputes about oversight/audit findings and other significant issues shall also be implemented and include provisions for independent technical reviews of significant issues. To ensure that all potential issues are addressed on a timely basis, the EM-23 audit team leader shall provide a technical briefing to the site management upon conclusion of onsite visit identifying QA findings and issues, those that require a corrective action plan, significance of the finding/issue, and their significance/relevancy to safety and reliability of project. A listing and definition of most frequently used audit terms is presented in Appendix B.

iv. QA Requirements and Performance Objectives: EM-23 QA oversight evaluates performance against the approved organization specific Quality Assurance Implementation Plan (QIP). The core EM QA performance objectives and expectations for the review of QAP and QIP are maintained and kept up-to-date in *EM-HQ Review Protocol for Quality Assurance Program (QAP) and Quality Assurance Implementation Plan (QIP), dated September 2009*. Appendix C provides the QA lines of inquiry (LOIs) that are currently presented in the Review Protocol document. These LOIs are intended to serve as a generic starting point for programmatic and implementation evaluation of QA programs. More detailed LOIs need to be developed by the audit team, as needed, to fully address the specific needs and scope of each audit. These should be based on: 1) approved site-specific QAP/QIP, 2) project specific issues and concerns, and 3) scope and complexity of the topical areas and functions planned for review. For audits that provide input to the Critical Decision (CD) review and approval process, the LOIs included in EM Standard Review Plan (SRP) Review Modules (RMs) provide the generic starting point for the audit team to developed detailed audit-specific LOIs. The EM SRP RMs and the Review rotocol document are posted EM portal and EM-23 website.

v. QA Audit Reports: EM-23 audit reports shall provide sufficient technical basis and specificity to serve as a value-added roadmap for site management to develop an effective corrective action plan to improve integration of QA in day-to-day project activities. Appendix D provides the QA audit report template. EM-23 shall ensure that all audit reports are consistent and methodically document the audit process and results. Appendix E and F present the templates for documenting all audit issues that require a corrective action plan, agreed upon QA corrective action commitments and milestones, and subsequent tracking and follow-up by EM-23 audit team leader.

vi. QA Personnel Competence: EM-23 personnel and support contractors responsible for managing and performing QA oversight functions possess experience, knowledge, skills, and abilities commensurate with their responsibilities. EM-23 ensures that their personnel and contractors with oversight and audit responsibilities meet applicable qualification standards, including NQA-1. Continuing QA training and professional development activities are encouraged to supplement individual experience and provide a means to maintain awareness of changes and advances in the various fields of expertise. Consistent

with NQA-1 Requirement 18-Subparts 302 and 303: "*Audit personnel shall have organizational freedom to make the audit process meaningful and effective*".

vii. Baseline QA Oversight Program: EM-23, working with EM HQ and Field line management, establishes and implements a baseline QA oversight program that provides for an adequate assessment of programs, management systems, and assurance systems.

viii. Resources: EM-23 management works with federal and contractor management to provide sufficient resources and access to conduct an effective QA oversight program.

ix. Priorities: EM-23 QA oversight priorities are based on a systematic analysis of hazards, risks, and past performance of organizations, programs, and facilities, including previous assessment results. Projects awaiting Critical Decision (CD) review and approval milestones, higher hazard facilities or risk activities (e.g., Hazard Category) and less mature programs may be assessed more frequently and/or in more depth. The scope and results of QA reviews by external regulators (e.g., the Environmental Protection Agency) and organizations (e.g., the Defense Nuclear Facilities Safety Board) are important factors in determining oversight priorities, but they are not a substitute for effective EM oversight.

x. Performance Indicators and Measures: QA performance indicators and measures are used as one mechanism to help EM-23 identify adverse trends and promote improvements. This data is considered in a variety of management decisions, such as allocating resources, establishing goals, identifying performance trends, identifying potential problems, and applying lessons learned and good practices.

xi. Self-Assessments: EM-23 performs self-assessments of the EM-20 QA program.

xii. Annual QA Declaration: The annual Declaration provides an additional opportunity for EM-23 to review, analyze, and evaluate QA performance. Each fiscal year, EM-3 will direct each Field Manager to perform an annual QA declaration. The EM Field Manager will examine all assessment reports and QA metrics, and compare them to stated goals. The desired outcome is a conclusion stating that the EM Quality Assurance Program (QAP) is effective while focusing on improving any weaknesses and deficiencies. Declarations must meet the requirements set out in the *Annual Integrated Safety Management System (ISMS) Review Criteria and Declaration Guidance*; issued by EM's Chief Operating Officer.

b. QA Operational Awareness. Operational awareness refers to those activities taken by EM-23 personal to maintain cognizance of overall facility or activity QA status, major changes planned, and the overall QA trends and developments.

i. EM-23 reviews and monitors contractor evaluations and corrective actions for events and issues and assesses whether effective recurrence controls are identified and implemented.

c. Facilities, Operations, and Programs. EM-23 will establish and implement a QA assessment program to determine contractor compliance with requirements.

i. EM-23 QA assessments are planned and scheduled based on Critical Decision (CD) review and approval milestones, requirements, analysis of hazards and risk, past performance, and effectiveness of contractor assurance systems for organizations, facilities, operations, and programs.

ii. EM-23 QA assessments are based upon contractual requirements and include reviews of personnel qualification standards, training programs, and individual training and qualifications as they relate to quality assurance.

iii. EM-23 verifies that QA corrective actions are complete and performed in accordance with requirements before findings are closed, and requires that deficiencies are analyzed both individually and collectively to identify causes and prevent recurrence.

(1) Assess the effectiveness of EM Fields QA issues management and corrective action processes, lessons learned processes, and other feedback mechanisms (e.g., worker feedback).

(2) Validate that EM Field QA corrective actions have been implemented and are effective in resolving deficiencies and preventing recurrence.

(3) Assess the EM Fields QA reporting processes and performance to confirm that contractors meet reporting requirements for events and incidents and take effective actions to prevent recurrence of deficiencies or findings.

(4) Assess the EM field effectiveness of processes for collecting, evaluating, and reporting performance data to ascertain the accuracy, completeness, and validity of the performance measures.

d. EM Field Element Assistance.

i. Plans, Programs, and Procedures. EM Field elements transmit copies of QA documents including the organization-specific QAP and the Quality Assurance Implementation Plan (QIP) to EM-20 for review, and, where appropriate, approval. These documents include QA program plan revisions, implementing procedures, POMCs, annual declarations, assessment reports, and correspondence relating to corrective actions and other aspects of EM HQ QA Program implementation. EM Field Managers may request EM-23 assistance in reviewing draft documentation, problem solving, or QA program plan revisions.

ii. Mentoring: EM-23 may, as requested by the Field manager, provide QA training, onsite assistance, and to complement the EM Field element QA staff. EM-23 also encourages the Field elements to perform and to permit QA benchmarking assessments at or by other EM Field elements to exchange information and improve performance.

iii. Participation in field element QA assessments: EM-23, upon request by an EM Field element, may provide a HQ QA expert or arrange for the assistance of a QA expert from another EM Field element to participate in an assessment.

e. Self-Assessments. As requested by EM-3, EM-23 assists EM HQ line management during their QA self-assessments of programmatic and line management oversight processes and activities to assess whether QA requirements and management expectations are met.

11. APPENDICES:

a. Template for Scheduling EM-23 QA Oversight and Audits
b. Listing and Definition of Most Frequently Used Audit Terms
c. Sample Lines of Inquiry Presented in EM-HQ QAP/QIP Review Template
d. Template for EM-23 QA Audit Reports

e. Template for Documenting All Audit Results Requiring Corrective Action Plan and Subsequent Tracking/Follow-up by EM-23 Audit Team Leaders
f. Corrective Action Report Template

Approved by: STEVEN L KRAHN

Signature:

Name & Title: EM-20

Date: 3/29/10

Appendix A: Template for Scheduling EM-23 QA Oversight and Audits

FY	Audited Organization	Scope of Audit	Requirements Basis for the Audit	EM-23 Audit Team Leader	Planned Onsite Visit[1]

[1] For routine planned audits, EM-23 shall notify the audited organization at least 30 days prior to onsite visit. The notification shall include the audit scope and the QA requirements that will be used as the technical basis to perform the audit.

Appendix B: Listing and Definition of Most Frequently Used Audit Terms

Condition Adverse to Quality (CAQ)

A state of noncompliance with regulatory, Safety Analysis Report for Packaging (SARP), Certificate of Compliance (CoC), quality assurance requirements, or when implementing document requirements are not met. CAQs can be identified as a "Finding," "Deficiency," or "CAQ."

Corrective Action

Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Corrective Action Report (CAR)

A report to document and track corrective actions.

Issue

An issue or concern needing further evaluation which has the potential to become a condition adverse to quality, recommendation, or observation.

Recommendation

A method to document opportunities for improvement.

Observation

A condition which, if uncorrected, could become a condition adverse to quality. The following are examples of conditions that may be documented as Observations:

a. Conditions that depart from specified program requirements, but have not passed milestones requiring the condition to be completed;
b. Conditions that, while not representing a departure from specified program requirements, do represent poor engineering, management, or laboratory practices;
c. Conditions that are identified as issues for further evaluation during subsequent audits and surveillances.

Significant Condition Adverse to Quality

A condition which, if uncorrected, could have serious effect on the worker, public, and the environment. The following are examples of criteria used to determine if an identified condition is a significant condition adverse to quality:

a. a condition determined to be repetitive in nature;
b. a condition indicating a QA Program breakdown;
c. a condition that, were it to remain uncorrected, could have an adverse impact on the ability to meet regulatory, SARP, CoC, and QA Program requirements;
d. a condition that could result in invalid or indeterminate safety data;

Appendix C: Sample Lines of Inquiry Presented in EM-HQ QAP/QIP Review Template

Criterion 1 – Program[2]		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP describe the established organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work?	
	▪ Has the organization designated the senior management position responsible for the development and maintenance of the QAP/QIP?	
	▪ Are the senior managers listed in the Federal (and contractor) organizational charts responsible for assuring planning, scheduling, and providing adequate resources?	
	▪ Is there an explicit set of criteria used in applying a graded approach to the QAP/QIP? Do these criteria include meets to past quality performance?	
	▪ Does the QAP/QIP describe the relations of the roles and responsibilities, levels of authority, and interfaces in the organizational structures of both the Federal and contractor organizations that are explicitly addressed in a FRAM?	
	▪ Are senior management expectations for implementation defined and delineated?	
	▪ Are the requirements of ISM addressed and integrated into the QAP/QIP?	
	▪ Is the responsibility for integrating quality into work activities described for all workers?	
	▪ Does the QAP/QIP establish authority, direct access to management, organizational freedom, and access to work to perform their function for those personnel responsible for verifying quality achievement?	
	▪ Are the responsibilities interface, and authority of each organization clearly defined when more than one organization is involved in the execution of activities?	
	Does the QAP/QIP describe the management processes including planning, scheduling, and providing resources for the work?	

[2] ***The questions and criteria listed should be viewed as core performance expectations. The listed questions need to be modified and expanded upon based on a) specific details provided in the approved QAP/QIP,) site/ project-specific issues, and 3) scope and complexity of the audit.***

Criterion 1 – Program[2]		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Does the program address control over activities affecting quality to an extent consistent with their importance?	
	▪ Has the management established processes and procedures for project mission-related activities in a controlled manner?	
	▪ Are processes described to make employees aware of management expectations through initial indoctrination and periodic training?	
	Does the QAP/QIP define a process for grading the application of QA requirements for activities that identifies consequences, requirements, and depth/extent/rigor necessary in application of those requirements?	
	Is the process for determining the quality requirements applicable to subcontractors/suppliers and passing those requirements down through contracts clearly defined? Is it applicable to all contracts?	
	Is the QAP/QIP developed and maintained using the guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 1 on Organization?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 2 on Quality Assurance Program?	

Criterion 2 – Personnel Training and Qualification		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP identify the methodology for establishing requirements to train and qualify personnel so that they are capable of performing their assigned work?	
	▪ Is there a process to ensure that indoctrination and training commensurate with scope, complexity, importance of the activities, education, experience, and proficiency of the person?	
	▪ Is there a process for initial indoctrination and training of new hires?	
	Is there evidence that the organization has an established and documented training plan in providing continuing training to personnel to maintain job proficiency?	
	Is there a process in place to ensure that adequate resources been identified to support the selection, training, and qualification of personnel conducting work?	
	Does the training and qualification program describe the positions and functions to which it applies?	
	Is there a process in place to ensure employee-specific training needs are documented and updated as required to ensure the maintenance of competencies required by the position?	
	Is a specific organizational member responsible for operating the technical qualification program?	
	Are there provisions in the training program for further enhancement of employee skills beyond minimum requirements through independent reading or off-site training?	
	Are positions with specialized certification of skills identified, with responsibilities for achieving certification assigned?	

Criterion 2 – Personnel Training and Qualification		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Are processes in place to ensure that there is sufficient redundancy of personnel with critical skills to allow the organization's mission to be accomplished during occasional absences due to vacations and sick leave?	
	Is there a list of all skills, competencies, and personnel certifications needed for each position within the organization?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 2 on Quality Assurance Program?	

Criterion 3 – Quality Improvement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the organization has established, implemented, and documented processes to detect and prevent quality problems?	
	▪ Do work processes and procedures call for identification and reporting of quality problems?	
	▪ Does senior management policy encourage problem detection and prevention?	
	▪ Are there processes for communicating lessons leaned and performance information?	
	▪ Is there a method for categorizing the significance of quality problems?	
	▪ Is there a requirement for management to set performance goals and standards?	
	▪ Is there a process for management to establish metrics that monitor performance to identify processes needing improvement?	
	▪ Are goals and standards set by management required to be communicated to those responsible for meeting them, and is there a process for this communication?	
	▪ Is there a process for measuring and documenting quality performance to identify items, services and processes capable of improvement?	
	Does the QAP/QIP establish an approach to identify, control, and correct items, services, and processes that do not meet established requirements adequately described?	
	▪ Does this approach include the requisite discipline involvement to adequately evaluate and disposition the nonconforming item, service, or process?	
	▪ Does this approach address the identification and control of nonconforming items such that it prevents inadvertent use consistent with DOE G 414.1-3?	
	▪ Does the QAP/QIP address documentation and correction of quality problems associated with services and processes?	
	▪ Is there a procedure for removing defective or suspect equipment and materials from the workplace to prevent inadvertent use with assigned responsibilities?	
	▪ Are personnel injuries, equipment failures, and other off-normal events included in the quality problem process?	

Criterion 3 – Quality Improvement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP provide for the identification of the causes of problems and require identification of actions to prevent recurrence as a part of correcting the problem?	
	▪ Are corrective/preventive actions developed and implemented for problems/findings related to item characteristics, process implementation, or services?	
	▪ Are managers assigned responsibility for determining root causes of problems, where these problems are of sufficient severity (see DOE G 231.1-2), and pursuing a search for all occurrences related to the problem (extent of condition)?	
	▪ Are deficiencies identified as “significant" (as defined in NQA-1) documented, extent of conditions identified, and corrective/preventative actions implementation verified?	
	▪ Are completed corrective/preventative actions independently verified for implementation and closure?	
	Does the QAP/QIP describe methods for addressing cause, extent, and remedial and preventative actions for quality problems?	
	Is a process identified to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement?	
	▪ Is there a quality performance analysis system?	
	▪ Does the performance analysis system provide a mechanism for feedback to affected and related entities in the organization?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 2 on Quality Assurance Program?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 15 on Control of Nonconforming Items?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 16 on Corrective Action?	

Criterion 4 - Documents and Records		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the organization has a document control system to prepare, review, approve issue, use and revise documents to prescribe processes, specify requirements, or establish design?	
	▪ Do approved documents, such as procedures, describe key functions relating to quality criterion?	
	▪ Do documents prescribe internal processes as well as processes to oversee contractors and suppliers?	
	▪ Are policies, procedures, and plans maintained current and deployed in a manner that makes the documents readily available to users?	
	▪ Do procedures identify records that need to be created and maintained?	
	Does the QAP/QIP address how the organization specifies, prepares reviews, approves, and maintains records?	
	▪ Are new or revised requirements analyzed to determine impact on implementing procedures and/or contracts?	
	▪ Are policies, procedures, and plans maintained current and deployed in a manner that makes the documents readily available to the users?	
	▪ Are procedures developed for identifying records that need to be created and maintained?	
	▪ Are records maintained until they are transferred to permanent storage?	
	▪ Are records transferred to permanent storage in a timely manner when they are no longer needed by the organization?	
	▪ Is there an assigned responsibility for electronic records management?	
	▪ Is there an assigned responsibility for creating and implementing a disaster recovery plan?	
	▪ Are there established locations for maintaining records, and documents, and a system for searching and retrieving data from them?	
	▪ Is there an established set of criteria for classifying documents and records to establish which must be duplicated to assure preservation and which may be transferred to permanent storage or destroyed after set periods of time?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 17 on Quality Assurance Records?	

Criterion 4 - Documents and Records		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 6 on Document Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 5 on Instructions, Procedures and Drawings?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP provide a method for ensuring work that is performed consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.?	
	▪ Are the core functions and guiding principles of the DOE ISMS addressed?	
	▪ Do the approved documents meet regulatory or contract requirements?	
	▪ Are management processes that are routinely performed incorporated in the QAP/QIP?	
	Does the QAP/QIP provide methods to identify and control items to ensure their proper use?	
	▪ Is the process consistent with DOE G 414.1-3 for suspect/counterfeit items?	
	▪ Are there documented procedures and assigned personnel dedicated to the generation, revision, review and approval of instructions and work processes?	
	▪ Are there documented procedures for periodic inventory surveys and inspections to ensure work items are controlled and used properly?	
	▪ Is there an assigned responsibility for maintaining and executing emergency management plans?	
	Is there a method to maintain items to prevent their damage, loss, or deterioration adequately described?	
	▪ Does the method address the requirements of DOE O 433.1?	
	Does the QAP/QIP describe an adequate calibration and maintenance system for equipment used for process monitoring or data collection?	
	Does the process for development, use, control, and oversight of software include elements that are consistent with those described in the DOE Directives and NQA-1?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	▪ Is safety software managed and controlled in accordance with the requirements of DOE 414.1C, Attachment 2, section 5 (EM Contractors) and Attachment 5 (EM HQ and EM Field/Project offices)	
	▪ Are non-safety, quality-related software for nuclear facility or EM mission critical applications managed and controlled in accordance with the requirements of NQA-1-2004 Part II, Subpart 2.7, and "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications"?	
	▪ Do safety and quality-related software have the appropriate controls in place as required by DOE O 414.1C and NQA-1 2004, even if it is off-the-shelf?	
	Are procedures adequately developed, controlled and executed by employees?	
	▪ Do documents clearly establish the roles and responsibilities for employees?	
	▪ Do employees follow approved processes written to accomplish the EM mission, meeting regulatory and contract requirements when performing assigned tasks?	
	▪ Do employees identify and assist in making changes that improve project processes and documents?	
	Are resources assigned and scheduled established for the maintenance and calibration of equipment used to monitor work processes or data collection?	
	Are managers responsible for collecting and analyzing worker suggestions for improvements?	
	Is there an assigned responsibility for cyber security?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 5 on Instructions, Procedures, and Drawings?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 8 on Identification and Control of Items requirements?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 9 on Control of Special Processes?	

Criterion 5 - Work Processes		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 12 on Control of Measuring and Test Equipment?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 13 on Handling, Storage, and Shipping?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 14 on Inspection, Test and Operating Status?	

Criterion 6 - Design		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that the design inputs correctly translated into design documents in a timely manner?	
	▪ Has the design been developed using sound engineering/scientific principles and appropriate standards?	
	▪ Does the design incorporate applicable requirements and design bases?	
	▪ Does the design provide for appropriate acceptance, inspection, testing, and maintenance criteria to ensure continuing reliability and safety of the items? (DOE G 414.1-2A)	
	▪ Are the design inputs specified to the level of detail necessary to permit design activities to be correctly carried out and to provide a consistent basis for making design decisions, accomplishing design verification activities, and evaluating design changes?	
	▪ Are the design inputs based upon contractual requirements and customer expectations and are technically correct and complete?	
	Are the changes to design controlled in a manner commensurate with the original design?	
	▪ Are the design and specification changes, including field changes, subject to the same design controls that were applicable to the original design?	
	Is there a verification and validation process for the design?	
	▪ Is there a process to define the responsibilities of personnel verifying the design, the areas and features that require design verification, the pertinent considerations to be verified, and the extent of documentation required to document verification?	
	▪ Are the guidelines or criteria established and described for determining the method of design verification (design review, alternate calculations, or tests)?	
	▪ Have the design products been verified or validated by individuals or groups other than those who performed the design work?	
	▪ Has the design been verified or validated before approval and implementation of the design? (DS-3.4)	
	Are the design control interfaces identified and controlled?	

Criterion 6 - Design		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify that independent design reviews shall be implemented?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 3 on Design Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Part II, Subpart 2.7 on Computer Software for Nuclear Facility Applications?	

Criterion 7 - Procurement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify a documented procedures for Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration, Source Evaluation and establishing requirements to be met by approved suppliers (integrated acquisition strategy), and is there an assigned responsibility for the oversight of these procedures?	
	Does the QAP/QIP specify that appropriate personnel assigned the responsibility of creating and maintaining an approved supplier list?	
	Does the QAP/QIP specify an explicit delegation of procurement authorities to specific employees?	
	Does the QAP/QIP specify an assigned responsibility for monitoring and oversight of contractor performance, with sufficient authority to assure correction of deficiencies?	
	Does the QAP/QIP specify that oversight shall focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished?	
	Does the QAP/QIP specify how the requirements for the procurement of items and services are established?	
	▪ Do the requirements include performance specifications provided by the design authority and expectations?	
	Are procurement document changes managed and controlled at the same level as the original?	
	▪ Does this process require design authority approval of changes to their requirements?	
	Is there a system to evaluate and select prospective suppliers based on specified criteria?	

Criterion 7 - Procurement		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Is there a system for identification of potential suspect/counterfeit items and prevention of their procurement is developed and implemented?	
	▪ Does the organization have standard contract clauses for this purpose?	
	Is supplier documentation managed and controlled?	
	Does QAP/QIP address how established processes ensure that approved suppliers continue to provide acceptable items and services established and implemented?	
	▪ Is it graded to ensure safety-related items and mission critical items are subject to more rigorous methods?	
	▪ Does oversight focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished?	
	▪ Are government-furnished services/items (GFS/I) provided according to contract provisions?	
	Does the QAP/QIP have a defined process to ensure that procured items and services meet established requirements and perform as specified?	
	Does the QAP/QIP define a software quality assurance process that is implemented and executed?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 4 on Procurement Document Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 7 on Control of Purchased Items and Services?	

Criterion 8 - Inspection and Acceptance Testing		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP include a clear statement of specifications to be met by procured items, and are the qualifications of those able to develop those specifications described?	
	Does the QAP/QIP specify that personnel assigned to receive deliveries have the training and resources necessary to assure that the delivered items meet specifications?	
	Is there an assigned responsibility for assuring that Federal personnel involved in contractor oversight have the data, equipment and skills needed to assess contractor performance?	
	Does the QAP/QIP specify the process used to conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and components are fit for use and acceptable?	
	Does the QAP/QIP specify an oversight or assessment process of the contractor's program to ensure acceptability of work or items related to inspection and testing?	
	Does the QAP/QIP specify how inspections and tests specified for items, services, and processes should be performed?	
	▪ How are acceptance and performance criteria established and used?	
	Are inspection and acceptance tests planned and controlled consistent with DOE G 414.1-3?	
	Is there a system for documenting the results of inspections and tests?	
	▪ Are the procedures that address the inspection and testing process identified in the project QIP? (IT-3.1)	
	Is inspection and test equipment controlled by a process to ensure it is calibrated and maintained?	

Criterion 8 - Inspection and Acceptance Testing		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the contractor conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and components are fit for use and acceptable?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 3 on Design Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 8 on Identification and Control of Items?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 10 on Inspection?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 11 on Test Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 12 on Control of Measuring and Test Equipment?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 14 on Inspection, Test and Operating Status?	

Criterion 9 - Management Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP describe how managers, at all levels, assess their management processes?	
	▪ Are management assessments one of the means for identifying areas needing correction and/or improvement?	
	▪ Are management assessments performed by managers knowledgeable in the subject area and trained in assessment techniques?	
	▪ Do the assessments address their organization's performance with regards to such things as safety, quality, mission completion and performance against technical and financial goals and objectives?	
	▪ Are specific managers assigned the responsibility of recording, tracking and analyzing operating experience?	
	▪ Are the responsibilities for conducting a program of lessons learned and implementing its recommendations assigned?	
	▪ Are the responsibilities for scheduling and documenting assessments assigned?	
	▪ Are managers responsible for providing written procedures for assessments and for developing measures of performance?	
	Does the QAP/QIP provide for the identification and correction of problems that hinder the organization from achieving its objectives?	
	▪ Are results of management assessments documented and deficiencies tracked with corrective actions taken until corrective actions have been completed and verified?	
	Do managers take responsibility for, and directly participate in the assessments?	

Criterion 9 - Management Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the project Management Assessment process implement the intent, focus and concepts described in DOE Guide, G 414.1-1B, *Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4-1, Integrated Safety Management System Manual; and DOE O 226.1A, Implementation of Department of Energy Oversight Policy?*	
	Does management consolidate the ISMS and QA annual validation and declaration activities?	
	Does the QAP/QIP specify that senior management should be informed of the assessment results and engaged in ensuring responsible management response to identified issues?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 2 on Quality Assurance Program?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 18 on Audits?	

Criterion 10 - Independent Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP specify an independent assessment process?	
	▪ Does the QAP/QIP specify that guidance provided in DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*, should be used to develop independent assessment strategy?	
	▪ Does the independent assessment process constitute a comprehensive plan and schedule to independently assess and conduct audits of reporting organizations against technical, programmatic, administrative and quality program requirements?	
	Are independent assessments planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement?	
	Does the group performing independent assessments have sufficient authority and freedom from line management?	
	Are the personnel conducting independent assessments technically qualified and/or knowledgeable in the areas being assessed including lead auditors qualified in accordance with NQA-1?	
	Is there a process to obtain technical experts for assessments when they are not available in the organization?	
	Is there a system for reporting assessment results to responsible management, and for them to assure that action has been taken place to correct identified issues and that they will be tracked to completion/verification?	
	▪ Are deficiencies identified as "significant (as defined in NQA-1) documented, extent of conditions identified, and corrective/preventative actions implementation verified? (IA-6.1)	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 1 on Organization?	

Criterion 10 - Independent Assessment		
QAP/QIP Section(s)	**Review topic**	**Comments**
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 2 on Quality Assurance Program?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 10 on Inspection?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 11 on Test Control?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 15 on Control of Nonconforming Items?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 16 on 1 Corrective Action?	
	Does the QAP/QIP meet the requirements of ASME NQA-1 Requirement 18 on Audits?	

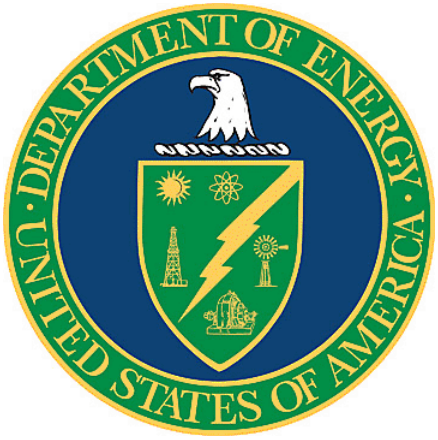
Appendix D: Template for EM-23 QA Audit Reports

Quality Assurance Audit

Office of Environmental Management (EM)

Audited Organization/Project:…..

Audit Number:…..



Onsite Audit Dates:

Report Issue Date:

Quality Assurance Audit

Office of Environmental Management (EM)

Audited Organization/Project:…..

Audit Number:…..

Prepared by: _____ **Date:** _____
xxxx
Audit Team Leader,
Office of Standards and Quality Assurance, EM-23

Concurred by: _____ **Date:** _____
xxxx,
Director, EM-23
Office of Standards and Quality Assurance

Approved by: _____ **Date:** _____
xxxxx, Director, EM-20
Office of Safety & Security Programs

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Appendix E: Template for Documenting All Audit Results Requiring Corrective Action Plan and Subsequent Tracking/Follow-up by EM-23 Audit Team Leaders

Table E.1 Audit Results Requiring a Corrective Action Plan (CAP)

Issue Description	Affected QA Requirement	Significance	Root Cause Analysis Needed? (Y/N)	Special Characteristics
		Significant Condition Adverse to Quality		Repeat Issue Software QA

Table E.2 Tracking and Follow-up on Implementation of Corrective Action Plans by EM-23 Audit Team Leaders

Proposed CAP Description	EM-23 Review of Proposed CAP	CAP Commitments Due Dates	Responsible Organization For Implementation of CAP	Actual Date of Completion For CAP Commitments	EM-23 Verification of Implementation	EM-23 Effectiveness Review
	Date: Accepted Rejected		Name, title, Contact info		Date: Accepted Rejected	

Appendix F. Corrective Action Report Template

CORRECTIVE ACTION REPORT (CAR) Pg 1 of

CAR No. _____ **Date of Discovery** _____ **Activity Evaluated Org/Rep**_____ **Location**
Immediate Corrective Action? Y____N

Requirement(s) Not Met

Deviation Description

Classification: Significant? Yes____ No____ (If yes, Corrective Actions 1, 2 , 3 & 4 Below Apply):
Is Stop Work Warranted? Yes____ No

Corrective Actions Required:

1. Remedial Actions Required and, (Always)
2. Root Cause analysis Yes____ No
3. Action to Prevent Recurrence Yes____ No____
4. Action Regarding Similar Work Yes____ No____

Response Due Date _____ (Normally 30 days after CAR approval)

Initiator Date EM Management Date

Proposed Corrective Actions (Attached) Acceptance

The above required corrective action(s) has/have been evaluated and considered acceptable, and a proposed completion date and a responsible individual has been specified.

Evaluator _____ Date _____

EM Responsible PM _____ Date _____

EM Management _____ Date _____

Completed Corrective Action Verification and Closure:

Verification Method - Audit/Surveillance/Review (Number)

Verifier: Date EM PM/Management: Date

CORRECTIVE ACTION REPORT (CAR)

(CONTINUATION)

CAR # _____ **Corrective Action Response** **Pg of**
Remedial Action (Response Always Required):
Root Cause Analysis:
Action to Prevent Recurrence:
Action Regarding Similar Work (Extent of Condition):
Proposed Completion Date: **Responsible Individual:**
Organization's Representative **Date**