



EM *Environmental Management*

safety ❖ performance ❖ cleanup ❖ closure

Quality Assurance Program Plan (QAPP) for the Oversight of QARD-Based Programs at Sites with High Level Waste and Used Nuclear Fuel

EM-QA-002

Effective Date: 04/14/2011



Quality Assurance Program Plan (QAPP) for the Oversight of QARD-Based Programs at Sites with High Level Waste and Used Nuclear Fuel

Prepared by: *Christian M. Palay* 03/18/2011
Christian M. Palay, QA Lead for HLW/UNF Oversight, Office of Standards and Quality Assurance, EM-23

Approved by: *[Signature]* 3/18/2011
Robert D. Murray, Director, Office of Standards and Quality Assurance, EM-23

Concurred by: *Kenneth G. Picha, Jr.* 3/18/11
Kenneth G. Picha, Jr., Acting Deputy Assistant Secretary, Safety and Security Program, EM-20

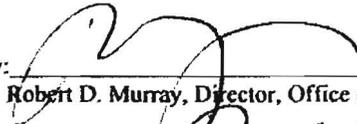
Concurred by: _____
Jack Craig, Director, Consolidated Business Center Ohio

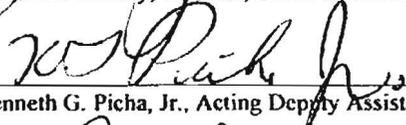
Concurred by: *Yvette Collazo* 3/23/2011
Yvette Collazo, Deputy Assistant Secretary, Technology Innovation and Development Program EM-30

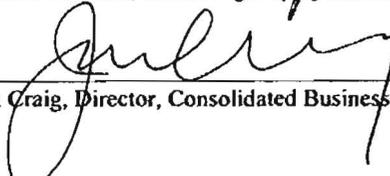
Concurred by: *Frank N. Marcinowski* 4/14/11
Frank N. Marcinowski, Deputy Assistant Secretary, Technical and Regulatory Support Program, EM-40

Quality Assurance Program Plan (QAPP) for the Oversight of QARD-Based Programs at Sites with High Level Waste and Used Nuclear Fuel

Prepared by:  03/18/2011
Christian M. Palay, QA Lead for HLW/UNF Oversight, Office of Standards and Quality Assurance, EM-23

Approved by:  3/18/2011
Robert D. Murray, Director, Office of Standards and Quality Assurance, EM-23

Concurred by:  3/18/11
Kenneth G. Picha, Jr., Acting Deputy Assistant Secretary, Safety and Security Program, EM-20

Concurred by:  3/24/11
Jack Craig, Director, Consolidated Business Center Ohio

Concurred by: _____
Yvette Collazo, Deputy Assistant Secretary, Technology Innovation and Development Program, EM-30

Concurred by: _____
Frank N. Marcinowski, Deputy Assistant Secretary, Technical and Regulatory Support Program, EM-40

Page left blank on purpose.

Introduction

This Quality Assurance Program Plan (QAPP) describes the process that the Office of Environmental Management (EM) utilizes in conducting its independent oversight of Quality Assurance (QA) programs at the High Level Waste (HLW) and Used Nuclear Fuel (UNF) sites that are a major part of the mission for EM. These QA programs at the EM HLW and UNF sites are based on revision 20 of the Quality Assurance Requirements Description (QARD), DOE/RW-0333P, from the former Office of Civilian Radioactive Waste Management (OCRWM). Prior to the establishment of this QAPP, EM conducted oversight of those QA programs jointly with OCRWM's Office of QA. A Memorandum of Agreement (MOA) with OCRWM described the oversight process, which included the understanding that EM would use OCRWM procedures and programs (e.g., Corrective Action, Records, etc.).

In light of the Administration's decision regarding OCRWM, the Secretary of Energy has established a Blue Ribbon Commission (BRC) to evaluate alternative disposal strategies for HLW and UNF. The BRC, created in January 2010, is to submit its recommendations for disposal via a draft report to the Secretary within 18 months and a final report within 24 months. In the interim, EM shall continue with established QA Programs that maintain HLW or UNF at its sites. In addition, the EM Consolidated Business Center (EMCBC) along with the EM Office of Standards and Quality Assurance (EM-23) shall continue its oversight of those QA programs without OCRWM.

This QAPP shall also describe the organizational structure, the interfaces, and the general QA program principles applicable to the oversight of HLW and UNF QA programs.

Quality Assurance Oversight Policy

Pending the BRC's recommendations and the subsequent decisions for the disposition of HLW and UNF, EM has an interim policy for its HLW and UNF Custodians to maintain their existing QARD based programs, which have been previously qualified via the EM and OCRWM MOA. To facilitate the interim policy and to provide consistency and pedigree of those QARD programs, EM shall continue to conduct QARD oversight without OCRWM in compliance with revision 20 of the QARD. It is the mandatory responsibility of EM's personnel to comply with EM QARD Program implementing documents.

Quality Assurance Program Plan

To accomplish the mission of the QARD oversight of HLW and UNF sites, EM-23 is to oversee and implement the following general principles of the QARD. EM-23's QARD Requirement Matrix provides a definitive road map from each applicable QARD section.

Work Planning

The Director of EM-23 coordinates with EM Senior Management at Headquarters (HQ) to approve budget and work scope for HLW and UNF Oversight. The Director shall appoint a QA Lead for HLW/UNF Oversight within EM-23. The QA Lead plans the implementation of that approved work scope in accordance with controlled implementing documents as required by the QARD.

Based on the input from the HLW and UNF sites and other EM HQ organizations, the QA Lead shall ensure that adequate oversight of HLW and UNF related activities are conducted appropriately and assessed on an appropriate scheduled basis.

Scheduled Frequency Tolerance

Oversight Activities addressed by EM-23 and implementing documents that specify a scheduled frequency for the performance of an oversight activity, may be extended by 25% at the discretion of the QA Lead for HLW/UNF Oversight in EM-23. The justification for each individual use of this flexibility shall be documented in accordance with the governing document for that oversight activity.

TABLE OF CONTENTS

- 1.0 ORGANIZATION
 - 2.0 QUALITY ASSURANCE PROGRAM
 - 3.0 DESIGN CONTROL
 - 4.0 PROCUREMENT DOCUMENT CONTROL
 - 5.0 IMPLEMENTING DOCUMENTS
 - 6.0 DOCUMENT CONTROL
 - 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES
 - 8.0 IDENTIFICATION AND CONTROL OF ITEMS
 - 9.0 CONTROL OF SPECIAL PROCESSES
 - 10.0 INSPECTION
 - 11.0 TEST CONTROL
 - 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT
 - 13.0 HANDLING, STORAGE, AND SHIPPING
 - 14.0 INSPECTION, TEST AND OPERATING STATUS
 - 15.0 NONCONFORMANCES
 - 16.0 CORRECTIVE ACTION
 - 17.0 QUALITY ASSURANCE RECORDS
 - 18.0 AUDITS
- SUPPLEMENT I, SOFTWARE
- SUPPLEMENT II, SAMPLE CONTROL
- SUPPLEMENT III, SCIENTIFIC INVESTIGATION
- SUPPLEMENT IV, FIELD SURVEYING
- SUPPLEMENT V, CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA

1.0 ORGANIZATION

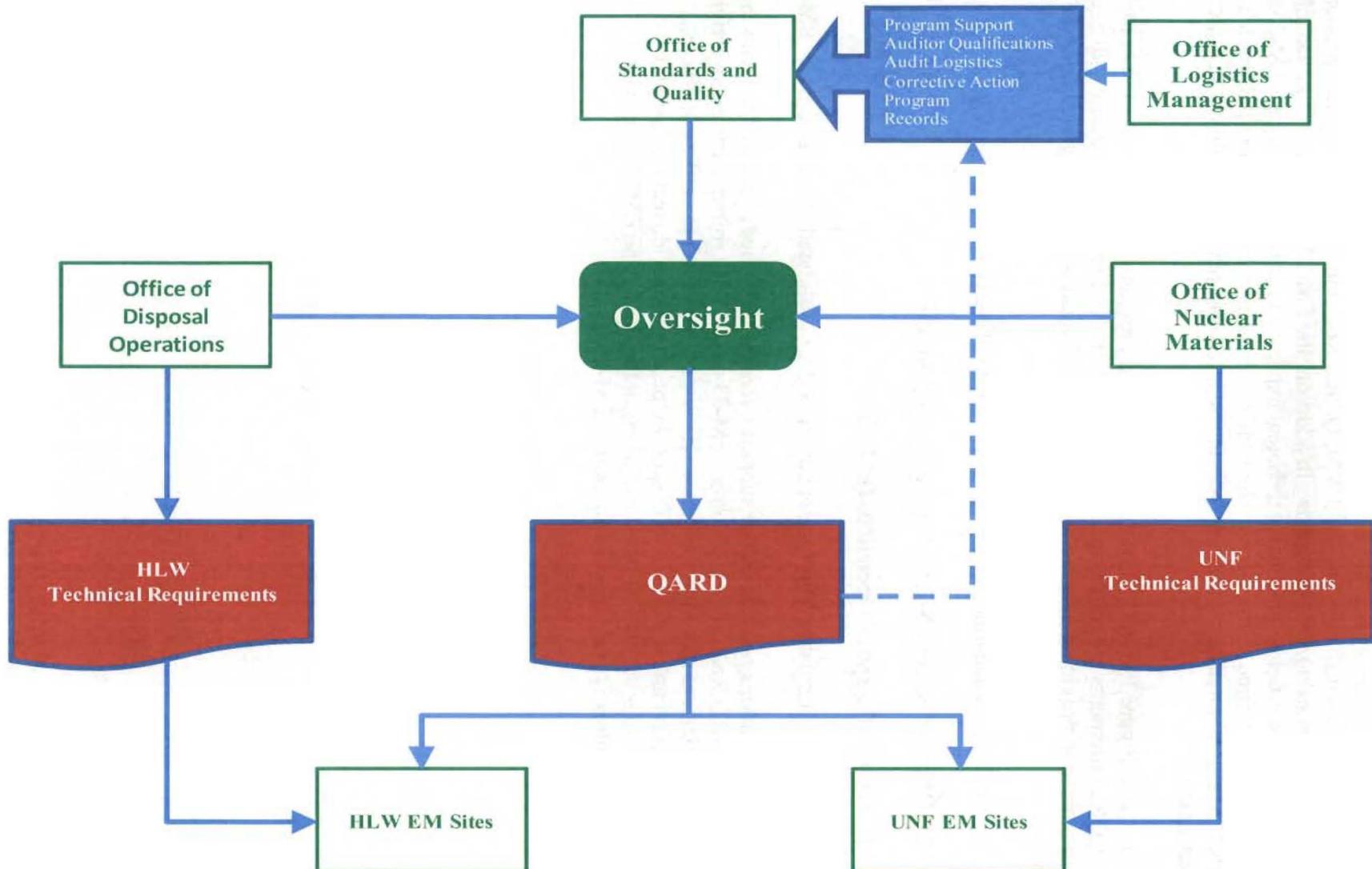
EM-23 shall establish an organizational structure to manage and accomplish the technical and quality objectives established by the OCRWM, QARD Revision 20, to provide independent oversight of those sites' QARD programs. In addition, the EM-23 interfaces with other EM HQ organizations and field elements for technical expertise to conduct oversight. EM-23 also interfaces with the Office of Logistics at the EMCBC for support in providing Subject Matter Experts (SMEs); maintaining procedures, documents, records, personnel training, qualification, and certification.

As indicated in Figure 1, oversight of the QARD based programs for sites with HLW or UNF Technical Requirements are composed of three interfacing EM HQ organizations with one other organization providing programmatic support and logistics. These organizations are as follows:

1. Office of Standards and Quality Assurance (EM-23)
2. Office of Nuclear Materials Disposition (EM-33)
3. Office of Disposal Operations (EM-43)
4. Office of Logistics Management at the EM Consolidated Business Center (EMCBC)

The above organizations perform and/or support oversight activities in accordance with this QAPP and the QARD Requirements Matrix. EM-23 has the lead role in ensuring oversight of the field sites, which are custodians for either HLW or UNF. Both the Office of Nuclear Materials Disposition and the Office of Disposal Operations provide technical support to EM-23 for conducting the QARD based programs in the field. The EMCBC provides technical, programmatic and logistical support to EM-23.

FIGURE 1. ORGANIZATIONAL STRUCTURE



Office of Standards and Quality Assurance

EM-23 is under the auspices of the Office of Safety and Security Program. The Program's many duties include the oversight of QA for EM. EM-23 is comprised of the Director and support staff. This office has been delegated the responsibility by EM Senior Management to conduct QARD oversight of the EM Custodians of HLW and UNF. The Director also provides overall program management in coordination with a designated QA lead for HLW/UNF QARD oversight.

Office of Nuclear Materials Disposition

The Office of Nuclear Materials Disposition provides the technical requirements necessary to EM sites with UNF to follow and ensure compliance with the applicable regulations and commitments for UNF. In addition, this program provides oversight support as needed.

Office of Disposal Operations

The Office of Disposal Operations provides the technical requirements necessary to EM sites with HLW to follow and ensure compliance with the applicable regulations and commitments for HLW. In addition, this program provides oversight support as needed.

Office of Logistics Management at the EM Consolidated Business Center

The Office of Logistics Management at the EMCBC has responsibility for coordinating the development, implementation, and maintenance of the HLW and UNF QARD Oversight Program. This includes providing services such as:

- Development, maintenance, configuration control, and electronic availability of policies, procedures, and other documents important to the conduct of the HLW and UNF Oversight program;
- Maintenance and tracking of lead auditor and auditor certifications and/or qualifications;
- Maintenance and storage of all records associated with the activities listed above as well as records generated during the conduct of assessments.

In addition, the Office of Logistics Management may provide technical support as needed by EM-23 to assist in the conduct of HLW and/or UNF site assessments and in the coordination of training activities. The Office of Logistics Management may also be requested to assist EM-23 with management of the HLW/UNF QARD Oversight Program.

2.0 QUALITY ASSURANCE PROGRAM

EM-23 shall establish, implement and maintain a QA Oversight Program to control work activities that affect the quality of this work conducted under the QARD program. The oversight program shall provide control over activities to the extent consistent with their importance. The oversight program requirements shall be implemented through established procedures developed to control the activities that affect the quality of the tasks performed under the QARD program.

QA Documents developed to implement the QA Program shall be reviewed and approved at a minimum by the manager responsible for the work, a qualified technical individual, and the QA Lead for HLW/UNF Oversight. Prior to performing activities that affect the quality of tasks conducted for the program, personnel shall be: 1) qualified to appropriate education and experience; 2) trained to the appropriate implementing documents; and 3) indoctrinated in the requirements of the QA Program. Verification of education, experience and training shall be documented.

EM-23 shall conduct surveillances as needed to provide quality assurance oversight of ongoing work at a frequency commensurate with the status and importance of work. These surveillances shall be performed by personnel who are independent of the task and knowledgeable of the work under surveillance.

Personnel Indoctrination, Training, Qualification and Certification shall be performed in accordance with the established procedures. The process shall ensure that indoctrination and training is completed prior to performing oversight. The EMCBC provides resources for coordination of training activities for EM-23. The EMCBC provides Lead Auditor training, qualification, and certification processes for EM-23. The training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

The QA Lead for HLW/UNF Oversight in EM-23 shall request the performance of surveillances, audits and/or management assessments of the program, and shall be responsible for planning, performing, and evaluating the effectiveness of the QA Program and reporting results through the appropriate management.

3.0 DESIGN CONTROL

Design activities are not a part of this program at this time. If design activities become a responsibility of the program at a later date, then the EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

4.0 PROCUREMENT DOCUMENT CONTROL

Procurement Document Control activities are not a part of this program at this time. If procurement document control activities become a responsibility of the program at a later date, then the EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

5.0 IMPLEMENTING DOCUMENTS

EM-23 maintains a QARD Requirements Matrix that is approved by the Director of EM-23 and is updated as necessary, to demonstrate that it develops and implements procedures responsive to the requirements of the QARD for oversight functions.

The established procedures shall include appropriate guidance to control the performance of work including, but not limited to, a description of the work/activity to be performed; the responsibilities and organizational interfaces affected by the document; technical and quality requirements; qualitative or quantitative acceptance criteria; prerequisites, limits, precautions, environmental conditions; and required QA records.

EM-23 shall structure implementing procedures so that quality is achieved and maintained by those who have been assigned responsibility for the work performance. Anyone that is not directly responsible for performing the work at HLW and UNF sites shall not verify quality achievement and compliance at the HLW and UNF sites.

6.0 DOCUMENT CONTROL

Written processes establish criteria for implementing documents and control of documents that specify technical or quality requirements. EM-23 shall perform its work in accordance with controlled procedures. If EM-23 cannot accomplish the work as described in its implementing documents or the accomplishment of such work would result in an undesirable condition, EM-23 shall stop work. The work shall not resume until EM-23 formally changes the implementing documents in accordance with established document control processes to reflect the correct work practices. Implementing documents are maintained at the EMCBC where configuration controls and electronic availability are performed using established procedures.

This QAPP establishes measures to assure documents, including changes, are reviewed for adequacy, approved for release, and distributed to and used at the location where work is being performed. Individuals, other than the preparer of the document, who are technically competent, shall review project documents, including changes, for applicability, correctness, completeness, and accuracy.

Documents shall be reviewed, approved for release and documented by the QA Lead for HLW/UNF Oversight to verify that they include appropriate quality requirements, and are in compliance with the requirements of the program.

Documents, including changes, (either in hardcopy or electronic media) that are used to perform work shall be distributed to, or made available, and used at the work location. Documents shall be identified with effective dates, and electronic database files shall be available to determine the current status of documents used to perform work. Obsolete or superseded documents shall be marked to assure they are not inadvertently used.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

Control of Purchased Items and Services activities are not a part of this program at this time. If control of purchased items and services activity become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

Identification and Control of Items activities are not a part of this program at this time. If identification and control of items activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

9.0 CONTROL OF SPECIAL PROCESSES

Special Processes activities are not a part of this program at this time. If special processes activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

10.0 INSPECTION

Inspection activities are not a part of this program at this time. If inspection activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

11.0 TEST CONTROL

Test Control activities are not a part of this program at this time. If test control activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Control of Measurement and Test Equipment activities are not a part of this program at this time. If control of measurement and test equipment activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

13.0 HANDLING, STORAGE, AND SHIPPING

Handling, Storage, and Shipping activities are not a part of this program at this time. If handling, storage, and shipping activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

14.0 INSPECTION, TEST AND OPERATING STATUS

Test and Operating Status activities are not a part of this program at this time. If inspection, test and operating status activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

15.0 NONCONFORMANCES

Nonconformance activities are not a part of this program at this time. If nonconformance activities become a responsibility of the program at a later date, then EM-23 shall develop the appropriate implementing document to ensure compliance with the QARD.

16.0 CORRECTIVE ACTION

EM-23 shall establish and maintain methods to ensure prompt identification and correction of conditions adverse to quality relative to HLW and UNF activities. EM-23 shall document and report to the appropriate levels of management conditions adverse to quality identified during oversight activities at HLW and UNF sites. EM-23 shall evaluate conditions adverse to quality for significance against established criteria as well as tracking, trending, and following to closure. EM-23 shall evaluate significant conditions adverse to quality for stop work and have a process to issue formal stop direction work from EM HQ.

17.0 QUALITY ASSURANCE RECORDS

EM-23 shall have implementing documents that describe the process of capturing and protecting quality records resulting from the performance of HLW and UNF Oversight at the EM Consolidated Business Center.

This QAPP shall establish measures for the specification, preparation, protection, storage, retention, and maintenance of quality assurance records. Implementing documents based on this QAPP shall identify the documents that are generated as QA records. Records shall be legible, accurate and complete, appropriate for the work, and identifiable to the item or activity to which they apply. Documents shall be considered records when they are complete and verified. Records may be originals or copies and shall be protected from damage, deterioration or loss until they are submitted to the Records Management System.

18.0 AUDITS

EM-23 is to perform assessments of HLW and UNF activities at the EM Sites, which includes surveillances and audits, as required by the QARD. As circumstances warrant, EM-23 may perform audits and surveillances of suppliers for EM Site Projects and EM Prime Contractors.

EM-23 and CBC will be subject to an annual internal audit to be performed by personnel that are independent of the work being audited.

The QA Lead for HLW/UNF Oversight in EM-23 is to report the status, adequacy, and compliance aspects of the HLW UNF Oversight Program to the Director of EM-23 and the Deputy Assistant Secretaries for the Office of Safety and Security Program, Technology Innovation and Development and for the Office of Technical and Regulatory Support. Through reports, meetings, audits, surveillance, and observations, EM-23 shall regularly review the scope, status, adequacy, and compliance aspects of the HLW and UNF Oversight Program to assure its effective implementation.