



## Office of Environmental Management

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*Quality Assurance Program Plan for the*

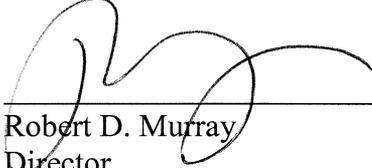
*High-Level Waste and Used Nuclear Fuel Oversight Program*

**EM-QA-002, Revision 1**

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## A. 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. With the exception of the Waste Stabilization and Disposal Project in Hanford, 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). The Waste Stabilization and Disposal Project QA program is based on revision 18 of the QARD.

Prior to the establishment of this QAPP, EM conducted oversight of those QA programs jointly with OCRWM's Office of Quality Assurance. The Memorandum of Agreement Revision 2 with OCRWM described the oversight process, which included the understanding that EM would use OCRWM procedures and programs (e.g., Corrective Action, Records, etc.).

The Principal Deputy Assistant Secretary for EM on 01/24/2011 established that in OCRWM's absence, EM Sites that possess, maintain, or produce HLW or UNF shall continue their QARD based programs in the interim until a permanent disposition path for HLW or UNF is reestablished for EM.

## B. EM Quality Assurance Oversight Policy

The Office of Standards and Quality Assurance shall conduct QARD oversight without OCRWM in compliance with revision 20 of the QARD. It is the mandatory responsibility of affected personnel to comply with the HLW and UNF Oversight Program implementing documents.

## C. Quality Assurance Program Plan

This Quality Assurance Program Plan (QAPP) describes the organizational structure, the interfaces, and the general QA program principles applicable to the oversight of HLW and UNF QA programs. The *DOE EM Oversight QARD Implementation Requirements Matrix*, EM-MTX-1.1, provides the road map for each applicable QARD requirement to the specific procedure.

## D. Work Planning

The Director of the Office of Standards and Quality Assurance coordinates with EM Senior Management at Headquarters (HQ) to approve budget and work scope for HLW and UNF Oversight. The Director of the Office of Standards and Quality Assurance shall appoint a QA Lead for the HLW and UNF Oversight Program. The QA Lead ensures 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.

## **E. Scheduled Frequency Tolerance**

Oversight Activities addressed by HLW and UNF Oversight Program 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. The justification for each individual use of this flexibility shall be documented in accordance with the governing document for that oversight activity

## **1.0 ORGANIZATION**

The Office of Standards and Quality Assurance shall establish an organizational structure to manage and accomplish the independent oversight of EM sites' QARD programs. In addition, Office of Standards and Quality Assurance interfaces with the EMCBC for support in maintaining procedures, documents, records, personnel training, qualification, and certification of Audit Team Leaders.

### **Safety, Security, and Quality Programs**

The Deputy Assistant Secretary for the Safety, Security, and Quality Programs is responsible to certify Audit Team Leaders based on the recommendation by the EM CBC. In addition, the Deputy Assistant Secretary concurs on the implementing documents for the HLW and UNF Oversight Program and approves the Corrective Action Reports that it issues to the sites that manage, possess, or produce HLW and UNF.

### **Office of Standards and Quality Assurance**

The Office of Standards and Quality Assurance under the auspices of the EM Safety, Security, and Quality Programs The Office of Standards and Quality Assurance has been delegated the responsibility by EM Senior Management to conduct QARD oversight of the EM Custodians of HLW and UNF. The Director of the Office of Standards and Quality Assurance also provides overall program management in coordination with the QA Lead.

### **Office of Technical Support and Asset Management at the EM Consolidated Business Center (CBC)**

The Office of Technical Support and Asset Management at the EMCBC has responsibility for coordinating the development, implementation, and maintenance of the HLW and UNF 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 the records associated with the activities listed above as well as records generated during the conduct of assessments.

In addition, the Office of Technical Support and Asset Management may provide technical support as needed by the Office of Standards and Quality Assurance to assist in the conduct of HLW and/or UNF site assessments and in the coordination of training activities. The Office of Technical Support and Asset Management may also be requested to assist with the management of the HLW and UNF Oversight Program.

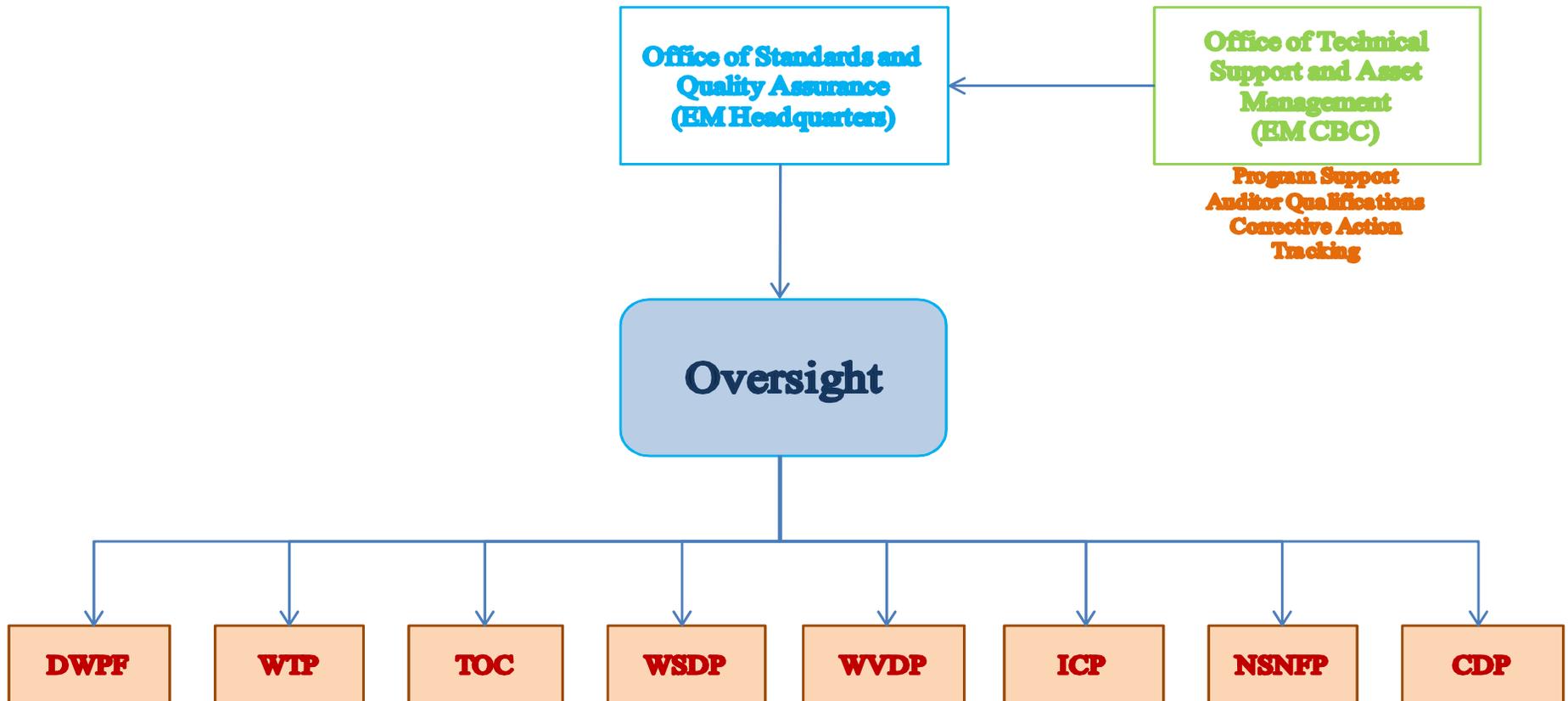
Differences of professional opinion regarding the HLW and UNF Oversight Program shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated to higher levels of management consistent with DOE Order 442.2, *Differing Professional Opinions for Technical Issues Involving Environment, Safety and Health*. For more guidance, refer to the DOE Health, Safety, and Security website ([www.hss.doe.gov/nuclearsafety/qa/dpo.html](http://www.hss.doe.gov/nuclearsafety/qa/dpo.html)).

The following individuals are responsible for establishing and executing the QA program may delegate any or all of the work to others but shall retain responsibility for the delegated work:

- Deputy Assistant Secretary for the Safety, Security, and Quality Programs
- Director for the Office of Standards and Quality Assurance
- QA Lead for the HLW and UNF Oversight Program
- EM CBC Coordinator

Such delegation shall be documented by memorandum and the memorandum shall be included in the record file for the activity that was conducted under the delegation.

FIGURE 1 – ORGANIZATIONAL STRUCTURE



- ICP** Idaho Cleanup Project at the Idaho Falls Site
- NSNFP** National Spent Nuclear Fuel Program at the Idaho Falls Site
- CDP** Calcine Disposition Project at the Idaho Falls Site
- DWPF** Defense Waste Processing Facility at the Savannah River Site
- WVDP** West Valley Demonstration Project at the West Valley Site
- TOC** Tank Farms Operating Contractor at the Hanford Site
- WTP** Waste Treatment Plant at the Hanford Site
- WSDP** Waste Stabilization Disposition Project as the Hanford Site

## 2.0 QUALITY ASSURANCE PROGRAM

The Office of Standards and Quality Assurance shall establish, implement and maintain a HLW and UNF Oversight Program to control work activities that affect the quality of this work conducted under the QARD program. The program shall provide oversight over activities to the extent consistent with their importance. The oversight program requirements shall be implemented through approved procedures developed to control the activities that affect the quality of the tasks performed under the QARD program.

The QA Lead maintains the *DOE EM Oversight QARD Implementation Requirements Matrix*, EM-MTX-1.1, which is approved by the Director of the Office of Standards and Quality Assurance and is updated as necessary, to demonstrate the relationship between the QARD to implementing documents

QA documents developed for this program shall be reviewed and approved at a minimum by the Director, of the Office of Standards and Quality Assurance a qualified technical individual, and the QA Lead. 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.

The HLW and UNF Oversight Program shall conduct surveillances as needed to provide quality assurance oversight of ongoing work at a frequency commensurate with the status and importance of work. Personnel who are independent of the task and knowledgeable of the work under surveillance shall perform these surveillances.

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 training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person. The EMCBC provides certification processes for Audit Team Leaders.

The QA Lead shall direct the management assessment of the HLW and UNF Oversight Program and shall be responsible for planning, performing, and evaluating the effectiveness of the HLW and UNF Oversight Program. The results will be reported to 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

#### **5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS**

The established procedures shall include appropriate guidance to control the performance of work including, but not limited to, a description of the 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. The Director shall structure implementing procedures so that quality is achieved and maintained by those who have been assigned responsibility for the work performance.

#### **6.0 DOCUMENT CONTROL**

The HLW and UNF Oversight Program shall perform its work in accordance with controlled implementing documents. If personnel cannot accomplish the work as described in its implementing documents or the accomplishment of such work would result in an undesirable condition, personnel shall suspend work. The work shall not resume until the QA Lead formally changes the implementing documents in accordance with established processes to reflect the correct work practices.

Implementing documents shall establish 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 and qualified, shall review project documents, including changes, for applicability, correctness, completeness, and accuracy. The Director is responsible for approving the document for release.

Documents that are used to perform work shall be made available and used at the work location. Documents shall be identified with effective dates. Only approved current implementing documents shall be made available with established procedures. Obsolete or superseded documents shall be managed in such a way to ensure that they are not available to be used.

#### **7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND COMPONENTS**

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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance 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 later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

**15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS**

Nonconformance activities are not a part of this program at this time. If nonconformance activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

**16.0 CORRECTIVE ACTION**

The HLW and UNF Oversight Program shall establish and maintain methods to ensure identification and correction of conditions adverse to quality. The HLW and UNF Oversight Program shall document and report to the appropriate levels of management conditions adverse to quality identified during oversight activities at HLW and UNF sites. The HLW and UNF Oversight Program shall evaluate conditions adverse to quality for significance against established criteria as well as tracking, trending, and following to closure. The HLW and UNF Oversight Program shall evaluate significant conditions adverse to quality for stop work conditions and coordinate with the DOE EM Field Offices to issue formal stop work orders.

**17.0 QUALITY ASSURANCE RECORDS**

The HLW and UNF Oversight Program shall have implementing documents that describe the process for the management of QA records resulting from the performance of HLW and UNF oversight activities. Implementing documents shall identify the QA records generated resulting from activities associated with the HLW and UNF Oversight Program. Records shall be legible, accurate and complete, appropriate for the work, and identifiable to the item or activity to which they apply. Records may be originals or copies and shall be protected from damage, deterioration or loss until they are submitted to the EM Consolidated Business Center. The EM Consolidated Business Center shall retain the QA records until they are needed for the final disposition of the HLW and UNF at EM sites.

## 18.0 AUDITS

The HLW and UNF Oversight Program shall perform a comprehensive system of planned and periodic QA audits to verify compliance with all applicable aspects of the QARD at sites that possess, maintain, or produce HLW or UNF.

The HLW and UNF Oversight Program shall audit areas where the requirements of the QARD program description document are applicable. The audits shall be coordinated with the sites and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work. The audits shall be conducted annually, unless a decrease in the frequency of oversight activities is determined jointly between the HLW and UNF Oversight Program and the DOE Field Office, based on the scope and complexity of work. In no case will the frequency be less than once every three years for a site performing work under an accepted QARD-compliant program.

The HLW and UNF Oversight program shall ensure that audits are scheduled at a frequency commensurate with the status and importance of the work. These audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

The HLW and UNF Oversight Program audit schedule shall be developed annually, reviewed periodically, and revised as necessary to ensure that coverage is maintained current.

The HLW and UNF Oversight Program may supplement the regularly scheduled audits with additional audits of specific subjects, as necessary, to provide any needed additional assessment for compliance and effectiveness.

The HLW and UNF Oversight Program shall schedule an audit of modified requirements at a site when a major change in the contract scope, work methodology, or organization occurs. This audit shall start a new audit period (triennial or annual).

The HLW and UNF Oversight Program shall develop and document an audit plan for each scheduled audit.

The HLW and UNF Oversight Program shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

The HLW and UNF Oversight Program will be subject to an annual internal audit to be performed by personnel that are independent of the work being audited.

## **SUPPLEMENT I SOFTWARE**

Software activities are not a part of this program at this time. If software activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **SUPPLEMENT II SAMPLE CONTROL**

Sample Control activities are not a part of this program at this time. If Sample Control activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **SUPPLEMENT III SCIENTIFIC INVESTIGATION**

Scientific Investigation activities are not a part of this program at this time. If Scientific Investigation activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **SUPPLEMENT IV FIELD SURVEYING**

Field Surveying activities are not a part of this program at this time. If Field Surveying activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **SUPPLEMENT V CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA**

Control of the Electronic Management of Data activities are not a part of this program at this time. If Control of the Electronic Management of Data activities becomes a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **APPENDIX A            WASTE CUSTODIAN INTERFACE**

For the activities in the QARD that describe requirements involving Systems Structures, and Components that are Important to Safety (ITS) and Important to Waste Isolation (ITWI), the HLW and UNF Oversight Program shall verify that those requirements have been adequately and appropriately implemented for items and activities that are important to or otherwise impact Waste Acceptance of HLW or UNF.

It is the expectation of the HLW and UNF Oversight Program that sites that maintain, possess, or produce HLW or UNF (i.e. Waste Custodians) will have analyzed the items and activities that are either important or impact Waste Acceptance. This analysis should be the basis of developing a list of those items and activities that are important or impact Waste Acceptance. This expectation is consistent with the Amplifications and Clarifications in Appendix A governing Subsection 2.2.3.

The HLW and UNF Oversight Program has no specific activities governed by Appendix A except as specified in EM-MTX-1.1. In some cases, the exceptions or exemptions for other section of the QARD (e.g., Subsection 2.2.2) contained in the Amplifications and Clarifications of Appendix A are used in EM-MTX-1.1 as justification. Refer to OCRWM interpretation, 12/30/2008, of Appendix A.

## **APPENDIX B            \*\*\*\*\*INTENTIONALLY BLANK\*\*\*\*\***

## **APPENDIX C            STORAGE AND TRANSPORTATION**

Storage and Transportation activities are not a part of this program at this time. If Storage and Transportation activities become a responsibility of the program later, then the Director of the Office of Standards and Quality Assurance shall develop the appropriate implementing document to ensure compliance with the QARD.

## **GLOSSARY**

The HLW and UNF Oversight Program adopts the glossary of the QARD. In instances that require specific definitions or clarifications, those specific definitions shall be documented within the implementing documents that require them.

**Form 5.1-1 – Record of Revision**

DOCUMENT: EM-QA-002, *Quality Assurance Program Plan for the High-Level Waste and Used Nuclear Fuel Oversight Program*

<b>Revision Number</b>	<b>Description of Changes</b>	<b>Revision on Pages</b>	<b>Effective Date</b>
0	Initial Issue	All	4/14/2011
1	General Revision	All	12/14/2012