Table of Contents

1.0 INTRODUCTION ......................................................................................................................................... 5
1.1. DEFINITIONS ................................................................................................................................................... 5
1.2. ABBREVIATIONS/ACRONYMS ......................................................................................................................... 6

2.0 APPLICATION ............................................................................................................................................. 8
2.1. OFFICE OF THE MANAGER .............................................................................................................................. 8
2.2. QUALITY ........................................................................................................................................................ 9
2.3. INTEGRATED SAFETY MANAGEMENT ............................................................................................................. 9

3.0 DISCUSSION ............................................................................................................................................. 10

4.0 GUIDANCE ................................................................................................................................................ 11
4.1. MANAGEMENT/PROGRAM ............................................................................................................................ 13
4.2. MANAGEMENT/PERSOENEL TRAINING AND QUALIFICATION ................................................................. 16
4.3. MANAGEMENT/QUALITY IMPROVEMENT ................................................................................................. 18
4.4. DOCUMENTS AND RECORDS ......................................................................................................................... 23
4.5. WORK PROCESSES ........................................................................................................................................ 26
4.6. PERFORMANCE/DESIGN ............................................................................................................................... 30
4.7. PERFORMANCE/PROCUREMENT .................................................................................................................. 32
4.8. PERFORMANCE/INSPECTION AND ACCEPTANCE TESTING ................................................................. 34
4.9. ASSESSMENT/ MANAGEMENT ASSESSMENT (INCLUDING SELF-ASSESSMENT) ............................... 36
4.10. ASSESSMENT/INDEPENDENT ASSESSMENT (INTERNAL AND EXTERNAL) ....................................... 38

5.0 ATTACHMENT 1: QUALITY ASSURANCE IMPLEMENTATION PLAN ......................................................... 42

Figures

Figure 1: The Portsmouth/Paducah Project Office Organizational Chart (Example) ........................................... 15
## Revision Log

<table>
<thead>
<tr>
<th>Rev. No.</th>
<th>Description</th>
<th>Date Implemented</th>
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</table>
| 1        | Incorporated changes based upon comments provided in November 2, 2004, Memorandum from Patrice M. Bubar, Deputy Assistant Secretary for Integrated Safety Management and Operations Oversight. Significant changes made to the QAP include:  
1. Including clear identification of consensus standards (DOE regulation/Order and NQA-1)  
2. Incorporating specific implementation procedures (utilizing ORO and PORTS existing procedures until PPPO directives are issued).  
3. Identifying the applicability of Technical Qualification Program requirements for DOE personnel assigned responsibilities.  
4. Differentiating DOE and contractor actions related to QAP implementation | February 18, 2005 |
| 2        | Incorporated changes based upon electronic mail message provided November 22, 2005, from Colette Broussard, EM-3.2. Because prior EM direction anticipated new requirements contained in DOE O 414.1C, no substantive changes were made. Specific changes made to the QAP include:  
1. Updated the QAP to reference the new Order  
2. Updated sections pertaining to implementation of procedures and authority to reflect current status of PPPO Procedures | February 24, 2006 |
| 3        | Incorporated changes from Dr. Ines R. Triay, EM-3, memorandum dated March 28, 2006 as follows:  
1. All reference to DOE P 450.5, Line Environment, Safety and Health Oversight Policy, was deleted.  
2. The reference to the Office of Oversight (EH-2) was changed to the Office of Independent Oversight (SP-40) | April 30, 2006 |
| 4        | 1. Changed responsibilities from Senior Technical Advisor to Quality Assurance Manager.  
2. Added definitions and acronym sections  
3. Updated Organization Chart and made it an example.  
5. Added 10 CFR 851 as being applicable  
6. Changed FR to performing walkthroughs instead of surveillances and participating in assessments as assigned.  
7. Added references to EM-QA-001.  
8. Updated requirements and crosswalk to NQA-1-2004 and addenda through 2007  
9. Updated DOE Orders and Policy references. | May 1, 2009 |
| 5        | Incorporated comments from Environmental Management Headquarters review as follows:  
1. Expanded references to include EM-QA-001.  
2. Added Management Expectations and expanded identification of applicable NQA-1 requirements in Section 4.  
3. Updated Organization Chart example.  
4. Changed references to Senior Technical Advisor to Nuclear Safety Oversight Lead.  
5. Updated PPPO procedure references.  
6. Changed Attachment title to “Quality Implementation Plan.”  
7. Made technical editing corrections (grammar, spelling, etc.) throughout. | February 10, 2010 |
| 6 | 1. Incorporated changes introduced by DOE O 414.1D: |
|   | 4. Add discussion of expectations for validation and verification of computer models; and |
|   | 5. Add Transportation QA requirements from DOE O 460.1C, *Packaging and Transportation Safety*. |
|   | 6. Updated DOE, ISMS, NQA-1, etc. references and reconciled overall document. |
| Date | October 3, 2013 |
| 7 | 1. Update DOE and PPPO references and reconciled overall document. |
|   | 2. Address audit findings from EM-43’s EM-PA-16-12 audit of the PPPO QA Program. |
| Date | March 2017 |

**CONCURRENCE:**

PPPO Quality Assurance Lead

Russell McCallister

[Signature]

[Date] 3/7/17

PPPO Deputy Manager

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[Date] 3/13/17

**APPROVAL:**

PPPO Manager

Robert E. Edwards, III

[Signature]

[Date] 3/13/17
1.0 INTRODUCTION

To accomplish the Department of Energy (DOE) Portsmouth/Paducah Project Office (PPPO) missions and objectives, the PPPO and its contractors are responsible for a wide range of work activities. These include:

- basic and applied research;
- construction, operation, modification;
- decommissioning, surveillance, and maintenance;
- depleted uranium hexafluoride (DUF6) conversion;
- waste management and environmental remediation of DOE facilities and sites; and
- management and oversight functions relating to these activities.

To help fulfill this mission and these objectives and to ensure that the risks and environmental impacts are identified and minimized and that safety, reliability, and performance are optimized, it is the policy of PPPO to establish, implement, and maintain an effective Quality Assurance (QA) program that supports compliance with applicable Federal, State, and local regulations and DOE Orders (O) and requirements. The criteria of 10 CFR 830, Subpart A, Quality Assurance Requirements, (i.e., QA Rule) and DOE O 414.1D, Quality Assurance, and the American Society of Mechanical Engineers’ (ASME) NQA-1-2008 and addenda through 2009, Quality Assurance Requirements for Nuclear Facility Applications, (hereafter referred to as NQA-1) are used to provide a quality management system for accomplishing and assessing DOE work in accordance with requirements. The Office of Environmental Management Quality Assurance Program (EM-QA-001, Rev. 1) (EM QAP) provides additional interpretation and communication of the application of these requirements. The PPPO QA system is compliant with and integrated with the Integrated Safety Management Policy (ISMP) required by DOE Policy (P) 450.4A, Integrated Safety Management Policy, and Executive Order (EO) 13514, Federal Leadership in Environmental, Energy, and Economic Performance and EO 13423 Strengthening Federal Environmental, Energy, and Transportation Management. These federal mandates ensure the ISMP is effectively implemented. In addition to DOE O 414.1D Quality Assurance, this Quality Assurance Program Plan (QAP) also encompasses packaging and transportation QA requirements of DOE O 460.1C, Packaging and Transportation Safety. The quality management system provides processes and tools for ensuring that the integrated ISMP achieves its objectives. It is the intent of PPPO to establish a culture and work environment that encourages setting and maintaining effective standards, identifying and resolving problems, emphasizing a continued pursuit of improvement, and fostering mutual respect and effective communication within PPPO and among its contractors, their suppliers and subcontractors, the public, and other stakeholders.

1.1. Definitions

A **Condition Adverse to Quality (CAQ)** is an all-inclusive term used in reference to any of the following:

- problems,
- failures,
- malfunctions,
• deficiencies,
• defective item, and
• nonconformances.

**Corrective action** is an action undertaken to eliminate the cause(s) of a condition adverse to quality (CAQ) in order to prevent the repetition of the CAQ.

**Independent Assessment** is an assessment conducted by individuals within the organization but are independent from the work or process being evaluated or by individuals from an external organization or operation.

**Management Assessment** is a periodic introspection self-analysis, conducted by management, to evaluate management systems, processes, and programs ensuring the organization’s work is properly focused on achieving desired results.

**Quality improvement** is a management process that is carried out to improve an item, service, product, or process. All aspects of work activities and the management system are subject to continuous improvement through an assessment and feedback process. Feedback originates from workers, customers, and suppliers. The process includes use of corporate operating experience (lessons learned) from local and other organizations. Identified improvement actions are also shared with other organizations.

The **Responsible Organization Leads** are the senior manager held responsible and accountable for successfully developing, safely executing, and managing DOE projects within the project baseline (performance, cost, schedule, and scope).

**Self-Assessment** is a critical and objective evaluation of performance against expectations for excellence, established standards, and practices to identify whether processes or activities meet specified requirements; whether the processes or activities are adequate and effective and properly focused on achieving desired results; and, to identify opportunities that would contribute to continuous improvement performed by the organization responsible for the performance of the activity.

A **Significant Condition Adverse to Quality (SCAQ)** is a condition adverse to quality, which, if left uncorrected, could have a serious effect on safety, the environment, or operability.

**Subject Matter Expert (SME)** is an individual with qualifications and experience in a particular field or work process; an individual who by education, training, and/or experience is a recognized expert on a particular subject, topic, or system. This is equivalent to the NQA-1 definition of technical specialist.

### 1.2. Abbreviations/Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASME</td>
<td>American Society of Mechanical Engineers</td>
</tr>
<tr>
<td>BCCB</td>
<td>Baseline Change Control Board</td>
</tr>
<tr>
<td>CAMP</td>
<td>Corrective Action Management Program</td>
</tr>
</tbody>
</table>
2.0 APPLICATION

As identified in PPPO-2649582, **PPPO Management Plan** (MP), the Manager of the PPPO is responsible for implementing the Functions, Responsibilities, and Authorities identified in the MP. This includes the implementation of a QAP. In order to perform these functions, the PPPO organization is structured with a single management office and two operations oversight group offices. Their addresses are:

- **Office of the Manager**
  - U.S. Department of Energy
  - Portsmouth Operations
  - Oversight Group Office
  - 3930 U.S. Route 23 South
  - Piketon, Ohio 45661

- **U.S. Department of Energy**
  - Paducah Operations
  - Oversight Group Office, C-103
  - 5501 Hobbs Rd
  - Kevil, Kentucky 42053

The QAP establishes QA Program requirements for all quality-affecting programs, projects, and activities sponsored by PPPO. PPPO and the organizations/contractors supporting PPPO shall implement the applicable requirements of the QAP within their systems for management and control of these activities.

It is the responsibility of all personnel assigned to PPPO-sponsored activities to achieve quality, identify CAQs, and recommend improvements. PPPO management establishes and cultivates principles and practices that integrate QA Program requirements and performance standards into their management approach and control systems. Although the Office of the Manager is located in the Lexington Office, frequent and routine site interactions occur by this office at both operations oversight group offices. Specific organizational roles and responsibilities are identified in the following sections.

2.1. **Office of the Manager**

Effective implementation of the PPPO QA Program is dependent on the efforts at all levels of the program participants. The PPPO Manager is responsible for defining quality, developing appropriate plans to attain quality, and supporting workers in pursuit of quality. Specific responsibilities associated with the QAP include the following:

1. Develop and implement an approved QAP governing the PPPO work, including software development/use, in accordance with requirements detailed in DOE O 414.1D, Section 4: Requirements; suspect/counterfeit items (S/CI) prevention requirements; DOE Headquarters Corrective Action Management Program (CAMP) requirements; and Safety Software Quality requirements. In addition, the QAP shall meet the requirements of EM-QA-001, Rev. 1, **EM Quality Assurance Program (QAP)** and NQA-1 2008 and addenda through 2009 version. For the PPPO, the Quality Assurance Lead is assigned the responsibility for ensuring these actions are performed.
2. Submit the PPPO QAP to DOE’s Office of Environmental Management (i.e., EM-HQ) for review and approval for changes that are more than just minor editorial in nature.

3. Review and forward new and revised QAP for PPPO contractors to the appropriate approval authority. The scope and rigor of review will be graded based on the status of the contractor’s scope of work and prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification). The QAPs for PPPO contractors must be reviewed and approved or rejected within 90 days of receipt. Depending on the requirements of the specific contract, if a contractor has the option and does not wish to submit a QAP, they shall implement the PPPO QAP. If a contractor chooses to implement the PPPO QAP, they must provide a QIP and supplemental information for requirements that may not be adequately covered by the PPPO QAP.

4. Perform independent assessments of contractor organizations to evaluate the adequacy of the contractor’s QAP and QAP implementation effectiveness. The frequency and scope of assessments are based on the status of prior quality performance and any third-party QAP certification. Other suitable methods may be used in combination with independent assessments.

5. Report assessment results periodically to DOE’s Office of Environmental Management (i.e., EM-HQ) describing the effectiveness of field element and contractor QA implementation.

6. Prepare and implement a Corrective Action Plan (CAP) to address all findings (including those findings from external agencies) required for entry into its external agency’s tracking system or designated agency tracking system. PPPO shall track PPPO CAP commitments in a PPPO Management Tracking System (MTS).

7. Complete the CAP and conduct follow up review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and follow up on any report recommendations.

8. Responsible for ensuring adequate planning, scheduling, and resources are provided to implement the QA Program.

2.2. Quality
This QAP provides information on principles, requirements, and practices used to establish and implement an effective PPPO Quality Assurance Program in accordance with the requirements of 10 CFR 830 Subpart A, DOE O 414.1D, EM-QA-001, Rev. 1, and NQA-1. This QAP also describes the relationship of quality assurance to other organization processes that aid compliance with Integrated Safety Management System (ISMS) requirements. The requirements described in this QAP are based on the principle that work shall be planned, documented, performed under controlled conditions, and periodically assessed to establish work item/activity quality and process effectiveness and to promote improvement. Management, line personnel, and organizations are responsible for planning and achieving quality and promoting continuous improvement. The PPPO QA Lead is responsible for the verification of the achievement of quality.

2.3. Integrated Safety Management
DOE P 450.4A expresses a fundamental expectation that all work be performed safely. Effective implementation of the QAP requirements will also provide processes and tools to support
principles and functions of the SMS Policy and related portions of the DOE acquisition regulation (DEAR, 48 CFR 970.5204-2). The QAP and the SMS Policy have been selected as DOE management systems.

The DOE fundamental quality expectation is that all work meets established requirements. In this regard, the Quality Management System (QMS) ensures compliance with the approved standards set, so that the expectation for safe work within controls is met (i.e., approve plans, develop and implement procedures, training, etc.). This also ensures each worker, the environment, and the public are reasonably protected from harm. The DOE quality, environmental, security, and safety requirements share a Project Management System’s approach to achieving their objectives. As such, they offer many opportunities for sharing a single document (QAP or ISMS description) to describe how the organization intends to implement the requirements. Likewise, a single process (e.g., procedures and plans) that satisfies quality, environmental, security and safeguards, and safety requirements should be employed. Shared attributes of quality and safety management systems include:

- expectations for implementation (DEAR 48 CFR 970.5204-2 (c))
- documentation of the Management System (ISMS Guiding Principle 7)
- clear roles and responsibilities (ISMS Guiding Principle 2)
- balanced priorities (resources) (ISMS Guiding Principle 4)
- feedback and improvement (ISMS Core Function 5)
- line management responsibility (ISMS Guiding Principle 1)
- competence and qualifications (ISMS Guiding Principle 3)
- standards and controls for work (ISMS Guiding Principle 5 and Core Function 4)
- graded and tailored controls (ISMS Guiding Principle 6)

The QMS also supports implementation of Executive Order (EO) 13693, Planning for Federal Sustainability in the Next Decade and DOE O 226.1B, Implementation of Department of Energy Oversight Policy.

3.0 DISCUSSION

The quality attained in a product or service is described by the extent to which that product or service satisfies the requirements, needs, and expectations of the customer. The attainment of quality is the responsibility of each member of an organization. The quality requirements of 10 CFR 830 Subpart A and DOE O 414.1D provide the framework for a results-oriented management system that focuses on performing work safely and meeting mission and customer expectations while allowing the organization to become more efficient through process improvement. The development and implementation of a QMS, integrated throughout the organization, will improve performance and provide assurance that the requirements of DOE O 414.1D, Quality Assurance, EM-QA-001, Rev.1, EM QAP, NQA-1, and the DOE Safety Management System Policy/Acquisition Regulation (DOE P 450.4A, 48 CFR 970.5204-2, and 970.1001) are being satisfied.

PPPO uses the QAP to guide its QMS for federal employees. PPPO conducts awareness training for this QAP. The QAP will be reviewed periodically as determined by PPPO’s procedure
requirements by the PPPO QA Lead to assess the effectiveness of the QAP and develop revisions as necessary.

*Note regarding flow down of requirements and applicability*
Although a directive may have requirements that are applicable to a contractor, the contractors who have Standards/Requirements Identification Documents (S/RID) or Work Smart Standards (WSS) sets do not automatically include any or all of the requirements from the applicable directives in their S/RID or WSS sets. Applicable directives are reviewed and added to the new/existing S/RID or WSS sets in accordance with the Contract Management Plans by the Lexington Operations Group Contracting Officer. Directives are identified by contract, or modification to a contract, throughout the life of a contract. The Operations Oversight Group offices are responsible for ensuring contractors comply with their requirements as discussed above.

Specific compliance validation and general oversight of contractor management systems are provided in separate procedures in accordance with DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*

### 4.0 GUIDANCE

When reviewing NQA-1, the term nuclear facility as used by PPPO refers to those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition. Over the road transportation of radioactive materials is not included in the definition a nuclear facility. Included are activities or operations that:

1. Contain or store radioactive liquid or solid waste, fissionable materials, or other radioactive material;
2. Conduct separations operations;
3. Conduct cleanup and decontamination operations that potentially involve radioactive material;
4. Perform environmental remediation or waste management activities involving radioactive materials; or
5. Deactivate or decommission items with radioactive materials and/or fissionable materials that in such form or quantity can present a potential nuclear hazard.
6. Involve construction projects that address remediation activities at the sites.

PPPO and its contractors adopt NQA-1, as required by EM QAP Part I and Part II, in a graded approach. For the application of the requirements and guidance, the use of the term “nuclear power plant” shall not be used a limiting factor. Part III of NQA-1 provides explanatory information and guidance for use by contractors in developing and implementing their programs. Part IV of NQA-1 provides comparisons and additional guidance for the application of NQA-1, and the use of the subparts within Part IV can enhance the contractors QAP. Unless otherwise approved by PPPO in the contractor’s QAP, NQA-1 Parts III and IV guidance will be considered
applicable to the work scope. If additional standards are required to address unique/specific work activities, the standards shall be identified in the contractor’s QAP and approved by PPPO.

**Graded Approach**

The scope, depth, and rigor of PPPO management systems are driven by requirements and guidance documents for specific application. A graded approach is used when a single or uniform method of applying a requirement across PPPO activities does not add value or reduce risk. The graded approach is the process by which the level of analysis, documentation, verification, and other controls necessary to comply with QMS requirements are developed to consider hazards or risks to determine the appropriate management system for the activity based upon function, complexity, consequence of failure, reliability, repeatability of results, and economic considerations. The following applications are examples of PPPO activities where a graded approach should be applied:

- preparing assessment schedules,
- performing surveillance activities,
- performing technical reviews,
- controlling office and safety software applications, and
- controlling office procedures.

The extent of management and QA controls applied to an item or activity will vary as a function of the degree of confidence needed to achieve the desired quality of the item or activity to achieve adequate protection of workers, the public, and the environment, taking into account the work performed and associated hazards. However, the graded approach process cannot be used to eliminate a requirement by a zero grade.

PPPO is responsible for defining and approving work to be performed to deactivate, decommission, and environmentally remediate both sites safely and ensure depleted uranium hexafluoride conversion is safely implemented. This responsibility includes identifying and evaluating risk levels from both a safety and a mission perspective; identifying and securing resources necessary to complete the defined scope of work; and increasing and improving effectiveness and efficiency of the PPPO and its contractor(s). When deciding the oversight of technical activities and issues, consideration shall be given to hazards or risks associated with the activity/issue and controls put in place to address hazards or risks. The PPPO activities are accomplished through deliberate quality planning and are based on activity-specific factors, such as:

- relative importance to safety, safeguards, and security,
- magnitude of any hazard or risk involved,
- life-cycle stage of a facility,
- impact/consequences on programmatic mission of a facility,
- particular characteristics of a facility or activity,
- nuclear safety classification or hazard category of the item or activity,
- adequacy of existing safety documentation,
- complexity of products or services involved, and
- history of contractor incidents at the site or in a specific facility.
PPPO QAP Organization
This QAP implements the flow down of the QA requirements of EM QAP. Therefore, the sections below are organized to match the implementing sections of EM-QA-001, Rev. 1. Also included are references to the DOE O 414.1D and NQA-1 requirements. The Quality Assurance Implementation Plan (QIP), which includes the necessary procedures to implement the QAP, is provided as Attachment 1.

4.1. Management/Program

Applicable Requirements

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 1 Management/Program Requirements</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.</td>
<td>Requirement 1 – Organization</td>
</tr>
<tr>
<td>(b) Establish management processes, including planning, scheduling, and providing resources for the work.</td>
<td>100 - Basic</td>
</tr>
<tr>
<td></td>
<td>200 - 202 Structure and Responsibility</td>
</tr>
<tr>
<td></td>
<td>300 - Interface Control</td>
</tr>
<tr>
<td></td>
<td>Requirement 2 - Quality Assurance Program</td>
</tr>
<tr>
<td></td>
<td>100 - Basic</td>
</tr>
<tr>
<td></td>
<td>200 - 202 Indoctrination and Training</td>
</tr>
<tr>
<td></td>
<td>300 - 305 Qualification Requirements</td>
</tr>
<tr>
<td></td>
<td>400 – Records of Qualification</td>
</tr>
<tr>
<td></td>
<td>500 – Records</td>
</tr>
</tbody>
</table>

Non-Mandatory Appendix 1A-1 was considered in defining the quality organization during development of the QAP.

Non-Applicable Requirements
None

Management Expectations
- The PPPO QAP provides specific guidance to ensure flow-down of the DOE O 414.1D, EM QAP, and NQA-1 requirements into PPPO work activities.
- PPPO employees shall be familiar with and participate in the implementation of the PPPO QMS as outlined in the QAP and associated QIP.
- The QAP is a “living” document.

Approach to Implementation
The principal factor representing performance of PPPO is quality of its products and services. The QAP requires that PPPO develop, document, and maintain an effective quality program. The goal of the QMS is delivery of safe, reliable products and services that meet or exceed the DOE’s requirements, needs, and expectations. To do so, the QMS describes methods for planning, performing, and assessing adequacy of work, including work assigned to parties outside the organization. DOE directives and other requirements applicable to the PPPO management system are specified in the QAP.
The PPPO QMS is intended to support and function with DOE’s ISMS. The QMS focuses on accomplishing mission properly and safely. Therefore, every component and employee of the organization are included within the QMS’s scope, which addresses organizational structure and interfaces, functional responsibilities, and levels of authority.

**Organizational Structure**

The PPPO is organized within the existing framework of the DOE as noted in Figure 1. The PPPO Manager is a field element manager, and is the most senior person within the organization and is ultimately responsible for quality and safety. Within the QA organization, the PPPO QA Lead is independent and reports directly within the PPPO Management structure. Site QA Specialists administratively report to the Site Lead as their work activities are primarily assigned at the site. However, to assure their independent function within the QA organization, they technically report to the PPPO QA Lead through a dotted reporting structure.

The PPPO MP further identifies delegation of implementation and oversight of those programs to qualified staff, including the QA Lead. In addition to the QAP, PPPO-3184699, *PPPO Oversight Program Plan* describes the overall PPPO approach to conducting oversight. The PPPO is organized through the three sites (PAD, LEX, and PORTS) to accomplish departmental mission requirements. However, Quality Assurance is an interdisciplinary function involving all PPPO personnel and should not be regarded as the sole responsibility of the QA Organization.

**Implementing Procedures and Authority**

The PPPO uses the MP to address Operations Oversight Group office functions and authorities. The PPPO MP identifies the PPPO Nuclear Safety Oversight Lead (NSOL) as having the responsibility to develop oversight program requirements. All PPPO employees shall be familiar with the QAP and those responsible for implementation shall be trained on the requirements of the QAP and its QIP.

The QAP will be reviewed periodically to assess the effectiveness of the QAP and generate revisions as necessary. The PPPO Manager is responsible for ensuring adequate planning, scheduling, and resources are provided to implement the QA Program.

PPPO-2649582, *Portsmouth/Paducah Project Office Management Plan*, establishes the technical requirements and responsibilities to manage the DOE PPPO. The MP outlines the responsibilities for DOE technical oversight and serves as the following:

- Functions, Responsibilities, and Authorities Document
- PPPO Safety Management System Description
- Project Management Plan
All management plans are dynamic, will periodically be revised, and will satisfy the requirements of DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, and its implementing manual DOE M 413.3-1, *Project Management for The Acquisition of Capital Assets, as well as other DOE Orders*.

**Interface Control**

The PPPO Responsible Organization Leads (ROLs) are ultimately responsible for the quality achievement of the work for their respective areas/functions. These ROLs coordinate QA needs through either the PPPO QA Lead or site QA Specialists. PPPO technical support contractors provide additional QA assistance at each site. In addition to their line management reporting responsibilities, the PPPO prime contractors’ respective QA Managers provide contractual reporting through the Contracting Officer to the PPPO QA Lead for QA issues. This dual reporting ensures that the QA program maintains sufficient independence from line management for quality verification.

![Figure 1: The Portsmouth/Paducah Project Office Organizational Chart (Example)](image-url)
4.2. Management/Personnel Training and Qualification

**Applicable Requirements**

<table>
<thead>
<tr>
<th><strong>DOE O 414.1D – Criterion 2</strong></th>
<th><strong>ASME NQA-1 Requirements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Management/Personnel Training and Qualification</td>
<td>Requirement 2 – Quality Assurance Program</td>
</tr>
<tr>
<td>(a) Train and qualify personnel to be capable of performing their assigned work.</td>
<td>100 - Basic</td>
</tr>
<tr>
<td>(b) Provide continuing training to personnel to maintain their job proficiency.</td>
<td>200 - 202 Indoctrination and Training</td>
</tr>
<tr>
<td></td>
<td>300 - 305 Qualification Requirements</td>
</tr>
<tr>
<td></td>
<td>400 - Records of Qualification</td>
</tr>
<tr>
<td></td>
<td>500 - Records</td>
</tr>
<tr>
<td></td>
<td>Non-Mandatory Appendices 2A-1 and 2A-3 were considered to aid in development of the QAP.</td>
</tr>
</tbody>
</table>

**Non-Applicable Requirements**

None

**Management Expectations**

- PPPO and technical support contractor personnel shall have the required training, qualifications, and certifications necessary to effectively and compliantly execute their assigned responsibilities according to minimum labor requirements established in their respective contracts.
- Employee-specific training needs shall be documented and updated as required to ensure the maintenance of competence required by the position.

**Approach to Implementation**

A fundamental requirement for effective accomplishment of PPPO mission is that all personnel be capable of performing their assigned tasks as they affect quality. The PPPO qualification and training processes ensure that personnel achieve and maintain required capabilities. Principle 3 of the ISMS policy contains a similar expectation for personnel to possess experience, skills, and abilities commensurate with their responsibilities.

**Qualification of Personnel**

The PPPO uses the U.S. Office of Personnel Management (OPM) qualification standards to identify the minimum education, training, and/or experience level required by each PPPO position. Additionally, the PPPO uses the Technical Qualification Program (TQP), along with the supporting technical qualification standards established by DOE O 426.1 Chg 1, *Federal Technical Capability*, to ensure that employees have the requisite technical competency and capability to support the mission of the PPPO. The TQP forms the basis for the development and assignment of DOE personnel responsible for ensuring the safe operation of defense nuclear facilities. Detailed operating requirements for the TQP and Functional Area Qualification Standards are described in DOE O 426.1 Chg 1, *Federal Technical Capability*. In addition, specific qualification programs have been developed for the Facility Representatives (PPPO-2691323, *Facility Representative Program Plan*) and the Safety Systems Oversight Engineers...

PPPO personnel and technical support contractors who participate in QA oversight under PPPO-2533131, *Assessment and Surveillance Process – Rev. 3* are certified by the responsible line manager as Auditors or Lead Auditors, consistent with NQA-1, Requirement 2, Section 303.

**Training**

The training and qualification programs as described in PPPO-M-426.1-0, *PPPO Technical Qualification Program Plan* provide PPPO personnel with knowledge of correct and current processes, methods, and requirements to accomplish assigned tasks. The PPPO ensures personnel complete TQP, site-specific training for assigned duties, required reading, and self-study training requirements as identified in DOE/PPPO documents. Completion of these activities enable personnel to understand fundamentals of work, associated hazards, context within which work is performed, and the reasons for any special work requirements. A record of completed training is maintained with individual training development plans.

Initial and continuing education and training programs are provided to employees to develop new skills, maintain or improve current job performance, and enhance existing skills. The PPPO, through the applicable site or organizational manager, is responsible for ensuring personnel are fully qualified for their position.

**Individual Training Development Plans**

Training plans are prepared for all functions, including those personnel responsible for managing, planning, and controlling work. Initial training prepares personnel to perform the job. Continuous training maintains and promotes improved job performance.

**Implementing Procedures and Authority**

The PPPO has implemented PPPO-M-426.1-0, *PPPO Technical Qualification Program Plan*, to satisfy the requirements of this section of the QAP. The NSOL has responsibility to develop and implement program requirements. Administrative staff at each Operations Oversight Group office is responsible for distribution of training communications from the Manager’s Office and collection of completed training documentation for their specific office. The administrative staff ensures completed training documentation is forwarded to the Human Resource Management Analyst for inclusion in the individual’s training file.
4.3. Management/Quality Improvement

Applicable Requirements

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 3</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management/Quality Improvement</td>
<td>Requirement 2 – Quality Assurance Program</td>
</tr>
<tr>
<td>(a) Establish and implement processes to detect and prevent quality problems.</td>
<td>100 - Basic</td>
</tr>
<tr>
<td>(b) Identify control and correct items, services, and processes that do not meet established requirements.</td>
<td>200 - 202 Indoctrination and Training</td>
</tr>
<tr>
<td>(c) Identify the causes of problems, and include prevention of recurrence as part of the corrective action planning.</td>
<td>300 - 305 Qualification Requirements</td>
</tr>
<tr>
<td>(d) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.</td>
<td>400 - Records of Qualification</td>
</tr>
<tr>
<td></td>
<td>500 - Records</td>
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<table>
<thead>
<tr>
<th>Requirement 15 – Control of Nonconforming Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 – Basic</td>
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<tr>
<td>200 – Identification</td>
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<td>300 – Segregation</td>
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<td>400 – 405 Disposition</td>
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</tbody>
</table>

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<tr>
<th>Requirement 16 – Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 – Basic</td>
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</tbody>
</table>

Non-Mandatory Appendices 2A-4, 16A-1, and Subpart 4.5 considered in development of the PPPO QAP.

Non-Applicable Requirements
None

Management Expectations

- Management shall set performance goals and standards.
- Management shall establish metrics, or other quantifiable methods, that monitor performance to identify processes needing improvement.
- Nonconforming items will be identified, segregated, and dispositioned.
- Nonconforming items shall be controlled to prevent inadvertent installation or use.
- Corrective/preventive actions shall be developed and implemented for CAQs related to item characteristics, process implementation, or services.
- Completed corrective/preventive actions shall be independently verified for implementation and closure.

Approach to Implementation
The PPPO uses an effectively planned and implemented quality management system that:
- uses feedback information to improve items, services, and the processes that produce them
- prevents or minimizes CAQs
- when necessary, corrects CAQs that occur
Identification of Conditions Adverse to Quality

CAQs are identified, documented, and evaluated. Services provided by contractors, in the form of deliverables and fieldwork, are evaluated through the PPPO oversight program. PPPO and technical support contractor Subject Matter Experts (SMEs) evaluate internally created or obtained and contractor-supplied items and services to identify CAQs. All reported CAQs are evaluated by the PPPO QA Lead, responsible site QA Specialist, or designee to determine significance. Line management, working with the PPPO Contracting Officer as necessary, ensures resources are applied to correct any identified CAQs. Significant conditions adverse to quality (SCAQs) have priority over project operations. Interim (and immediate) corrective actions are established to ensure continued safe operations. CAQs are tracked until corrective actions have been completed. Effectiveness verifications are periodically performed on corrective actions to ensure identified CAQs have been adequately addressed.

The identification and resolution of CAQs are also incorporated into a quality improvement process described in the next section.

Quality Improvement

Improvement in quality is a disciplined management process based on the premise that all work can be planned, performed, measured, and improved. PPPO management focuses on improving quality of products, processes, and services by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating lessons learned, and resolving significant management issues and problems that hinder the organization from achieving its objectives. The PPPO balances safety and mission priorities (ISMS Guiding Principle 4) when considering improvement actions.

Management encourages employees to develop and explore new ideas for improving products, processes, and services. Effective improvement processes require each employee to participate, and cannot be delegated to, a particular person or group.

CAQs as identified above, and other quality-related information, both positive and negative, from various internal and external sources, are reviewed to identify improvement opportunities in the QMS or PPPO’s processes, items, products, or services. Implemented improvements are monitored and methods established to verify their effectiveness.

The following are types of processes used for quality improvement:

1. Worker Feedback

The PPPO encourages feedback from workers. The PPPO has developed the MP document, PPPO-2649582, Management Plan that describes this feedback process in detail. PPPO assesses contractor procedures that implement DOE O 440.1B, Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees; 10 CFR 851, Worker Safety and Health Program; and DOE O 442.1A, Department of Energy Employee Concerns Program. DOE O 440.1B includes the requirement for DOE to implement procedures to allow workers, through their supervisors, to stop work when they discover employee exposures to imminent danger conditions or other serious hazards. The procedure ensures that any stop work authority is exercised in a justifiable and responsible manner.
2. Public Input
The PPPO encourages open communication from internal and external customers and solicits input on issues. Public meetings, when necessary, are conducted to invite local governments, tribal groups, and small businesses to discuss issues. Public participation and community outreach are integral and effective parts of PPPO activities and decisions are decided with the benefit of significant public perspectives. This involvement enables PPPO to make decisions that are more informed, and build mutual understanding and trust between DOE, the public it serves, and the communities that host its facilities.

3. Regulator Input
The PPPO conducts routine meetings with state and federal regulatory agencies to discuss commitments based on regulatory agreements and statutory requirements.

4. Contractor Feedback
The PPPO has established agreements with its prime contractors to support resolution of disputes. The partnering process, typically initiated at the beginning of a contractor’s period of performance is used to establish the protocol to raise and resolve issues at appropriate managerial level. PPPO meets periodically with its contractors to discuss project schedules and issues and to manage potential conflicts in safety priorities.

5. SMS Feedback and Improvement Mechanisms
The PPPO uses SMS Feedback and Improvement mechanisms, as identified in DOE Guide (G) 450.4-1C (Volume 2), Integrated Safety Management System Guide to close the SMS loop by connecting the practical experiences of work to the planning for future work. These mechanisms (i.e., assessments, corrective actions, lessons learned, and performance measures) are incorporated into daily operations through effective oversight.

6. Occurrence Reporting
The PPPO uses DOE O 232.2A, Occurrence Reporting and Processing of Operations Information, by meeting identified needs for added occurrence reporting guidance, clarification, or interpretations.

DOE O 232.2A, Occurrence Reporting and Processing of Operations Information, sets forth the minimum set of occurrence reporting requirements for DOE Departmental Elements and contractors responsible for the management and operation of DOE-owned and DOE-leased facilities.

7. Price-Anderson Amendments Act (PAAA)
The PPPO MP identifies areas of interface for the roles and responsibilities for key DOE organizational areas. Contractor CAQs are screened by the contractor against PAAA requirements to determine if further actions are required.
8. Environmental Data Collection
The PPPO receives and reviews contractor reporting on environmental project status; results of performance evaluations and system audits; results of periodic data quality assessments; and related environmental CAQs and recommended solutions.

9. Trends and Trend Analysis
The PPPO collects trending information from various sources, including but not limited to, contractor quality and safety issues and corrective action tracking, contractor project performance status reporting, and quarterly issued occurrence reports. The information is reviewed for trends that exceed expected variances, trends that identify recurring systemic issues, and trends that forecast predictable data based on environment, project activities, and site conditions. The PPPO uses trend information and analysis to measure consistency of issues and effectiveness of corrective actions. The PPPO uses forecast data to focus resources on preventive actions and on those CAQs that have the greatest potential:
- posing adverse risks to the environment and human health
- impacting the safety and reliability of operations and products
- affecting the ability to meet customer requirements

10. Ineffective Corrective Actions
Effectiveness of corrective actions is validated following successful completion of corrective action plans. The validation occurs sometime after completion of previous actions to allow stabilization of the process. Ineffective corrective actions, those actions that – after completion – did not prevent recurrence, also represent CAQs.

11. Performance Objectives, Measures, and Commitments (POMC)
PPPO and its contractors establish effective POMC used to monitor and evaluate actual performance against performance objectives. An effective ISMS ensures that line management is directly responsible for the protection of the public, workers, and the environment and for the quality of work produced. PPPO reviews contractor performance against its issued POMC.

Suspect/Counterfeit Items
PPPO ensures contractor implementation of the Suspect/Counterfeit Items (S/CI) program. DOE G 414.1-2B Admin Chg 2, Quality Assurance Program Guide, provides design organization guidance to help avoid the procurement and use of suspect/counterfeit items. Additional guidance is provided through individual PPPO training and DOE complex-wide lessons learned for evaluating S/CI that may have been accepted and/or installed.

The PPPO Manager receives prompt notifications of all S/CI through the Occurrence Reporting and Processing System (ORPS) process. The PPPO Facility Representative reviews ORPS reports associated with an S/CI problem. The PPPO NSOL at the Manager's Office is the point of contact for receipt, distribution, tracking, responses, and information related to S/CI alert actions. PPPO responses and information on alert actions are provided to the DOE Headquarters QA working group chair or PPPO NSOL.

Resolving Conditions Adverse to Quality
The PPPO has established and implemented a CAQ resolution process consisting of:
identifying a condition adverse to quality
implementing compensatory (immediate) actions, as necessary
evaluating its significance
analyzing the CAQ and determining its causes
reporting the planned actions to the organization identifying the CAQ
taking prompt corrective action and documenting that action
taking steps to prevent recurrence
replicating the actions where appropriate
verifying implementation
documenting closure
determining effectiveness of the corrective and preventive actions for CAQs

**NOTE:** Disputes (e.g., dissenting opinions) between assessed and assessing employees or organizations concerning CAP development, implementation, or completion should be resolved at the lowest possible organizational level. If informal discussions successfully resolve the dispute, the resolution should be documented in a mutually agreeable way. If the dispute cannot be resolved in informal discussions, it should be elevated to the minimum extent necessary to reach resolution through the organizational hierarchy. If agreement cannot be reached, persons who disagree may document a dissenting opinion.

Management is involved in approving corrective/preventive actions for SCAQs and following them through to closure. PPPO CAQs identified by management assessments and external sources are tracked through resolution in the PPPO corrective action system per PPPO-M-414.1-1, Corrective Action Program. In addition, findings and corrective actions identified by the Office of Independent Oversight and Performance Assurance environment, safety, and health and emergency management assessments, and Type “A” Accident Investigations are entered and tracked in the Corrective Action Management Program (CAMP). (Also, refer to the results paragraph in the Independent Assessment section of the QAP).

Guidance for implementing these requirements is outlined in Appendix G of DOE G 450.4-1C, Integrated Safety Management System Guide. DOE O 227.1A, Independent Oversight Program, includes additional reporting requirements.

**Implementing Procedures and Authority**

The PPPO implemented PPPO-2533131, Assessment and Surveillance Process, and PPPO-M-414.1-1, Corrective Action Program, to oversee project activities and to perform verification of corrective actions. Additionally, PPPO uses DOE O 232.2A, Occurrence Reporting and Processing of Operations Information, for problems identified as reportable under this order.

The PPPO uses trend reporting and analyses to develop multi-site feedback of issues to contractors. This reporting serves as lessons learned between sites and provides cause and effect information.

The PPPO QA Lead has responsibility to develop program requirements for the quality assurance program procedures.
4.4. **Documents and Records**

**Applicable Requirements**

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 4 Management/Documents and Records</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</td>
<td><strong>Requirement 5 – Instructions, Procedures, and Drawings</strong></td>
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<td></td>
<td>100 - Basic</td>
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<tr>
<td>(b) Specify, prepare, review, approve, and maintain records.</td>
<td><strong>Requirement 6 – Document Control</strong></td>
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<td>100 – Basic</td>
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<td>200 – Document Control</td>
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<td>300 – 302 Document Changes</td>
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<td><strong>Requirement 17 – Quality Assurance Records</strong></td>
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<td>100 – Basic</td>
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<td>200 – Generation of Records</td>
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<td>300 – Authentication of Records</td>
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<td>400 – 402 Classification</td>
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<td>500 – Receipt Control of Records</td>
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<td>600 – 603 Storage</td>
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<td>700 – Retention</td>
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<td>800 – Maintenance of Records</td>
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<tr>
<td>Non-Mandatory Appendices 17A-1, 17A-2, and Subpart 4.4 were considered in development of the PPPO documents and records policy and procedure.</td>
<td></td>
</tr>
</tbody>
</table>

**Non-Applicable Requirements**

None

**Management Expectations**

- New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
- Policies, procedures, and plans shall be maintained current and deployed in a manner that makes the document readily available to the users.
- Procedures identify QA records that are created and maintained in the implementation of the procedure.
- Identified QA records will be classified within the Maintenance/Use category for documents to be designated as either lifetime or non-permanent records in accordance with NQA-1 and EM-QA-001, Rev. 1 requirements.
- QA records are maintained in accordance with both NQA-1 and the National Archives and Records Administration (NARA) by incorporating the NQA-1 requirements into the federal records lifecycle.
Records

The Federal Records Management Program addresses the Federal records lifecycle, which is the period of time that Federal records are in existence and consists of three phases: Creation/Receipt; Maintenance/Use; and Disposition. QA records are defined as completed documents that furnish evidence of the quality of items and/or activities affecting quality. A QA record is a type of Federal record that requires more stringent maintenance and storage than those required by NARA.

Federal Records

In general terms, a Federal record is defined as recorded information, in any format, that is created in the course of business, received for action, or needed to document work activities. The legal definition of a record includes:

… all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them.¹

PPPO personnel performing work prepare, collect, protect, and retain Federal records in a manner that ensures records are retrievable, useable, and auditable.

QA Records

NQA-1 defines this section as Documents and Records, but in most cases, a document is a Federal record; therefore, both have been incorporated into this portion of the QAP.

Documents (procedures) address the first phase of the Federal records lifecycle (Creation/Receipt) in which QA records are identified within implementing procedures prior to start-up of work.

- Documents establish requirements or define how work is to be performed. Documents that establish policy, prescribe work, or specify requirements are prepared, reviewed, approved, issued, used, and revised in a controlled manner using appropriate technical standards, DOE Orders, NQA-1, and/or other consensus/quality standards.

- Requirements typically originate from laws, state, or Federal regulations [e.g., the QA Rule; RCRA; CERCLA; Clean Water Act; Clean Air Act; Toxic Substances Control Act (TSCA)], DOE directives (e.g., the QA Order), and selected consensus standards.

¹ United States Code, Title 44, Chapter 33, Sec. 3301, “Definition of records,” (44 USC 3301), as amended, et seq.
standards (i.e., NQA-1). New or revised requirements documents are analyzed to determine impact on implementing documents and/or contracts.

The maintenance of QA records falls within phase two of the Federal records lifecycle (Maintenance/Use) and consists of retention, classification, file arrangement, authentication, receipt control and active records storage.

A record contains information that is retained for its expected future value per PPPO-M-243.1-0, Records Management Policy, and associated procedures. Records support technical and regulatory decisions as well as PPPO operating and oversight activities. Records are in a variety of forms (e.g., electronic, written or printed, microfilm, photographs, radiographs, or optical disks). Regardless of the form, records are validated (authenticated), identified, and controlled. Records are compiled into the records management system to ensure appropriate records are maintained. The PPPO records management system of procedures, PPPO-M-243.1-0 through PPPO-M-243.1-4, includes provisions for retention, protection, preservation, change, tracing, accountability, and ability to retrieve. Records-retention periods are defined in the referenced requirements documents, as well as additional site-specific requirements. While in storage, records are protected from damage, loss, and deterioration.

The PPPO records management system requires processing and control of active and inactive records and schedules for retention and disposition according to DOE O 200.1A, Information Technology Management, as it applies to information technology and security. Additionally, the PPPO complies with records management requirements in the DOE Office of the Chief Information Officer, “Records Management Handbook” dated September 2006; as they apply to DOE Memorandum, New Department-Wide Records Management Program Order and Interim Records Management Program Policy, dated March 30, 2004; and as identified by the National Archives and Records Administration (NARA) for all records. NARA, according to 36 CFR, Parks, Forests, and Public Property, Chapter XII, is an independent federal agency that oversees the management of all federal records.

Additionally, the PPPO records management system ensures that records accurately reflect specific record keeping requirements defined in EPA Order 2160 and EPA Directive 2100, Chapter 10.

Approach to Implementation

Documents and records are required to effectively address the management, performance, and assessment of work. Documents and records include applicable requirements to indicate that quality and safety have been properly specified and addressed. Management should identify any documents and records that must be developed and controlled. PPPO commits resources necessary to accomplish document and record requirements.

Documents

Documents are required by organizations, projects, or programs to control policy, administrative, and/or technical information. A document may describe work, data used at different locations or by different people, or, in changing situations, data to be controlled from time to time for reference purposes. The PPPO has established a document system to supply documents necessary for personnel to perform their assigned responsibilities safely and correctly. The
PPPO document system consists of a hierarchy of documents including the QAP that lay out a graded-approach strategy for compliance with existing requirements, use of existing directives, and developing process-oriented procedures to ensure mechanisms are developed to implement the safety management functions of DOE P 450.4A, *Integrated Safety Management Policy*.

The QAP is an example of a PPPO document. The QAP is numerically identified and controlled per the DOE Directives System and includes administrative controls such as revision approval. The QAP will be reviewed annually and updated if necessary to validate its components by the QA Lead. The PPPO document system will be managed as part of the PPPO records management system. The system is designed to be centrally administered by the Program Support Specialist in the Lexington Operations Group office. Administrative and supporting Information Technology (IT) staff at each Operations Oversight Group office administers document control and computer programs/applications, respectively, for their site.

**Implementing Procedures and Authority**

The PPPO implemented PPPO-M-243.-0, *Records Management Policy* and associated procedures, to address this section of the QAP. The directive addresses consistent administrative controls, assigns responsibility, and defines protocols for the creation, identification, control, and management of unclassified DOE documents and records. The PPPO NSOL or designee has the responsibility to develop program requirements. Per PPPO-M-243.1-0, the Records Management Field Officer, supported by the administrative support staff at each of the three PPPO locations, is responsible for the implementation of the PPPO Records Management Program. The administrative staff supports day-to-day administration of controlled documents and proper identification and storage of records.

**4.5. Work Processes**

**Applicable Requirements**

- Non-safety software is evaluated on a graded approach depending on software applicability according to DOE O 414.1D and EM-QA-001, Rev. 1 requirements. Software Quality Assurance (SQA) is assigned to the Information Technology (IT) organization. Non-safety software, including off-the-shelf, used in the performance of administrative and technical activities is evaluated by IT. Evaluation is determined according to DOE O 414.1D and EM-QA-001, Rev. 1 requirements.

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 5 Performance/Work Processes</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means</td>
<td>Requirement 5 – Instructions, Procedures, and Drawings &lt;br&gt;100 - Basic</td>
</tr>
<tr>
<td>(b) Identify and control items to ensure</td>
<td>Requirement 8 – Identification and Control of Items &lt;br&gt;100 – Basic &lt;br&gt;200 – 202 Identification Methods</td>
</tr>
<tr>
<td>DOE O 414.1D – Criterion 5</td>
<td>ASME NQA-1 Requirements</td>
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<tr>
<td>Performance/Work Processes</td>
<td>300 – 303 Specific Requirements</td>
</tr>
</tbody>
</table>

(c) Maintain items to prevent their damage, loss, or deterioration.

(d) Calibrate and maintain equipment used for process monitoring or data collection.

**Requirement 9 – Control of Special Processes**
- 100 – Basic
- 200 – 203 Process Control
- 300 – Responsibility
- 400 - Records

**Requirement 12 – Control of Measuring and Test Equipment**
- 100 – Basic
- 200 – Selection
- 300 – 304 Calibration and Control
- 400 – 402 Records

**Requirement 13 – Handling, Storage, and Shipping**
- 100 – Basic
- 200 – Special Requirements
- 300 – Procedures
- 400 – Tools and Equipment
- 500 – Operators
- 600 – Marking or Labeling

**Requirement 14 – Inspection, Test, and Operating Status**
- 100 – Basic

**Requirement NQA-1 Part I Introduction**

**Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications**
- 100 – 102 General
- 200 – 204 General Requirements
- 300 – 302 Software Acquisition
- 400 – 407 Software Engineering Method
- 500 – Standards, Conventions, and Other Work Practices
- 600 – 602 Support Software
- 700 – References
Non-Applicable Requirements

- The PPPO does not procure or maintain any safety software.

Management Expectations

- Documents shall clearly establish the roles and responsibilities for employees.
- Employees shall follow approved processes written to accomplish the PPPO mission and meet regulatory and contract requirements when performing assigned tasks.
- Employees shall identify and assist in making changes that improve project processes and documents.
- Typically, PPPO only performs work activities applicable under Criterion 5(b), (c), or (d) as part of information technology and institutional type software programs. PPPO assigns implementation authority for these activities through contracts. PPPO monitors these practices to ensure proper implementation through oversight and assessment activities.

Approach to Implementation

The PPPO implements the requirements of DOE O 413.3B Chg 2, Program and Project Management for the Acquisition of Capital Assets, through the MP. The Order embodies the PPPO philosophy that the role of federal officials is to develop overall strategy; establish requirements and project performance expectations; manage the contract, not the contractor; monitor and assess project performance; and proactively anticipate and resolve issues that affect project success. While the overall project is executed under the direction of the federal staff, the contractor is actually managing the daily execution. Establishing the right balance and resources between federal and contractor roles is a key goal and is critical to improving DOE performance executing projects.

The PPPO regards all work as a process. Each work process consists of a series of actions planned and carried out by qualified, knowledgeable, and competent workers using specified work processes and equipment under administrative, technical, and environmental controls established by management to achieve a result.

Work Performance

The MP (PPPO-2649582 Management Plan) is the overall document on providing guidance and direction on how project planning and objectives are accomplished between the Headquarters Program Office and the field through established roles and responsibilities and defines how the projects are executed. The PPPO management is responsible for developing and supporting the MP and any site implementing plans. The MP and site plans are significant tools and guidance through the life of the projects.

- The PPPO MP contains all specific safety management roles and responsibilities, as well as references to the governing authorities (DOE Directives, external regulations, and agreements). The document is intended to identify “ownership” of safety management related documents, procedures, processes, and programs.

- The Project Baseline Summary (PBS) represents PPPO work activities and products. The PBS identifies top-level work products and shows a hierarchy of work.
- The Baseline Change Control Board (BCCB) establishes processes and procedures for providing support to the PPPO Manager’s Office, Site Leads, and assigned Federal Project Directors (FPDs) for control of changes to approved baselines.

- Government Furnished Services/Items (GFS/I) are identified by contract. The contractor provides the Contracting Officer with a periodic projection of needed GFS/I for DOE review and approval in accordance with the contract. The contractor notifies PPPO if GFS/I is not meeting contract requirements.

- Risk Management Plans (RMP) are developed to document the systematic, forward-looking approach to risk management that will be used in an iterative fashion at specific intervals to identify current and emerging risks requiring management, as well as to determine if identified risks remain credible and continue to require mitigation. Several types of risks are addressed including: management, cost, performance, schedule, programmatic, support, safety, and environment. The risks identified will consider factors such as complexity, interface with other contractors, technology, regulatory involvement, etc. Identifying and subsequently eliminating or mitigating project risks are important to project personnel who must execute work scope in order to effectively manage project cost and schedule.

Additionally, PPPO conducts targeted surveillances and assessments to ensure contractor management clearly identifies and conveys to workers prior to beginning work:

- customer and data requirements for the work and final product (ISMS Core Function 1)
- acceptance criteria applicable to work and final product (ISMS Core Function 1)
- hazards associated with the work (ISMS Core Function 2)
- technical standards applicable to work and final product (ISMS Core Functions 1 and 3)
- safety, administrative, technical, and environmental controls to be employed during the work (ISMS Core Functions 3 and 4)

PPPO and contractor management cooperate to identify processes that can be improved (ISMS Guiding Principles 1 and 3 and Core Function 5). Procedures, work instructions, or other means used to define work processes are documented. The scope and detail of documentation are commensurate with the complexity and importance of the work, the skills required to perform the work, and the hazards and risks or consequences of CAQs in the product, process, or service (ISMS Guiding Principle 6). Control of processes, skills, hazards, and equipment is clearly specified, understood, and fully documented (ISMS Guiding Principle 5 and Core Function 3).

Personnel performing work are responsible for the quality of their work. Because the individual worker is the first line in ensuring quality, it is expected they will be knowledgeable of requirements for work they perform and trained in the capability of the tools and processes to do their work correctly the first time, in accordance with established procedures and work instructions (ISMS Core Function 4). Since workers are the best resource for contributing ideas for improving work processes, products, and services, they are involved in work process design, process evaluation, and providing the feedback necessary for improvement (ISMS Core Function 5).
Item Identification and Use Control
The PPPO uses the DOE Property Information System (PRISM) system for the identification and control of items. PRISM is based on Federal Acquisition Regulations (FAR) Part 45.5. The system is used to assign individual accountability for all real and accountable government personal property.

The PPPO has developed a system to manage GFS/I to contractors in PPPO-M-412.1-1, Processing Government Furnished Services/Items. Contractor invoices are sent to contracting specialists at the Lexington Operations Group office for processing and payment approval.

Safety Software
The PPPO does not procure or maintain any safety software. Oversight is conducted regarding software quality assurance programs maintained by project contractors. This oversight assesses software quality assurance using the applicable PPPO requirements and (applying an appropriate graded approach) DOE Guide 414.1-4, Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance, Appendix F.

Implementing Procedures and Authority
Individual PPPO contracts that are awarded state the necessary requirements, authorities, terms and conditions, and guidance that will be conducted during the award period. PPPO uses the MP to address specific safety management roles and responsibilities, as well as references to the governing authorities. CMPs establish general quality requirements through the QAP. The PPPO Deputy Manager is responsible for ensuring PPPO Operations Oversight Group offices comply with CMP requirements. Once a contract is implemented, the assigned PPPO Contracting Officers at the LEX and applicable site offices have responsibility for reviewing PBS activities and approving contractor invoices. The assigned PPPO Contracting Officer at LEX has responsibility for ensuring contractor safety software application and assuring the appropriate PPPO staff approves contractor use of safety software.

PPPO-M-412.1-1 applies to PPPO and contractors to the extent set forth in their contract, and other contractors requested to perform work by PPPO contractors.

Equipment Control
The PPPO does not maintain safety systems or environmental equipment.

4.6 Performance/Design

Applicable Requirements

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 6 Performance/Design</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Design items and processes using sound engineering/scientific principles and appropriate standards.</td>
<td></td>
</tr>
<tr>
<td>(b) Incorporate applicable requirements and design bases in design work and</td>
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<tr>
<td>Requirement 3 – Design Control</td>
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<tr>
<td>100 – Basic</td>
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<tr>
<td>200 – Design Input</td>
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<td>300 – Design Process</td>
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<tr>
<td>400 – 402 Design Analysis</td>
<td></td>
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<tr>
<td>500 – 501.3 Design Verification</td>
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</tr>
<tr>
<td>DOE O 414.1D – Criterion 6 Performance/Design</td>
<td>ASME NQA-1 Requirements</td>
</tr>
<tr>
<td>---------------------------------------------</td>
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</tr>
<tr>
<td><em>design changes.</em></td>
<td>600 – 601.9 Change Control</td>
</tr>
<tr>
<td><em>(c) Identify and control design interfaces.</em></td>
<td>700 – Interface Control</td>
</tr>
<tr>
<td><em>(d) Verify or validate the adequacy of design products using individuals or groups other than those would perform the work.</em></td>
<td>800 – 802.3 Software Design Control</td>
</tr>
<tr>
<td><em>(e) Verify or validate work before approval and implementation of the design.</em></td>
<td>900 – Documentation and Records</td>
</tr>
</tbody>
</table>

**Non-Applicable Requirements**

- The PPPO does not design systems or items and is not responsible for developing approved engineering designs. Design responsibility is addressed by contractors through contracts with oversight conducted by PPPO.

**Management Expectations**

- Sound engineering and design principles and standards shall be applied.
- Applicable design bases shall be incorporated.
- Design interfaces shall be identified and controlled.
- Independent design review shall be implemented.
- Design work shall be verified before approval and implementation.

**Approach to Implementation**

The PPPO limits the responsibility of the federal government to review designs against approved contract requirements. Review authority is limited to appropriate qualifications and type of design. The PPPO controls design configuration and modifications that may result from DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, which discusses variances to the project baseline objectives resulting from design reviews, component and system tests, and simulations.

PPPO work activities are conducted using multiple contractors. The DUF₆ conversion facilities are located at both sites and are operated by a single contractor. Deactivation/remediation and infrastructure contractors involved with site cleanup and building deactivation and demolition of
the former gaseous diffusion plants are located at each site for a total of five prime contractors operating under the oversight of the PPPO. To ensure safe and compliant operations for all parties, each site utilizes a shared site process to addresses how work activity interfaces will be managed. Disagreements or unclear ownership issues are managed by a site council, which consists of the senior management of each organization.

The PPPO applies design requirements to assess work processes, such as software quality assurance, ISMS, procedure development, environmental sampling and monitoring, and nuclear and radiological safety. Once a requirement has been articulated and documented, it is checked to make sure it will do what it is supposed to do. This action is managed through assessments as addressed in the QAP sections that address Quality Improvement, Management Assessment, and Independent Assessment.

**Implementing Procedures and Authority**

The PPPO generated PPPO-M-243.1-0, *Records Management Policy* and associated procedures, to implement this section of the QAP. The directive addresses accountable and consistent administrative controls, assigns responsibility, and defines protocols for the creation, identification, control, and management of unclassified DOE documents and records. The PPPO NSOL or designee has the responsibility to develop program requirements. The administrative support staff at each of the three PPPO locations is responsible for the day-to-day administration of controlled documents and proper identification and storage of records.

**4.7. Performance/Procurement**

**Applicable Requirements**

<table>
<thead>
<tr>
<th><strong>DOE O 414.1D – Criterion 7 Performance/Procurement</strong></th>
<th><strong>ASME NQA-1 Requirements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Procure items and services that meet established requirements and perform as specified.</td>
<td><strong>Requirement 4 – Procurement Document Control</strong></td>
</tr>
<tr>
<td>(b) Evaluate and select prospective suppliers on the basis of specified criteria.</td>
<td>100 – Basic</td>
</tr>
<tr>
<td>(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</td>
<td>200 – 207 Content of the Procurement Documents</td>
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<td>300 – Procurement Document Review</td>
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<td>400 – Procurement Document Changes</td>
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<td><strong>Requirement 7 – Control of Purchased Items and Services</strong></td>
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<td></td>
<td>100 – Basic</td>
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<td></td>
<td>200 – Supplier Evaluation and Selection</td>
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<td></td>
<td>300 – Bid Evaluation</td>
</tr>
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<td></td>
<td>400 – Control of Supplier-Generated Documents</td>
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<td></td>
<td>500 – 507 Acceptance of Item or Service</td>
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<td>600 – Control of Supplier Nonconformances</td>
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<td>700 – 705 Commercial Grade Items and Services</td>
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<td>800 – Records</td>
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</tbody>
</table>

Non-Mandatory Appendix 4A-1 and 7A-1 were
<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 7 Performance/Procurement</th>
<th>ASME NQA-1 Requirements</th>
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<tr>
<td>considered in the development of procurement processes.</td>
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</table>

Non-Applicable Requirements
None

Management Expectations

- PPPO will develop and maintain an integrated acquisition strategy to ensure work is accomplished in compliance with applicable laws, acquisition regulations, state/Federal regulations, and DOE Order and directives.
- Oversight shall verify that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished.
- GFS/I shall be provided according to contract provisions.

Approach to Implementation

The PPPO does not procure safety items directly. The PPPO oversees contractor procurement processes, such as vendor surveys, bid evaluations, contract oversight, contract administration, source evaluation, etc., to ensure items and/or services provided by suppliers meet the requirements and expectations of the end-user.

Management controls exist for DOE procurement and subcontracts through applicable DOE Orders, the Department of Energy Acquisition Regulation (DEAR) in 48 CFR Part 9, and FAR 48 CFR Parts 1 to 99. The requirements in 10 CFR 830.120(c)(2)(iii) and Criterion 7 of DOE O 414.1D should not be interpreted to require the development of redundant procurement management systems, but rather to ensure that existing procurement management systems adequately respond to end-user requirements.

The PPPO procures services in accordance with DOE Acquisition Regulation and Federal Acquisition Regulation documents. The Contracting Officer, through the Contracting Officer Representative, evaluates, selects, and uses qualified service suppliers.

Implementing Procedures and Authority

Individual PPPO contracts that are awarded state the necessary procurement requirements which are reinforced through PPPO’s Contracting Officers. The PPPO Deputy Manager is responsible for ensuring PPPO’s personnel comply with CMP requirements. The assigned PPPO Contracting Officers in LEX and at the applicable site, with input from the Information Technology Specialist and the QA Lead, has responsibility for reviewing safety software application and approving contractor use of safety software.
## 4.8. Performance/Inspection and Acceptance Testing

### Applicable Requirements

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 8 Performance/Inspection and Acceptance Testing</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
</table>
| *(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.* | **Requirement 3 – Design Control**  
100 – Basic  
200 – Design Input  
300 – Design Process  
400 – 402 Design Analyses  
500 – 501.3 Design Verification  
600 – 601.9 Change Control  
700 – Interface Control  
800 – 802.3 Software Design Control  
900 – Documentation and Records  
**Requirement 8 – Identification and Control of Items**  
100 – Basic  
200 – 202 Identification Methods  
300 – 303 Specific Requirements  
**Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications**  
100 – 102 General  
200 – 204 General Requirements  
300 – 302 Software Acquisition  
400 – 407 Software Engineering Method  
500 – Standards, Conventions, and Other Work Practices  
600 – 602 Support Software  
700 – References |

| *(b) Calibrate and maintain equipment used for inspections and tests.* | **Requirement 10 – Inspection**  
100 – Basic  
200 – Inspection Requirements  
300 – Inspection Hold Points  
400 – 402 Inspection Planning  
500 – In-Process Inspection  
600 – 604 Final Inspections  
700 – Inspections During Operations  
800 – Records |
<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 8</th>
<th>ASME NQA-1 Requirements</th>
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</thead>
<tbody>
<tr>
<td>Performance/Inspection and Acceptance Testing</td>
<td>Requirement 11 – Test Control</td>
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<td>100 – Basic</td>
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<td>200 – Test Requirements</td>
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<td>300 – Test Procedures (Other Than for Computer Programs)</td>
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<td>400 – Computer Program Test Procedures</td>
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<td>500 – Test Results</td>
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<td>600 – 602 Test Records</td>
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<tr>
<td>Requirement 12 – Control of Measuring and Test Equipment</td>
<td>100 – Basic</td>
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<td>200 – Selection</td>
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<td>300 – 304 Calibration and Control</td>
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<tr>
<td>Requirement 14 – Inspection, Test, and Operating Status</td>
<td>100 – Basic</td>
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<td></td>
<td>Non-Mandatory Appendix 10A-1 and 11A-1 were considered to aid in the development of inspection and testing processes.</td>
</tr>
</tbody>
</table>

**Non-Applicable Requirements**

- The PPPO does not perform inspection and acceptance testing, nor does it calibrate or maintain equipment used for inspections and tests as defined by DOE O 414.1D. PPPO delegates implementation for inspection and acceptance testing through contracts. PPPO monitors inspection and acceptance testing practices through assessments and oversight.
- The PPPO does not internally conduct model development, use, and validation. The requirements of EM-QA-001, Rev. 1 – Attachment H – Model Development, Use, and Validation are non-applicable. However, PPPO conducts independent oversight of its contractors using a graded approach to ensure their contractual and DOE requirements are met according to Attachment H.

**Management Expectations**

- The contractor will conduct inspection and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and equipment are fit for use and acceptable.
Approach to Implementation
The PPPO does not perform inspection and acceptance testing, nor does it calibrate or maintain equipment used for inspections and tests as defined by DOE O 414.1D. PPPO delegates implementation for inspection and acceptance testing through contracts. PPPO monitors inspection and acceptance testing practices through assessments and oversight.

During the course of fieldwork, e.g., required self-monitoring when exiting radiological control areas, PPPO personnel use measuring and test equipment (M&TE) items provided by the contractor.

4.9. Assessment/Management Assessment (including Self-Assessment)

Applicable Requirements

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 9 Assessment/Management Assessment</th>
<th>ASME NQA-1 Requirements</th>
</tr>
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<tbody>
<tr>
<td>Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</td>
<td>Requirement 2 - Quality Assurance Program</td>
</tr>
<tr>
<td></td>
<td>100 - Basic</td>
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<td></td>
<td>200 - 202 Indoctrination and Training</td>
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<td></td>
<td>300 - 305 Qualification Requirements</td>
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<td>400 - Records of Qualification</td>
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<td>500 – Records</td>
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<td>Requirement 16 – Corrective Action</td>
<td>100- Basic</td>
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<td>Requirement 18 – Audits</td>
<td>100 – Basic</td>
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<td>200 – Scheduling</td>
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<td>300 – 303 Preparation</td>
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<td>400 – Performance</td>
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<td>500 – Reporting</td>
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<td>600 – Response</td>
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<td>700 – Follow-up Action</td>
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<td>800 - Records</td>
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</table>

Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 18A-1, and Subpart 4.5 were considered in the development of the assessment process.

Non-Applicable Requirements
None

Management Expectations

- Management assessments shall be one of the means for identifying areas needing correction and/or improvement.
- Management assessments will be performed by PPPO Management.
• Leads within all organizations will assess their organizations' performance with regard to such areas as safety, quality, mission completion, and performance against technical and financial goals and objectives. Management shall consolidate the ISMS and QA annual validation and declaration activities.
• Results of management assessments shall be documented, and CAQs identified and tracked with corrective actions taken.
• In addition to management assessments, PPPO conducts self-assessments as a critical and objective evaluation of performance against expectations. It is an internal organization review to identify whether processes or activities are adequate and effective and properly focused on achieving desired results. The assessor does not need to be an approved auditor but should have some understanding and knowledge of conducting assessments.

Approach to Implementation

PPPO management assesses performance of its Operations Oversight Group organization and functions (i.e., program and project elements) to determine how well it meets DOE requirements and expectations, and mission objectives, so that improvements can be made. Assessments (collectively meaning reviews, assessments, audits, and surveillances) address use of human and material resources to achieve the organization’s goals and objectives. Management assessment includes introspective evaluation to determine if an integrated management program exists and if it focuses on meeting both customer requirements and strategic goals (ISMS Core Function 5). Management assessments conducted by senior PPPO staff are implemented consistent with DOE O 226.1B, Implementation of the DOE Oversight Policy.

The PPPO has generated PPPO-2533131, Assessment and Surveillance Process, to perform management and self-assessments. The PPPO integrates requirements of DOE O 413.1B, Internal Control Program, to maintain stewardship of Federal resources and ensure they are used efficiently and effectively to achieve intended program results; take systematic and proactive measures to establish cost-effective and appropriate management controls; establish and maintain a separate management control program as required; and appoint a management control action officer to coordinate all planning, evaluating, and reporting related to the DOE Management Control Program.

Management assessment checklists are developed to address each QAP criterion. Additional checklists will be created simultaneously with new and/or revised quality, environmental, and safety documents. These checklists will provide management with a tool to observe performance in order to evaluate program effectiveness. Results will be used as the basis for improving the program and is an example of the ISMS Policy feedback and improvement function.

Management self-assessment checklists and/or questions may be generated to assist in formalizing the process to self-evaluate PPPO performance. The self-assessment process provides an opportunity to improve the process and increase the ability of PPPO employees to
meet the needs and expectations of PPPO Management. The self-assessment should be coordinated with the PPPO QA Lead to ensure there are no conflicts with other assessments.

**Implementing Procedures and Authority**

The PPPO uses PPPO-2533131, *Assessment and Surveillance Process*, and PPPO-M-414.1-1, *Corrective Action Program*, to meet the requirements of this section of the QAP.

Results of assessments will be shared between sites, provide cause and effect information, and identify PPPO expectations to improve quality. Additionally, program areas identified from results of contractor oversight will be assessed to identify federal management opportunities for improvement.

An Integrated Assessment Schedule will be established annually and revised at least quarterly. The PPPO Management, Federal Project Directors, Site Leads, and supervisory personnel have responsibility to develop program requirements and input into the development of the schedule. These requirements, the results of previous assessments, and DOE requirements are used by the QA Lead to develop the Integrated Assessment Schedule, obtain its approval, and monitor its implementation. A management assessment does not require an assigned Assessment Team Leader (ATL).

Results of assessments are reported to the QA Lead and PPPO Management.

For QMS, each of the 10 criteria of this QAP will be scheduled for assessment over a three-year period. This will ensure the QAP is current and expectations are communicated to PPPO staff.

**Results**

Management assessment results will be documented and used as input to the organization’s quality improvement process. Periodic review of performance metrics at appropriate management levels and with customers will be used to validate organizational performance. Through this process, the PPPO will track management issues and share results with similar organizations.

### 4.10. Assessment/Independent Assessment (Internal and External)

**Applicable Requirements**

<table>
<thead>
<tr>
<th>DOE O 414.1D – Criterion 10 Assessment/Independent Assessment</th>
<th>ASME NQA-1 Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.</td>
<td>Requirement 1 - Organization</td>
</tr>
<tr>
<td></td>
<td>100 - Basic</td>
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<td></td>
<td>200 - 202 Structure and Responsibility</td>
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<td>300 - Interface Control</td>
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<tr>
<td>(b) Establish sufficient authority and freedom from line management for independent assessment teams.</td>
<td>Requirement 2 - Quality Assurance Program</td>
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<td>100 - Basic</td>
</tr>
<tr>
<td></td>
<td>200 - 202 Indoctrination and Training</td>
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<td></td>
<td>300 - 305 Qualification Requirements</td>
</tr>
<tr>
<td>DOE O 414.1D – Criterion 10 Assessment/Independent Assessment</td>
<td>ASME NQA-1 Requirements</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
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</tbody>
</table>
| *(c) Ensure persons who conduct independent assessments are technically qualified and knowledgeable in the areas to be assessed.* | 400 - Records of Qualification  
500 – Records  

**Requirement 10 – Inspection**  
100 – Basic  
200 – Inspection Requirements  
300 – Inspection Hold Points  
400 – 402 Inspection Planning  
500 – In-Process Inspection  
600 – 604 Final Inspections  
700 – Inspections During Operations  
800 – Records  

**Requirement 11 – Test Control**  
100 – Basic  
200 – Test Requirements  
300 – Test Procedures (Other Than for Computer Programs)  
400 – Computer Program Test Procedures  
500 – Test Results  
600 – 602 Test Records  

**Requirement 15 – Control of Nonconforming Items**  
100 – Basic  
200 – Identification  
300 – Segregation  
400 – 405 Disposition  

**Requirement 16 – Corrective Action**  
100 – Basic  

**Requirement 18 – Audits**  
100 – Basic  
200 – Scheduling  
300 – 303 Preparation  
400 – Performance  
500 – Reporting  
600 – Response  
700 – Follow-up Action  
800 – Records  

Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 10A-1, 11A-1, 16A-1, and 18A-1 were considered in development of the independent assessment process.
Non-Applicable Requirements
None

Management Expectations

- Organizations will develop and implement a comprehensive plan and schedule to independently conduct assessments of reporting organizations against technical, programmatic, administrative, and quality program requirements.
- Independent assessments will be performed by those knowledgeable in the subject area and trained in assessment techniques.
- Assessments will be performed by auditors and lead auditors qualified in accordance with NQA-1. They may be assisted by SMEs depending on the technical support needed to conduct the assessment.
- Results of independent assessments shall be documented, CAQs identified and tracked, corrective action plans reviewed, and corrective actions verified.
- Assessments are consistent with NQA-1 guidance.

Approach to Implementation

The PPPO senior management has established a process to conduct internal independent assessment of the contractors’ organization, programs, projects, and services. The purpose of independent assessments is to evaluate contractors’ performance of work processes with regard to requirements, expectations of DOE, and efforts required achieving the mission and goals of the contractor. Results of independent assessments provide an objective form of feedback to senior management that is useful in confirming acceptable performance and used for identifying improvement opportunities (ISMS Core Function 5).

The purpose of external independent assessments (third party assessments) is to evaluate PPPO’s and/or PPPO contractor’s performance of work processes with regard to requirements, expectations of DOE, and efforts required achieving the mission and goals by organizations outside of PPPO. Results of external independent assessments provide an objective form of feedback to senior management that is useful in confirming acceptable performance and used for identifying improvement opportunities (ISMS Core Function 5). Independent assessments conducted by DOE headquarters and PPPO organizations support implementation of DOE O 226.1B, Implementation of the DOE Oversight Policy.

PPPO uses DOE and support contractor NQA-1 Certified Lead Auditors, Certified Auditors, and subject matter experts (SMEs) to assess PPPO and contractor programs. PPPO uses the expanded guidance of DOE G 414.1-1C for planning and performing independent assessments. Additionally for the QMS, each of the 10 criteria of this QAP will be scheduled for independent management assessment triennially. This will ensure the QAP is current and expectations are communicated to PPPO staff.
The PPPO uses PPPO-2533131, *Assessment and Surveillance Process*, and PPPO-M-414.1-1, *Corrective Action Program*, to meet the requirements of this section of the QAP.

An Integrated Assessment Schedule is established annually and revised quarterly, as necessary. PPPO Management has responsibility to develop program requirements and provides input into the development of the schedule. These requirements, the results of previous assessments, and DOE requirements are evaluated and used by the QA Lead to develop the Integrated Assessment Schedule. Results of assessments are reported to PPPO Management, the contractor, and the QA Lead.

*Results from Internal Independent Assessment of Contractors*

Documented assessment results are presented to the contractor and provided to the appropriate levels of management for review. Strengths and weaknesses affecting the quality of process outputs are identified so that management can take meaningful action to improve quality.

The Responsible Organization Lead, in consultation with the QA Lead and ATL, evaluates and may require approval of the contractor’s corrective action plan (CAP), and may approve or disapprove any request from the contractor for an extension of the due date for the CAP. Contractor corrective actions shall be verified as directed by the Responsible Organization Lead.

*Results from External Independent Assessment*

Documented assessment results are presented to PPPO and provided to the appropriate levels of management for review. As a minimum, all findings and observations from external assessments are tracked in the PPPO corrective action system. In addition, findings and corrective actions identified by the Office of Independent Oversight and Performance Assurance environment, safety and health and emergency management assessments, and Type “A” Accident Investigations will be entered and tracked in CAMP. Guidance for implementing these requirements is outlined in Appendix G of DOE G 450.4-1C, *Integrated Safety Management System Guide*. Note that DOE O 227.1A, *Independent Oversight Program*, include additional reporting requirements. Strengths and weaknesses affecting the quality of process outputs are identified so that management can take meaningful action to improve quality.

The Responsible Organization Lead evaluates assessment results to identify improvement actions and determine whether similar CAQs may exist elsewhere in the organization. Assessment results are communicated to other organizations with similar activities or concerns.

The Responsible Organization Lead, with assistance from QA as requested, tracks corrective actions until a resolution has been implemented and verified as completed.

*Implementing Procedures and Authority*

The PPPO generated PPPO-2533131, *Assessment and Surveillance Process*, and PPPO-M-414.1-1, *Corrective Action Program*, to implement this section of the QAP.

The PPPO QA Lead has the responsibility to develop program requirements and oversees development of schedules from each of the PPPO Operations Oversight Group offices.
## 5.0 ATTACHMENT 1: QUALITY ASSURANCE IMPLEMENTATION PLAN

|-------------------------------------|-----------------------------------------------|-----------------------------------------------|-------------------------------------------------|---------------------------------------------------------------|
| **Criterion #1**  
**Management/Program** | Guiding Principle (GP) - Line Management Responsibility for Safety. GP-Balanced Priorities | Requirement 1) Environmental Policy  
Requirement 2) Environmental Aspects and Impacts  
Requirement 3) Legal and Other Requirements | Requirement 1) Organization  
Requirement 2) QA Program |  
- PPPO-2649582, PPPO Management Plan  
- (No number assigned), Revision 4, Federal Risk Management Plan for the Paducah Operations Project, Paducah, Kentucky  
- DOE/PPPO/03-0235&D0, Revision 4, Federal Risk Management Plan for the Decontamination and Decommissioning Project at the Portsmouth Gaseous Diffusion Plant, Piketon, OH  
- PPPO-M-414.1-7G, PPPO Quality Assurance Program Plan  
- DUF6-BWCS-PLN-001, Project Management Plan |
| **Criterion #2**  
**Management/Personnel Training & Qualification** | GP-Clear Roles and Responsibilities  
GP-Competence Commensurate with Responsibilities | Requirement 5) Structure and Responsibility  
Requirement 6) Training, Awareness and Competence | Requirement 2) QA Program |  
- PPPO-M-426.1-0, PPPO Technical Qualification Program Plan  
- PPPO-2691323, Facility Representative Program Plan  
- PPPO-M-420.1-3, Safety Systems Oversight Program Plan |
| **Criterion #3**  
**Management/Quality Improvement** | Core Function (CF)-Provide Feedback and Continuous Improvement | Requirement 4) Objectives and Targets and Environmental Management Program | Requirement 16) Corrective Action  
Requirement 18) Audits |  
- PPPO-2533131, Assessment and Surveillance Process  
- PPPO-M-414.1-1, Corrective Action Program |
| **Criterion #4**  
**Management/Documents & Records** | Requirement 7) Communication  
Requirement 8) EMS Documentation  
Requirement 9) Document Control  
Requirement 15) Records | Requirement 6) Document Control  
Requirement 17) Quality Assurance Records Subpart 2.7) Quality Assurance Requirements for Computer Software for Nuclear Facilities Applications |  
- PPPO-M-243.1-0, Records Management Policy  
- PPPO-M-243.1-2, File Plan Creation and Maintenance Procedure  
- PPPO-M-243.1-1, Vital Records Identification and Protection  
- PPPO-M-243.1-3, Identifying, Filing, and Maintaining Records |
## Attachment 1: Quality Assurance Implementation Plan (cont.)

<table>
<thead>
<tr>
<th>DOE Order 414.1D Quality Assurance</th>
<th>DOE Policy 450.4A Integrated Safety Management</th>
<th>DOE Order 436.1, Departmental Sustainability</th>
<th>ASME NQA-1-2008 and addenda through 2009 Quality Assurance Requirements for Nuclear Facility Applications</th>
<th>PPPO implementing documents for DOE O 414.1D, Quality Assurance</th>
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<tbody>
<tr>
<td><strong>Criterion #5</strong> Performance/Work Processes</td>
<td>GP-Identification of Safety Standards and Requirements</td>
<td>Requirement 10) Operational Control</td>
<td>Requirement 5) Instructions, Procedures and Drawings</td>
<td><strong>Portsmouth/Paducah Project Office Systems and Service Acquisition Policy</strong></td>
</tr>
<tr>
<td></td>
<td>CF-Define the Scope of Work</td>
<td>Requirement 12) Monitoring and Measuring</td>
<td>Requirement 9) Control of Processes</td>
<td><strong>Contract Management Plans (a CMP is developed for each PPPO contract)</strong></td>
</tr>
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<td></td>
<td>CF-Analyze the Hazards</td>
<td></td>
<td>Requirement 12) Control of Measuring &amp; Test Equipment</td>
<td><strong>PPPO-2649582, PPPO Management Plan</strong></td>
</tr>
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<td>CF-Perform Work within Controls</td>
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<td>Requirement 13) Handling, Storage and Shipping</td>
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<td></td>
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<td>Requirement 15) Control of Nonconforming Items</td>
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<td></td>
<td>Subpart 2.4) Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities</td>
<td></td>
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**Criterion #6 Performance/Design**

| CF-Develop and Implement Hazard Controls | Requirement 3) Design Control | **Portsmouth/Paducah Project Office Systems and Service Acquisition Policy** |
| | | **Portsmouth/Paducah Project Office Configuration Management Policy** |
| | | **PPPO-M-243.1-0, Records Management Policy** |
| | | **PPPO-M-243.1-3, Identifying, Filing, and Maintaining Records** |
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| **Criterion #7**                    | **Performance/Procurement**                   |                                               | Requirement 4) Procurement Document Control Requirement 7) Control of Purchased Items & Services | ▪ Portsmouth/Paducah Project Office Systems and Service Acquisition Policy  
▪ Portsmouth/Paducah Project Office Configuration Management Policy |
| **Criterion #8**                    | **Performance/Inspection and Acceptance Testing** | Requirement 14) Nonconformance and Corrective and Preventive Action | Requirement 10) Inspection Requirement 11) Test Control Requirement 14) Inspection, Test, and Operating Status | ▪ Not applicable |
▪ PPPO-M-414.1-1, Corrective Action Program  
▪ PPPO-3184699, Oversight Program Plan |
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